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SLEEP HEART HEALTH STUDY MANUAL OF OPERATIONS

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SHHS participants will be drawn from nine existing parent cohorts: ARIC, CHS, Framingham, three cohorts in New York City, SHS, and two cohorts in Tucson, Arizona. The parent studies for these cohorts are described in this chapter.

1.1 The Atherosclerosis Risk in Communities (ARIC) Study

1.1.1 Cohort Selection

ARIC was initiated by the NHLBI in the mid-1980s with the broad objective of studying prospectively “the etiology and natural history of atherosclerosis and the etiology of clinical atherosclerotic disease.” ARIC is a multi-center population-based study in four communities: Jackson (Mississippi), Forsyth County (North Carolina), Washington County (Maryland), and Suburban Minneapolis (Minnesota). Two ARIC Field Centers (Washington County and Minneapolis) participate in the Sleep Heart Health Study. ARIC has two complementary components: a cohort and community surveillance. The surveillance component of ARIC involves monitoring of coronary heart disease occurrence in the ARIC source communities and identifying cardiovascular endpoints (primarily acute MI and stroke) among the cohort members. For the cohort component, each Field Center recruited about 4,000 men and women, 45-64 years old, from a geographically-defined community. Recruitment and baseline measurements took place between 1987 and 1989 (exam 1). Cohort members were re-examined three years later, between 1990-1992 (exam 2), and are currently being re-examined for the third time (1993-1995). A fourth exam of the cohort is scheduled to be conducted between 1996-1998. For each participant, a three-year interval between exams has been maintained. ARIC exams are conducted in a Field Center Clinic and include a wide range of demographic, lifestyle, biochemical, physiological, and clinical measurements. In addition to the clinic exams, cohort participants are contacted every year by telephone to assess the occurrence of cardiovascular outcomes. The study investigators remain in contact with over 99% of the cohort using a number of tracing items from the baseline exam such as maiden name, social security number, driver’s license number, and names of two contact persons.

In all ARIC centers, age-stratified random samples of individuals were selected, without replacement, in monthly cycles. A trained interviewer visited the home of the selectee, enumerated the household, and invited all age-eligible household members to attend a clinic exam. The sampling frames differed in the different centers.

1.1.1.1 ARIC Minneapolis Field Center

This population-based sample was selected from all residents of eight contiguous suburbs of Hennepin County: Brooklyn Center, Brooklyn Park, Crystal, Golden Valley, Medicine Lake, New Hope, Plymouth, and Robbinsdale. The sampling frame was the county’s jury selection list, which is comprised of all persons with a driver’s license, a state identification card, or a voter registration card. A pilot study indicated that the sampling frame was more than 99% complete for non-institutionalized age-eligibles. Residents eligible for selection were identified by birthdate, zip code, and street address. The total number of eligibles was estimated at 6,021. Of these, 4,009 (67%) completed the first ARIC exam, including approximately 600 spouse pairs. At the time of second exam (1990-92), about 2% of the participants at baseline have died and 2% have left the Twin Cities area. A total of 3,828 (95%) returned for the second exam (1990-1992), the highest return rate among ARIC centers. So far, the return rate for exam 3 (currently in progress) has exceeded 90%.

1.1.1.2 ARIC Washington County Field Center

The sampling frame in Washington County, Maryland, consisted of a private census conducted by the Johns Hopkins Training Center in 1975 and driver's license records. Among 6,177 potential eligibles identified, 4,020 (65%) completed the baseline clinic exam. Among the participants who attended the baseline examination and were still alive, 93.4% returned for exam 2. Preliminary data from exam 3 shows that over 95% of cohort participants who attended the second exam and are scheduled to return to the clinic in 1993 did so.

1.1.2 Cohort Governance

ARIC is directed by a Steering Committee composed of the Principal Investigators of the four Field Centers, the Principal Investigator of the Coordinating Center (Department of Biostatistics, University of North Carolina at Chapel Hill), and the NHLBI Project Officer. An NIH Policy Board provides external review to the project. The ARIC Steering Committee and Policy Board have endorsed the use of the ARIC cohorts for the Sleep Heart Health Study.

1.1.3 Demographic Characteristics of Current Cohort

1.1.3.1 Johns Hopkins (N=4,020)

1. Age Distribution

Mean = 62.21 years; SD = 5.73

Age	Frequency	Percent
LE 39		
40-49		
50-59	1,438	36
60-69	2,084	52
70-79	498	12
80-89		
90-99		
100+		
Total	4,020	100

2. Race Distribution

Race	Frequency	Percent
White	3,975	99
Black	33	1
Native American/Alaska Native	3	< 1
Asian/Pacific Islander	9	< 1
Hispanic		
Other		
Total	4,020	100

3. Gender Distribution

Gender	Frequency	Percent
Male	1,884	47
Female	2,136	53
Total	4,020	100

1.1.3.2 Minnesota (N=3,827)***1. Age Distribution**

Mean = 61.43 years; SD = 5.67

Age	Frequency	Percent
LE 39		
40-49		
50-59	1,560	41
60-69	1,897	49
70-79	370	10
80-89		
90-99		
100+		
Total	3,827	100

2. Race Distribution

Race	Frequency	Percent
White	3,796	99
Black	19	< 1
Native American/Alaska Native	4	< 1
Asian/Pacific Islander	8	< 1
Hispanic		
Other		
Total	3,827	100

3. Gender Distribution

Gender	Frequency	Percent
Male	1,837	48
Female	1,990	52
Total	3,827	100

* N=3,827 due to loss of one individual since exam 2.

1.1.4 Information Collected

ARIC's clinic examinations include numerous procedures and last about 3-4 hours.

PredictorsAscertained at every examination

current medications
 smoking and alcohol intake
 medical history
 anthropometric measures
 12-lead electrocardiography
 blood pressure
 fasting lipid levels
 hematologic and hemostatic factors
 blood chemistry

Ascertained at some examinations

pulmonary function
 cognitive function
 diet
 physical activity
 retinal photography

Outcomes

hospitalized acute myocardial infarction
coronary heart disease death
fatal and non-fatal stroke
silent myocardial infarction
angina pectoris (Rose questionnaire)
transient ischemic attacks
intermittent claudication
incident hypertension
subclinical atherosclerosis (measured by B-mode ultrasound of the carotid arteries)

ARIC has a limited number of questions related to sleep and sleepiness (“often feel tired”; “often have trouble falling sleep”; “wake up repeatedly at night”; “wake up feeling exhausted”; “wake up breathless”). ARIC did not ask about snoring or other SRBD-associated symptoms; these will be collected as part of this project.

See Section 1.7 for a complete summary of data collected stratified by parent cohort.

1.1.5 Data Quality Assurance and Control

Methods for ARIC measurements are detailed in a series of manuals of operation and are described in more than 50 published ARIC manuscripts. Since its inception, ARIC has maintained high standards of data collection. Technicians and interviewers undergo extensive training, meet certification standards, and are being retrained and recertified periodically. Interviews are occasionally taped to check their adherence to the protocol. To reduce transcribing error, a direct data entry system is used in all Field Centers. Biochemical measurements (lipids, chemistry, hemostasis) and physiological measurements (ECG, spirometry, carotid ultrasound, retinal photography) are conducted in carefully standardized central laboratories or reading centers. The ARIC Coordinating Center periodically generates quality control reports for the study’s Quality Control Committee and feedback is given to the Field Centers who take corrective actions such as retraining or reassigning staff.

The quality of ARIC data is reflected in the results of several reliability studies. The following are a few examples of reliability coefficients: anthropometry (inter-technician) - above 0.90 for most measurements; total cholesterol - 0.94; LDL cholesterol - 0.92; HDL cholesterol - 0.94; triglycerides - 0.85; fibrinogen - 0.72; apolipoprotein A₁ - 0.60; carotid intimal-medial thickness - 0.70; nutrient intake (three-year interval) - 0.40 to 0.60. Simple correlation coefficients for FEV₁ and FVC (exam 2 versus exam 1) were 0.94 and 0.92, respectively.

1.1.6 References

Among the large number of ARIC publications, the following references provide an overview of ARIC's background, methods, and some key findings:

1. The ARIC Investigators: The decline of ischemic heart disease mortality in the ARIC Study communities. Int J Epidemiol 1989;18:588-98.
2. The ARIC Investigators: The Atherosclerosis Risk in Communities (ARIC) Study: Design and objectives. Am J Epidemiol 1989;129:687-702.
3. Heiss G, Sharrett AR, Barnes R, et al. Carotid atherosclerosis measured by B-mode ultrasound in populations: associations with cardiovascular risk factors in the ARIC Study. Am J Epidemiol 1991;134:250-6.
4. Howard G, Sharrett AR, Heiss G, et al. Carotid artery intimal-medial thickness distribution in general populations as evaluated by B-mode ultrasound. Stroke 1993;24:1297-304.
5. Toole JF, Chambless LE, Heiss G, et al. Prevalence of stroke and transient ischemic attacks (TIA) in the Atherosclerosis Risk in Communities (ARIC) Study. Ann Epidemiol 1993;3:500-3.
6. White AD, Folsom AR, Chambless LE, et al. Community surveillance of coronary heart disease in the Atherosclerosis Risk in Communities (ARIC) Study: methods and initial two years' experience. J Clin Epidemiol, in press.

1.2 Cardiovascular Health Study (CHS)

1.2.1 Cohort Selection

The Cardiovascular Health Study (CHS) is a population-based study of risk factors for cardiovascular disease in adults ages 65 and older. A cohort of 5,201 men and women were recruited in 1989-90 from a random, age-stratified (65-74, 75-84, 85 and older) sample of the Health Care Financing Administration's (HCFA) Medicare eligibility lists in four U.S. communities: Sacramento County, California; Washington County, Maryland; Forsyth County, North Carolina; and Pittsburgh, Pennsylvania. Three of these four sites will be participating in SHHS (California, Pennsylvania, and Maryland sites). Sampled persons and age-eligible household members were recruited for the study. Those who were institutionalized, wheelchair-bound or under active treatment for cancer were excluded. Of those who were eligible 57.6% agreed to participate. Participants were interviewed in their homes and examined in the Field Center clinics.

In 1992 - 1993 a second cohort of African-Americans was recruited at three of the centers (California, Pennsylvania, and North Carolina) in order to increase the ethnic balance of the study. The same recruitment techniques were used as in the original recruitment but limited to those individuals who classified themselves as African-American to HCFA. A total of 687 new participants were recruited.

1.2.2 Cohort Governance

CHS is directed by a Steering Committee composed of the Principal Investigators from: the four Field Centers, the Coordinating Center at the University of Washington, the reading and lab centers and the NHLBI Project Officer. An NIH Monitoring Board provides external review for the project. The Sleep Heart Health Study, in its original formation, was agreed to by the Steering Committee and the Monitoring Board. The final protocol will need to be re-reviewed.

1.2.3 Demographic Characteristics of Current Cohort

1.2.3.1 Johns Hopkins (N=1,134)

1. Age Distribution

Mean = 78.77 years; SD = 5.43

Age	Frequency	Percent
LE 39		
40-49		
50-59		
60-69		
70-79	702	62
80-89	384	34
90-99	46	4
100+	2	< 1
Total	1,134	100

2. Race Distribution

Race	Frequency	Percent
White	1,118	99
Black	9	1
Native American/Alaska Native	1	< 1
Asian/ Pacific Islander		
Hispanic	5	< 1
Other	1	< 1
Total	1,134	100

3. Gender Distribution

Gender	Frequency	Percent
Male	450	40
Female	684	60
Total	1,134	100

1.2.3.2 Pittsburgh (N=1,364)**1. Age Distribution**

Mean = 78.20 years; SD = 5.15

Age	Frequency	Percent
LE 39		
40-49		
50-59		
60-69	28	2
70-79	859	63
80-89	433	32
90-99	44	3
100+		
Total	1,364	100

2. Race Distribution

Race	Frequency	Percent
White	1,045	77
Black	300	22
Native American/Alaska Native		
Asian/Pacific Islander		
Hispanic	12	1
Other	7	< 1
Total	1,364	100

3. Gender Distribution

Gender	Frequency	Percent
Male	578	42
Female	786	58
Total	1,364	100

1.2.3.3 Sacramento (N=1,424)**1. Age Distribution**

Mean = 78.07 years; SD = 5.61

Age	Frequency	Percent
LE 39		
40-49		
50-59		
60-69	33	2
70-79	894	63
80-89	439	31
90-99	56	4
100+	2	< 1
Total	1,424	100

2. Race Distribution

Race	Frequency	Percent
White	1,144	80
Black	237	17
Native American/Alaska Native	7	< 1
Asian/Pacific Islander	3	< 1
Hispanic	21	1
Other	12	1
Total	1,424	100

3. Gender Distribution

Gender	Frequency	Percent
Male	578	41
Female	846	59
Total	1,424	100

1.2.4 Information Collected

Predictors

- current medications
- smoking and alcohol intake
- medical history
- anthropometric measures
- 12-lead electrocardiography
- blood pressure
- fasting lipid levels
- hematologic and hemostatic factors
- blood chemistry
- pulmonary function
- cognitive function
- diet
- physical activity
- echocardiograms
- carotid ultrasounds
- abdominal ultrasounds to detect aortic aneurysms
- head MRIs
- bone density and body composition (on a subsample at CA and PA sites)
- ankle/arm index
- orthostatic blood pressure
- Holter monitors (on a subsample of 1432 participants)

Outcomes

- death
- myocardial infarction
- angina
- congestive heart failure
- stroke
- TIA
- claudication

Non-adjudicated data are available on all hospitalizations, including date, length of stay and the first ten ICD9 coded diagnoses.

See section 1.7 for a complete summary of data collected stratified by parent cohort.

1.2.5 Data Quality Assurance and Control

Methods for CHS measurements are detailed in a series of manuals of operation. Since its inception CHS has maintained high standards of data collection. Technicians and interviewers undergo extensive training and meet certification standards. Much of the data collected at the Field Centers undergoes statistical analysis to ensure internal validity (e.g., all measures are

checked to make sure no statistically significant differences can be attributed to the technician carrying out the test).

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1.3 The Framingham Heart Study (FHS)

1.3.1 Cohort Selection

The FHS is a longitudinal population-based investigation of the epidemiology of cardiovascular disease, with studies currently ongoing in three cohorts. The Original Cohort was established in 1948 with a random sample of residents of Framingham, Massachusetts aged 30-62 years. This group contained 5209 members including 1644 husband and wife pairs. In 1971 the children of these couples, and their spouses, were invited to participate in the study, and 5135 subjects became members of the Offspring Cohort. The clinical, biochemical and demographic features of the Offspring Cohort have been well characterized by data collected at "cycle examinations" conducted every 3.5 years. Prevalent cardiovascular and cerebrovascular disease and congestive heart failure status was adjudicated at the outset of the cohort formation, and incident and recurrent events have been adjudicated at each subsequent cycle. Of the original 5135 members of the cohort, 4467 subjects are projected to be alive and 3570 to participate in the Cycle 6 examination, which began in January, 1995. Subject tracking has been excellent with only 47 (1%) subjects lost to follow-up.

The Omni Cohort, established in 1994, is comprised of residents of Framingham, Massachusetts who are between the ages of 40 and 74 and members of minority groups. The racial and ethnic composition of the town has changed since the inception of the FHS. According to the 1990 US Census, 9.9% of town residents report a race other than white, and 8.1% report Hispanic origin. These figures include approximately 1340 Hispanic, 500 non-Hispanic black and 500 Asian residents in the targeted age range. Currently, 270 subjects have been recruited through multi-modality efforts. The Omni Cycle 1 examination is similar to the Offspring Cycle 6 exam. It includes a standardized physician history and physical exam, resting blood pressure measurements, anthropomorphic measurements, spirometry, cardiac and carotid ultrasounds, lifestyle questionnaires, and biochemical analyses including glucose tolerance, lipoprotein subfractions, and clotting studies. Prevalent cardiovascular and cerebrovascular disease and congestive heart failure will be adjudicated for these subjects in the identical manner as for the Offspring Cohort.

Subjects for the SHHS will be drawn from the Offspring and Omni Cohorts.

1.3.2 Cohort Governance

The FHS is directed by an Executive Committee composed of the Principal Investigator, co-Principal Investigators, and the NHLBI Project Officer. The Steering Committee has endorsed the participation of the FHS in the SHHS.

1.3.3 Demographic Characteristics of Current Cohort (N=2,038)

1. Age Distribution

Mean = 57.24 years; SD = 8.88

Age	Frequency	Percent
LE 39		
40-49	457	22
50-59	777	38
60-69	592	29
70-79	212	10
80-89		
90-99		
100+		
Total	2,038	99

2. Race Distribution

Race	Frequency	Percent
White	1,548	76
Black	143	7
Native American/Alaska Native		
Asian/Pacific Islander	46	2
Hispanic	301	15
Other		
Total	2,038	100

3. Gender Distribution

Gender	Frequency	Percent
Male	948	47
Female	1,090	53
Total	2,038	100

1.3.4 Information Collected

Predictors

- resting blood pressure
- anthropomorphic measurements
- spirometry
- cardiac and carotid ultrasounds
- biochemical analyses (glucose tolerance, lipoprotein subfractions, and clotting studies)
- ankle/arm index
- electrocardiography
- bone density
- dietary history
- physical activity questionnaire
- SF-36 Health Status questionnaire
- medications
- alcohol and tobacco consumption

Outcomes

- angina pectoris
- coronary insufficiency
- myocardial infarction
- coronary heart disease, any
- coronary heart disease mortality

- cerebrovascular accident
- cerebrovascular disease mortality

- congestive heart failure
- intermittent claudication

No sleep variables have been collected as yet.

See Section 1.7 for a complete summary of data collected stratified by parent cohort.

1.3.5 Data Quality Assurance and Control

The FHS has maintained high standards of data collection and quality assurance. A Clinic Protocol Manual is available to each nurse or medical technician providing a standardized protocol for each nursing task including anthropometric measurements, electrocardiographic lead placement, blood pressure measurement, and carbon monoxide analysis. In addition, periodic "site visits" conducted by trained researchers ensure that each nurse or medical technician is performing the tasks in the same manner. A separate Pulmonary Function Manual is also on site. Grading of the spirometry data and periodic retraining of the clinic nurses is supervised by Dr. Paul Enright. Biochemical analyses are performed under standardized conditions and with appropriate controls either at the FHS laboratory or under the supervision of FHS researchers.

1.3.6 References

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1.4 New York/Cornell

1.4.1 Cohort Selection

There are four cohorts, each of which is being studied as a project (Project 1, 2 and 3) as part of our Program Project (HL 47540; Psychosocial Factors in Cardiovascular Disease, T Pickering PI), which is funded until August, 1998.

Project One (the Pickering NYH-clinic study) is a prospective study of the role of ambulatory blood pressure monitoring in the prediction of cardiovascular morbidity independently of other risk factors including clinic blood pressure. The central hypothesis is that ambulatory blood pressure will predict cardiovascular morbidity independently of other risk factors. The subjects are patients referred to the Hypertension Center for evaluation of their blood pressure, most of whom have mild hypertension or are normotensive. The first patients were enrolled in 1978, and more than 1000 have been studied since 1990.

The entry criteria are normotension or mild uncomplicated hypertension (clinic blood pressure less than 105 mm Hg diastolic), an absence of secondary hypertension, excessive obesity (BMI>30), no other major medical condition. Patients are evaluated off medication with two clinic visits. They are followed either at the Center with visits at least every six months, or by their local physicians, in which case they are followed by telephone contact. Follow-up evaluation includes medication, blood pressure, and morbid events.

Harlem Substudy. A parallel group of subjects is being followed at Harlem Hospital. The initial evaluation is the same, but all the subjects are African-American. They are enrolled in the ratio of one normotensive for every two hypertensives.

Project Two (the Worksite Study) is a prospective study of occupational stress in employed men and women working at ten worksites in New York, which was started in 1986. The central hypothesis is that subjects in high strain jobs (defined as those combining a high workload with a low level of perceived control or decision latitude) will develop higher blood pressures and more target organ damage (echo LVH and carotid plaque) than those in less stressful jobs. Subjects are enrolled by first screening all eligible subjects at each worksite and then randomly selecting subjects from those who meet the eligibility criteria. For this project, subjects must be normotensive or with borderline hypertension. Those with hypertension requiring treatment are not eligible, although subjects who subsequently are started on medication are still followed. Subjects are reevaluated every three years, with all the measures being repeated.

Project Three is an examination of blood pressure and hormonal changes occurring in association with the menstrual cycle and menopause. In Study One, healthy women are evaluated on two occasions, once during the follicular and once during the luteal phase, with a 24-hour blood pressure recording, and urine collection for hormones of the reproductive system and renin-angiotensin systems. In Study Two, age-matched pre- and post-menopausal women are evaluated once with the same protocol. Study One is almost completed, and Study Two is just beginning.

1.4.2 Cohort Governance

The studies are coordinated by a committee consisting of Drs. Pickering, Schwartz, and James.

1.4.3 Demographic Characteristics of Current Cohorts

1.4.3.1 Project 1 (N=1,081)

1. Age Distribution

Mean = ??? years; SD = ?

Age	Frequency	Percent
LE 39		
40-49	184	17
50-59	305	29
60-69	326	30
70-79	255	24
80-89		
90-99		
100+		
Total	1070	100

2. Race Distribution

Race	Frequency	Percent
White	860	80
Black	155	14
Native American/Alaska Native		
Asian/ Pacific Islander		
Hispanic		
Other	66	6
Total	1081	100

3. Gender Distribution

Gender	Frequency	Percent
Male	476	44
Female	605	56
Total	1081	100

1.4.3.2 Project 2 (N=422)**1. Age Distribution**

Mean = ? years; SD = ?

Age	Frequency	Percent
LE 39		
40-49	186	44
50-59	139	33
60-69	97	23
70-79		
80-89		
90-99		
100+		
Total	422	100

2. Race Distribution

Race	Frequency	Percent
White	281	66
Black	96	23
Native American/Alaska Native		
Asian/Pacific Islander		
Hispanic		
Other	47	11
Total	424 (?)	100

3. Gender Distribution

Gender	Frequency	Percent
Male	271	64
Female	151	36
Total	422	100

1.4.3.3 Project 3 (N=19)**1. Age Distribution**

Mean = ? years; SD = ?

Age	Frequency	Percent
LE 39		
40-49		
50-59		
60-69		
70-79		
80-89		
90-99		
100+		
Total		

2. Race Distribution

Race	Frequency	Percent
White	9	47
Black	6	32
Native American/Alaska Native		
Asian/Pacific Islander		
Hispanic		
Other	4	21
Total	19	100

3. Gender Distribution

Gender	Frequency	Percent
Male		
Female	19	100
Total	19	100

1.4.4 Information Collected

Predictors

Variable	Project 1	Project 2	Project 3
Medical history	Yes	Yes	Yes
Demographics	Yes	Yes	Yes
Life style (alcohol, smoking, etc.)	Yes	Yes	Yes
Height, weight	Yes	Yes	Yes
Routine blood test (include TC, TG, HDL)	Yes	Yes	No
Anthropometrics (waist, hip, etc.)	Yes	Yes	Yes
Clinic blood pressure	Yes	Yes	Yes
24-hour blood pressure	Yes	Yes	Yes
Electrocardiogram	Yes	Yes	No
Echocardiogram	Some	Yes	Some
Carotid ultrasound	Some	Yes	Some
24-hour urine (electrolytes, creatinine)	Yes	Yes	Yes
Reproductive hormones	No	No	Yes
Psychosocial questionnaires	Yes	Yes	Yes

Outcomes

Project 1:
 myocardial infarction
 coronary bypass surgery
 coronary angioplasty
 sudden cardiac death
 completed stroke

Project 2:
 ambulatory blood pressure
 carotid artery atherosclerosis
 left ventricular hypertrophy

Project 3 (cross-sectional)

The outcome measures listed under the Project 1 will be collected for SHHS participants from all cohorts.

See Section 1.7 for a complete summary of data collected stratified by parent cohort.

1.4.5 Data Quality Assurance and Control

Standardization of procedures is ensured by the use of operating manuals to maintain continuity both over time and between the New York Hospital and Harlem sites. New technicians are trained by existing staff and investigators, and blood pressure measurement technique is taught and evaluated by the Shared Care procedures and videotapes. Data entry is done from preset forms with outlier detection and double entry.

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1.5 Strong Heart Study (SHS)

1.5.1 Cohort Selection

The SHS is a study of cardiovascular disease (CVD) among Native Americans. It involves 12 Native American communities in Arizona, Oklahoma, and North and South Dakota. The objective of the SHS is to employ standardized methodology to obtain estimates of CVD mortality and morbidity rates as well as to allow comparison of CVD risk factor levels among Native American groups living in three different areas: Phoenix, Arizona, Southwestern Oklahoma, and the Aberdeen area of South and North Dakota. The study population includes members of the following tribes:

- 1) The Pima/Maricopa Indians of central Arizona who live in the Gila River Indian Community (GRIC) and the Salt River Indian Community (SRIC).
- 2) The Seven Tribes of southwestern Oklahoma: Apache, Caddo, Comanche, Delaware, Fort Sill Apache, Kiowa and Wichita.
- 3) The Ogala Sioux Tribe (Pine Ridge), and the Cheyenne River Sioux Tribe (Eagle Butte) of South Dakota and the Devil's Lake Sioux Tribe (Ft. Totten) of North Dakota.
- 4) The study design and methods have been previously reported^{1,2}. After a mortality and morbidity survey (Phase I) using existing records initiated on October 1, 1988, the SHS entered its major phase (Phase II) involving clinical evaluations and follow-up of the population. Eligible to be enrolled were Native Americans aged 45-74 between July 1989 and January 1992 living in the aforementioned Indian communities. Tribal rolls were used; individuals who had died, moved, or were institutionalized were not included. Examinations (Exam 1) were performed on 4549 subjects with a 55-72% participation rate and at least 1500 from each area. Surveys included interviews, physical exams, blood pressure measurements, laboratory tests for cardiovascular risk factors, echocardiography and electrocardiograms. Exam 2 of SHS will be completed by November 1995, and Exam 3 is planned to start August 1996.

1.5.2 Cohort Governance

The SHS is funded by the NHLBI, and the operations of the study are directed by the SHS Steering Committee, which includes members from each of the 3 clinical centers and the NHLBI Project Manager. In addition to being Field Centers, the Oklahoma Center is the Data Coordinating Center; the Dakotas Center is the Electrocardiogram Reading Center; and the Arizona Center is the Core Laboratory. The Echocardiogram Reading Center is located at Cornell University Medical Center. The Pulmonary Function Reading Center is at the University of Arizona under the direction of Dr. Paul Enright, who is also a co-investigator for the TES and H&E cohorts and performs the same function for these latter studies. Participation in the SHHS has been approved by the SHS Steering Committee and by the local tribal councils. The PI's of the SHS clinical centers are co-investigators at the University of Arizona Investigative Center.

1.5.3 Demographic Characteristics of Current Cohort (N=4,549)

1. Age Distribution

Mean = 61.13 years; SD = 8.16

Age	Frequency	Percent
LE 39		
40-49	129	3
50-59	2,053	45
60-69	1,519	33
70-79	821	18
80-89	27	1
90-99		
100+		
Total	4,549	100

2. Race Distribution

Race	Frequency	Percent
White		
Black		
Native American/Alaska Native	4,549	100
Asian/Pacific Islander		
Hispanic		
Other		
Total	4,549	100

3. Gender Distribution

Gender	Frequency	Percent
Male	1,846	41
Female	2,703	59
Total	4,549	100

1.5.4 Information Collected

Predictors

- interviews
- physical examination
- laboratory tests
- spirometry
- electrocardiograms
- echocardiograms
- lipids and lipid proteins
- fibrinogen
- post-load fasting glucose
- urinary albumin and creatinine
- waist and hip circumferences
- bioelectric impedance measurement of body fat
- blood pressure
- ankle/arm index

Outcomes

- fatal and non-fatal myocardial infarction (MI)
- fatal CHD
- fatal and non-fatal stroke
- fatal and non-fatal CHF
- other fatal cardiovascular disease

See Section 1.7 for a complete summary of data collected stratified by parent cohort.

1.5.5 Data Quality Assurance and Control

The methods used in obtaining data in the SHS are described in the study's manual of operations and in recent publications^{1,2}. Technicians and interviewers undergo extensive training and must meet certification standards established by the study. There are standard quality control measures for maintenance of the scale, sphygmomanometer, doppler, impedance meter and electrocardiographic equipment at each Field Center. There is an established quality assurance procedure for laboratory specimens in which replicate unknown specimens are analyzed by the core laboratory. The electrocardiograms, echocardiograms and pulmonary function studies are read at central reading centers which have quality assurance programs in place. For medical record abstraction, quarterly evaluations of the correctness and completeness of abstraction are performed by checks against duplicate abstracts. Consistent errors and discrepancies are corrected. In addition, biannual quality control site visits are performed at each Field Center by representatives from the NHLBI Program Office and investigators and staff from the other centers. Written evaluations with suggestions for improvement are provided to the sites.

The methods used in data management are described in the SHS manual of operations. Standardized data collection forms are used at the Field Centers. Forms are checked for completeness at the Field Center and then subsequently at the Data Coordinating Center.

Ambiguous or erroneous items are clarified and corrected by the Field and Coordinating Centers. All forms are then double-entered on computers at the Coordinating Center. Summary statistics are generated periodically to identify unreasonable data which are then checked and if necessary corrected.

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1.6 Tucson Investigative Center

1.6.1 Tucson Epidemiological Study of AOD (TES)

1.6.1.1 Cohort Selection

The objectives of the TES Cohort are to investigate longitudinally the etiology and natural history of Airway Obstructive Diseases (AOD), including evaluations of cardiopulmonary correlates and cardiovascular outcomes (i.e., mortality). The cohort was selected as a multi-stage stratified cluster sample of the Tucson urban area in 1971-73; stratification was on age and socioeconomic status, using census block statistics; the blocks also were clustered geographically, outside of the "Model Cities" area (as the Mexican-American Hispanics felt overstudied at the time), thus providing an essentially non-Hispanic white population. Households were enrolled within each block chosen through random sampling; the sample contained 3,805 individuals in 1,655 households¹. Comparisons of the participant sample enrolled (1972-73) with the census data demonstrated that the population under study was representative of the Tucson non-Hispanic white population. The TES is a project within a National Heart, Lung and Blood Institute (NHLBI) Specialized Center of Research (SCOR) grant under the directorship of Dr. Benjamin Burrows, who is Director of the Respiratory Sciences Center at the University of Arizona.

In the greater than 20 years of this cohort's existence, there have been 12 surveys of the population. At the end of the twelfth survey in 1993, there were a total of 5647 who had been under study, a result of enrolling new household members (e.g., spouses and newborns); 3591 (64%) were still active participants. Mortality amounted to 837 (16%), which was greater in the elderly, ever smokers and males^{10,11}. There were 844 (16%) permanent refusals; they did not differ in characteristics from continuing participants. There were 375 (7%) permanently lost to follow-up; they differed from continuing participants only in that there were somewhat younger adults in this group, and they had less airway obstructive disease (AOD)¹⁰. The remainder are still being followed (including 1115 ages 40 and older); the current survey started with 3235 subjects. The refusal and loss rates in the total population has been smaller than expected, and the rate is stable; it is expected these trends will continue through current studies. Because no important differences can be found in sub-groups who have been lost to follow-up or in those who refused when compared to continuous participants, the sample is expected to be representative throughout the first 25 years of study.

1.6.1.2 Cohort Governance

The principal investigator (PI) of this Arizona AOD SCOR project is Dr. Michael Lebowitz; the co-PI is Dr. Burrows. They work with the PIs of the Clinical Core (Dr. Paul Enright), and the Computer-Biometry Core (Dr. Duane Sherrill), and are aided by their co-investigators (including Dr. Stuart Quan), to ensure proper conduct, data collection/management, quality assurance/quality control, analyses, and presentations and publications. In addition to daily activities, weekly staff meetings are conducted to ensure oversight.

1.6.1.3 Demographic Characteristics of Current Cohort (N=1,201)**1. Age Distribution**

Mean = 62.49 years; SD = 16.13

Age	Frequency	Percent
LE 39	22	2
40-49	346	29
50-59	209	17
60-69	179	15
70-79	215	18
80-89	170	14
90-99	58	5
100+	2	< 1
Total	1,201	100

2. Race Distribution

Race	Frequency	Percent
White	1,150	96
Black		
Native American/Alaska Native		
Asian/Pacific Islander		
Hispanic	39	3
Other	9	1
Total	1,198	100

3. Gender Distribution

Gender	Frequency	Percent
Male	514	43
Female	687	57
Total	1,201	100

1.6.1.4 Information Collected

The TES has been focused on pulmonary outcomes (25 years of pulmonary disease/diagnoses morbidity and mortality follow-up, as well as different types of pulmonary function measurements and chest x-rays). It also has data pertaining to the prevalence of self reported cardiac and non-cardiopulmonary diseases and diagnoses.

Predictors

- questionnaires on medical history, including CVD history
- family medical history
- smoking
- occupational and environmental exposures
- exercise
- socio-environmental characteristics
- height, weight and other anthropometric measurements
- blood pressure
- IgE determinations
- surveys pertaining to sleep disorders
- medication use
- lung function tests
- alpha one antitrypsin determinations
- cholesterol
- vectorcardiography
- chest radiographs
- electrocardiograms
- ankle/arm index
- 6-minute walk with pulse oximetry

Outcomes

The TES also has obtained mortality information on its subjects with ascertainment of the cause of death by clinical follow-up and death certificate analysis using state agencies, the National Death Index computer files and the Social Security Administration.

Questions pertaining to sleep disorders were asked on the ninth and twelfth surveys. Identical questions were asked on both surveys. Subjects were asked "Have you ever been troubled by any of the following sleep problems?": Trouble falling asleep, Trouble staying asleep, Not enough sleep, Too much sleep, Waking up too early and not being able to get back to sleep, Falling asleep during the day and Nightmares (dreams which frighten you). Responses were "Yes, still have the problem," "Yes, but no longer have the problem," or "No, have not had the problem." Subjects also were asked "How often do you snore loudly?" Responses were "Every night," "Most nights," "Some nights," "Rarely," and "Don't know." On survey 12, subjects were allowed to respond "Never" to the snoring question.

A special detailed sleep questionnaire was administered to participants who gave affirmative answers to having sleep problems or snoring in survey 9. This special questionnaire

elicited additional information pertaining to sleep habits and symptoms related to periodic limb movement disorder, sleep apnea and psychological disturbances.

See Section 1.7 for a complete summary of data collected stratified by parent cohort.

1.6.1.5 Data Quality Assurance and Control

Quality assurance/control procedures, as contained in working manuals, are developed for each task and are overseen by the co-investigators and staff. These include the development and review of detailed Standard Operating Procedures (SOPs) for each procedure. Working procedures are used for the extensive training and retraining of nurses and technicians, as well as to document the tasks completed during preparation and analysis. Questionnaires and Objective Tests: As documented, TES study instruments and procedures are usually based on and expanded from existing standards, such as ATS & DLD standards, and Lung Health Study SOPs. Some of these pulmonary instruments and procedures were developed by the TES investigators. Other SOPs, such as for cardiovascular studies, were derived from CHS or the Atherosclerosis Risk in Communities (ARIC) Studies by Dr. Enright.

Data Entry, Verification, Validation and Data Management: Data validation includes checks to ensure the accuracy and reliability of the data prior to performing further analyses. These checks include internal and external consistency evaluations, cross-comparisons with other data available (validation), integration of data collected by multiple people using multiple instruments at the sites, and determining that the data are reasonable (e.g., outlier identification and range checks). Data is double-entered and checked for acceptable range, incorrect values, or missing data.

Raw data are entered from and to pre-specified forms. Data entry is performed using an interactive system on a mini-computer network (Sun) with a database management program that permits flexible database specifications.

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1.6.2 Tucson Host Factors, Bronchial Reactivity, & Environmental (H&E) Cohort

1.6.2.1 Cohort Selection

This study is evaluating the role of bronchial responsiveness, host immunological status, smoking, environmental and occupational exposures in the acute and chronic processes in the etiology, natural history and type differentiation of airway obstructive diseases (AOD). One of its specific aims is to determine the important factors in the evolution of cardiopulmonary problems and the prediction of mortality.

The population studied is derived from a multistage stratified cluster sample drawn from the municipal employees of Pima County (Arizona), in which Tucson is located^{1,2}. The first stage of the study screened 2323 employees to obtain demographic characteristics and location of residence in 1987-88. Their demographic characteristics (age, sex, ethnic group, educational level) were similar to the employed population of Tucson; Hispanics represented about 25% of the population, and others (Black, Asian/Pacific Islanders, Native Americans) below 5% each. Prevalence rates of major symptoms, smoking rates (29%), and lung function were similar between the non-Hispanic white participants in this and in TES (described above), except for small differences within sub-groups. Subsequent follow-up has consisted of the health evaluation surveys in those residing in the Tucson urban area. Currently, there are over 2600 individuals in the study.

.6.2.2 Cohort Governance

This cohort is part of the University of Arizona Respiratory Sciences Center AOD SCOR grant under the directorship of Dr. Benjamin Burrows. The PI of this Arizona AOD SCOR project is Dr. Michael Lebowitz. He works with the PIs of the Clinical Core (Dr. Paul Enright), and the Computer-Biometry Core (Dr. Duane Sherrill), and is aided by the co-investigators to ensure proper conduct, data collection/management, quality assurance/quality control, analyses, and presentations and publications. In addition to daily activities, weekly staff meetings for both H&E and TES are conducted to ensure oversight. (H&E evaluations have been performed with the same clinical staff team as used for TES.)

1.6.2.3 Demographic Characteristics of Current Cohort (N=920)**1. Age Distribution**

Mean = 53.57 years; SD = 10.16

Age	Frequency	Percent
LE 39	13	1
40-49	388	42
50-59	257	28
60-69	190	21
70-79	67	7
80-89	3	< 1
90-99	2	< 1
100+		
Total	920	100

2. Race Distribution

Race	Frequency	Percent
White	742	81
Black	23	2
Native American/Alaska Native	15	2
Asian/Pacific Islander		
Hispanic	117	13
Other	18	2
Total	915	100

3. Gender Distribution

Gender	Frequency	Percent
Male	437	47
Female	483	53
Total	920	100

1.6.2.4 Information Collected

Predictors

Basic assessments of individual health have involved physiological, clinical, immunological and epidemiological techniques utilized in the TES cohort. Individual characteristics were determined from the standardized health questionnaires.

Serum was obtained for IgE, IgG, IgG subclasses, blood counts (including eosinophils) and cholesterol.

pulmonary function tests (MEFVs & PEFs)

ankle/arm index

6-minute walk with pulse oximetry

electrocardiograms

Outcomes

The H&E cohort has focused on pulmonary outcomes (diseases, diagnoses, morbidity and mortality, as well as different types of pulmonary function measurements, including bronchial lability and responsiveness); it also has information pertaining to self-reported cardiac and non-cardiopulmonary diseases and diagnoses.

This cohort was administered the TES Survey 12 sleep questions during the same time frame as the TES cohort (Sec 1.6.1.5), but was not given the Survey 9 instrument.

See Section 1.7 for a complete summary of data collected stratified by parent cohort.

1.6.2.5 Data Quality Assurance and Control

See 1.6.1.5 (as it is combined with TES)

1.6.2.6 References

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1.7 Summary of Information Collected

In the previous sections, the six parent cohorts described the outcome variables each collected, potential risk factors collected, and any sleep or sleep-related variables that were collected. This section contains tables summarizing variables collected stratified by parent cohort. Table 1.7.1 lists all outcome variables collected by the cohorts, Table 1.7.2 lists the potential risk factors associated with the cohorts, and Table 1.7.3 lists the sleep and the sleep-related variables.

1.7.1 Outcome Variables Collected by Parent Cohorts

Key: ✓ = collected; --- = not collected

Outcome Variable	ARIC	CHS	Framingham	New York	Strong Heart	Tucson
MI	✓	✓	✓	✓	✓	---
CHD Death	✓	✓	✓	✓	✓	---
Non-fatal Stroke	✓	✓	✓	✓	✓	---
Fatal Stroke	✓	✓	✓	✓	✓	---
Angina Pectoris	✓	✓	✓	---	✓	---
TIA	✓	✓	✓	---	✓	---
Intermittent Claudication	✓	✓	✓	---	✓	---
Incident Hypertension	✓	✓	---	✓	---	---
Death	✓	✓	---	✓	✓	✓
CHF	✓	✓	✓	---	✓	---
Pulmonary Disease	---	---	---	---	---	✓
Coronary Artery Bypass	✓	---	---	✓	---	---
Coronary Angioplasty	✓	---	---	✓	---	---

1.7.2 Potential Risk Factors Collected by Parent Cohorts

Key: ✓ = collected; --- = not collected

Potential Risk Factors	ARIC	CHS	Framingham	New York	Strong Heart	Tucson
DEMOGRAPHICS						
Age	✓	✓	✓	✓	✓	✓
Gender	✓	✓	✓	✓	✓	✓
Race/Ethnicity	✓	✓	✓	✓	✓	✓
Marital Status	✓	✓	✓	✓	✓	✓
SES						
Education	✓	✓	---	✓	✓	✓
Occupation	✓	✓	---	✓	✓	✓
Family Income	✓	✓	---	✓	✓	✓
OBESITY/OVERWEIGHT						
Weight	✓	✓	✓	✓	✓	✓
Standing Height	✓	✓	✓	✓	✓	✓
Skinfolds	✓	---	✓	---	---	---
Girths	✓	✓	✓	✓	✓	✓
Neck circum.	---	✓	---	---	✓	---
Bioelectrical impedance	---	✓	✓	---	---	---

1.7.2 Potential Risk Factors Collected by Parent Cohorts

Key: ✓ = collected; --- = not collected

Potential Risk Factors	ARIC	CHS	Framingham	New York	Strong Heart	Tucson
BLOOD PRESSURE/HYPERTENSION						
BP measured	✓	✓	✓	✓	✓	✓
Personal History	✓	✓	✓	✓	✓	✓
BP treatment	✓	✓	✓	✓	✓	✓
MEDICATIONS						
Current -- last 2 weeks	✓	✓	✓	✓	✓	✓
SMOKING						
Current/Past?	✓	✓	✓	✓	✓	✓
Current # cigs	✓	✓	✓	✓	✓	✓
Average past # cigs	✓	✓	✓	---	✓	✓
Year Start	✓	✓	✓	---	✓	✓
Year Quit	✓	✓	✓	✓	✓	✓
ALCOHOL INTAKE						
History	✓	✓	---	✓	✓	✓
Habits	✓	✓	✓	✓	✓	✓
Type	✓	✓	✓	✓	✓	✓

1.7.2 Potential Risk Factors Collected by Parent Cohorts

Key: ✓ = collected; --- = not collected

Potential Risk Factors	ARIC	CHS	Framingham	New York	Strong Heart	Tucson
SUBCLINICAL CVD						
ECG, 12-lead	✓	✓	✓	✓	✓	✓
B-mode Ultrasound						
Carotid	✓	✓	✓	Some	✓	---
Popliteal	✓	---	---	---	---	---
Abd. aorta	---	✓	---	---	---	---
Holter	---	✓	---	---	---	---
Echocardiogram	---	✓	✓	Some	✓	---
MRI	---	✓	---	---	✓	---
Ankle-Arm Index	✓	✓	✓	---	✓	✓
FAMILY HISTORY CVD						
Parents	✓	✓	---	✓	✓	✓
Siblings	✓	✓	---	✓	✓	---

1.7.2 Potential Risk Factors Collected by Parent Cohorts

Key: ✓ = collected; --- = not collected

Potential Risk Factors	ARIC	CHS	Framingham	New York	Strong Heart	Tucson
DIABETES						
Personal History	✓	✓	---	✓	✓	✓
Fasting glycemia	✓	✓	✓	✓	✓	---
Fasting insulin	✓	✓	✓	---	✓	---
Post-load insulin	---	---	✓	---	---	---
Glucose tolerance	---	✓	✓	---	✓	---
LIPIDS						
Total cholesterol	✓	✓	✓	✓	✓	✓
Triglycerides	✓	✓	✓	✓	✓	---
HDL	✓	✓	✓	✓	✓	---
LDL	✓	✓	✓	---	✓	---
Personal history hypercholest.	✓	✓	---	---	---	---

1.7.2 Potential Risk Factors Collected by Parent Cohorts

Key: ✓ = collected; --- = not collected

RESPIRATORY DISEASES and SYMPTOMS						
Chronic bronchitis	✓	✓	✓	---	✓	✓
Asthma	✓	✓	✓	---	✓	✓
Emphysema	✓	✓	---	---	✓	✓

1.7.3 Sleep and Sleep-related Variables Collected by Parent Cohorts

Key: ✓ = collected; --- = not collected

Variable	ARIC	CHS	Framingham	New York	Strong Heart	Tucson
Snoring	---	✓	---	---	✓	✓
Frequency of snoring	---	✓	---	---	✓	✓
Loudness of snoring	---	✓	---	---	---	---
Ever stopped breathing	---	✓	---	---	---	---
Stopped breathing frequency	---	✓	---	---	---	---
Epworth Sleepiness Scale	---	✓	---	---	---	---
Often feel tired	✓	✓	---	---	---	---
Often have trouble falling asleep	✓	✓	---	---	---	✓
Trouble staying asleep	---	---	---	---	---	✓
Wake up repeatedly at night	✓	✓	---	---	---	---
Wake up feeling exhausted	✓	✓	---	---	---	---
Wake up breathless	✓	✓	---	---	---	---
Don't get enough sleep	---	---	---	---	---	✓
Get too much sleep	---	---	---	---	---	✓

1.7.3 Sleep and Sleep-related Variables Collected by Parent Cohorts

Key: ✓ = collected; --- = not collected

Wake up too early and not being able to get back to sleep	---	---	---	---	---	✓
Falling asleep during the day	---	---	---	---	---	✓
Nightmares	---	---	---	---	---	✓

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SLEEP HEART HEALTH STUDY MANUAL OF OPERATIONS

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2.1 Overview

The parent cohorts for the Sleep Heart Health Study offer a sampling frame of over 20,000 individuals. In specifying criteria for sample selection from the parent cohorts, the Steering Committee carefully weighed the need to fully represent minorities and women and to cover the full age spectrum, recognizing that the cardiovascular consequences of sleep-disordered breathing may vary by age. The total sample size, which was generally fixed by the time frame and resources available to the investigators, was thus distributed in a fashion that assured that information would be gained on women and minorities and younger and older persons. In designing the sampling approach for selecting the Sleep Heart Health Study cohort, the Steering Committee agreed to the following criteria:

- **Each site will recruit all available minorities.**
 - **Rationale:** Guidelines of the National Institutes for Health specify that populations should be selected to assure representation of the population, including minority groups, to the fullest extent possible. To maximize representation of minority populations, all minorities will be recruited from the parent cohorts; 600 members of the Strong Heart Study, which includes only Native Americans, will be recruited such that over 10 percent of the full cohort for the Sleep Heart Health Study will be Native American. The other cohorts will contribute 450 African-Americans, 280 Hispanics, and 70 Asian-Americans. Thus, the total minority membership of the study will be approximately 1400 participants.
- **Each site will recruit equal numbers of men and women.**
 - **Rationale:** This criterion has been implemented to assure representation of men and women equally.
- **Habitual snorers will be over-sampled in sites that recruit subjects younger than age 65 years.**
 - **Rationale:** At the anticipated population prevalence of sleep-disordered breathing, power can be increased by increasing the prevalence of sleep-disordered breathing among participants in the cohort. At younger ages, habitual snoring predicts sleep-disordered breathing and consequently the sample will be enriched with snorers in the age stratum of less than 65 years. With increasing age, snoring is not similarly predictive.
- **Persons with prevalent cardiovascular disease and hypertension will not be excluded.**
 - **Rationale:** The information on prevalent disease is variable among the cohorts and the presence of prevalent disease cannot be uniformly determined among the cohorts before recruitment begins. Moreover, cross-sectional analyses addressing associations of prevalent disease with sleep-disordered breathing will contribute substantially to existing literature, given the size of the Sleep Heart Health Study Cohort. The information gained from follow-up of persons with prevalent disease will provide clinically relevant information. Follow-up of persons with prevalent disease will provide insight into the impact of sleep-disordered breathing on the natural history of hypertension and on risk for recurrent myocardial infarction and stroke.

Additionally, all participants will be at least 40 years of age. This criterion, specified in the Request for Applications, excludes young persons at low risk for cardiovascular and cerebrovascular disease.

- **Persons who have been treated for sleep apnea, utilize home oxygen therapy, or have a tracheostomy will be excluded.**
 - **Rationale:** Subjects having sleep apnea who have been treated will be excluded for two reasons: first, if treated with CPAP, monitoring their sleep would be technically difficult; second, treatment may have altered their “exposure” status and the measured indices of sleep apnea may no longer reflect their lifetime risk status. Other excluding conditions have been chosen because they impact either the feasibility or the interpretation of the sleep study.

The SHHS cohort will be comprised of members selected from six parent cohorts that will be recruited by six investigative centers, all of whom have access to ongoing cohort studies of cardiovascular disease. Several centers will recruit from more than one parent cohort, as described below.

Table 2.1.1 Sources of the SHHS Cohort

Investigative Center	Parent Cohorts	Parent Cohort Size	Number to be Recruited for SHHS
Sacramento/ Pittsburgh	CHS	2,788	1,000
Johns Hopkins	CHS	1,134	350
	ARIC	4,020	750
Minneapolis	ARIC	3,827	1,000
Framingham	Framingham Study	2,038	1,000
NYU/Cornell	New York Hospital sample Worksite sample Menopause sample Harlem Hospital sample	2,770	1,000
Univ. of Arizona	Tucson Epidemiological Study (TES) Health and Environment (H&E)	2,121	900
	Strong Heart Study (SHS) (Dakotas, Oklahoma, Arizona)	4,549	600
TOTAL		23,247	6,600

After the first 1,000 participants are recruited study-wide, the sampling fractions will be adjusted according to the interim participation rate and observed sleep apnea prevalence. Attention will also be paid to achieve balance by gender and age. Further revisions of the sampling fractions may occur subsequently, in accordance with the prevalence of sleep apnea in interim analyses to be conducted every 6 months.

The Steering Committee recognized that the resulting sample would not necessarily be representative of either the parent cohorts or of the general population. However, the sample should provide an internally valid assessment of the cardiovascular consequences of sleep-disordered breathing and of the impact of sleep-disordered breathing on quality of life. The findings will need to be generalized with caution and with careful assessment of the sampling that established the parent cohorts and of the subsequent sampling for the Sleep Heart Health Study cohort.

2.2 Sampling and Recruitment

This section describes the sampling and recruitment processes used by each of the investigative centers, with Strong Heart Study and Tucson studies described separately.

Included are the following topics:

- Time frame and time line for recruitment
- Sampling fractions
 - Description of sampling fractions
 - Demographic data
- Recruitment procedures
 - Administration of the Sleep Habits Questionnaire
 - Explaining SHHS
 - Schedule monitoring
 - Flow diagram

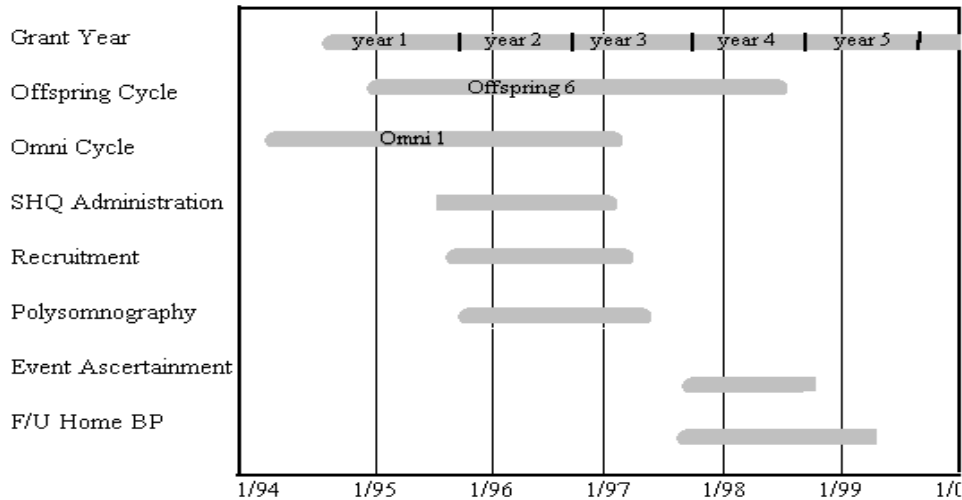
Section 2.2.8 summarizes the sampling fractions data by center and Section 2.2.9 summarizes the sampling and recruitment methods by center.

2.2.1 Framingham

2.2.1.1 Time Frame and Time Line for Recruitment

Overall strategy: Recruitment for the SHHS will be keyed to the subject's Offspring Cycle 6 or Omni Cycle 1 examination which will provide the baseline measurements for the SHHS. Subjects reporting for a Cycle exam after September 1, 1995 will be mailed the Sleep Habits Questionnaire shortly after their exam. Subjects who completed their Offspring Cycle 6 or Omni Cycle 1 exam prior to September 1, 1995 will be mailed the SHQ in waves of 100 subjects, proceeding chronologically. After classification as habitual snorers or non-snorers, respondents will be recruited based on the sampling fractions detailed below. Home PSG will be performed on 1000 subjects during the 18 months between October 1995 and March 1997. To achieve this

goal, we will attempt to schedule 4 studies per night, 5 nights per week, 48 weeks per year, generating 1440 PSG slots over the 18 month period. We anticipate 10% of the slots will go unfilled and another 10% canceled too late to reschedule another subject, leaving 1152 studies actually performed. This allows for ~ 10% of studies to be repeated if data quality is inadequate.



2.2.1.2 Sampling Fractions

2.2.1.2.1 Description of Sampling Fractions

In both the Offspring and Omni Cohorts, we anticipate a 80% return rate on the SHQ, and that the percentage of snorers will be 45% for the men and 30% for the women.

Offspring Cohort: Between the start of Cycle 6 in January, 1995 and the end of the recruitment period in April, 1997, 2296 members of the Offspring Cohort will be seen at FHS. Of this group, 67% live within a two-town radius of Framingham and are between the ages of 40 and 74, leaving a pool of 1538 subjects eligible for recruitment, of whom 53% are women.

Omni Cohort: By the end of the SHHS recruiting period in January 1997, we anticipate that 500 Omni subjects will have had an initial clinic evaluation. Based on current recruitment patterns, approximately 55% of this group will be women.

2.2.1.2.2 Demographic Data

The exact composition of the cohort will vary with the success of recruitment. All subjects will be between 40 and 74 years old.

50% consent	Men	Women	Total	75% consent	Men	Women	Total
White	292	328	620	White	353	354	707
Minority	89	108	197	Minority	135	163	298
Total	381	436	817	Total	488	517	1005

2.2.1.3 Recruitment Procedures

2.2.1.3.1 Administration of Sleep Habits Questionnaire

The SHQ will be mailed with a self-addressed stamped envelope to all subjects participating in the FHS. In August 1995, or as soon as the SHQ is available, questionnaires will be sent to the first wave of 100 members of the Offspring and Omni Cohorts who have already had their Cycle 6 or Cycle 1 exam. Subsequent mailings will be timed to allow adequate lead time for return of questionnaires and scheduling of PSGs. It is anticipated that 100 subjects will be mailed the SHQ at approximately one-month intervals. Subjects who do not return the questionnaires after 2 weeks will be sent a reminder postcard, followed by a telephone call, if necessary. Because there will be a backlog of ~ 450 subjects before SHHS recruitment begins, the time between the clinic examination and the PSG will vary from less than one month to 24 months (Omni subjects seen in mid-1994); however, the time between SHQ completion and PSG will vary only from two weeks to 3 months.

All Offspring participants who will not have their Cycle 6 exam before the end of the recruitment period (April, 1997) will be sent the SHQ with a self-addressed, stamped envelope after recruitment is completed. This data will be used in sub-study cross-sectional analyses.

2.2.1.3.2 Explaining SHHS

Subjects will be recruited in the order they were seen at clinic. Initially, the sampling fractions will be 100% for all groups, until the consent rate can be determined. If enthusiasm for the study is high and we have more subjects than needed, then Offspring non-snorers will be ordered by clinic exam date, and selected using tables of random numbers and an appropriate sampling fraction for their gender.

Subjects selected for recruitment will be sent a letter that explains the purpose of the SHHS, briefly describes a sleep study, and invites them to participate. A FHS employee will call the subject several days later to answer any questions and to schedule those subjects who agree to

participate. Tracking of the subjects during the recruitment period will be facilitated by the software developed by the CC.

2.2.1.3.3 Scheduling

Sleep studies will be performed Monday through Friday, with 4 slots available per night. If, as the study progresses, subjects profess a preference for Saturday or Sunday exams, we will adjust our schedule accordingly. Two teams, each consisting of a trained research technician and a less well trained assistant, will perform two studies per night -- an early set-up which should begin between 7 and 8 p.m., and a late set-up which should begin between 8:30 and 9:30.

Scheduling will be done by telephone, and recorded in a dedicated clinic calendar, as well as in the tracking software. To the extent possible we will list alternate dates before the scheduled date for each subject in case earlier subjects cancel. When the subjects are scheduled, they will be asked which time period they prefer. Each subject will be called two days before the scheduled study to confirm the directions and anticipated arrival time, as well as to assess for any acute conditions which may interfere with normal sleep. The technicians will carry beepers so they can communicate in case one team is running late and the other team could switch subjects to maintain the scheduled appointments. Each technician will carry a list of all 4 of the scheduled subjects' addresses and phone numbers.

2.2.1.3.4 Turnaround

Each week, the research technicians will generate a report summarizing the status of all aspects of recruitment: return of SHQ, data entry of SHQ, identification of subjects for recruitment, the status of explanatory letters, recruitment success, PSGs scheduled, and PSGs performed. The three research technicians, the other FHS staff involved in scheduling, and a SHHS researcher (Dr. Givelber or Dr. Gottlieb) will meet to identify, discuss, and solve any problems.

2.2.1.3.5 Flow Diagram

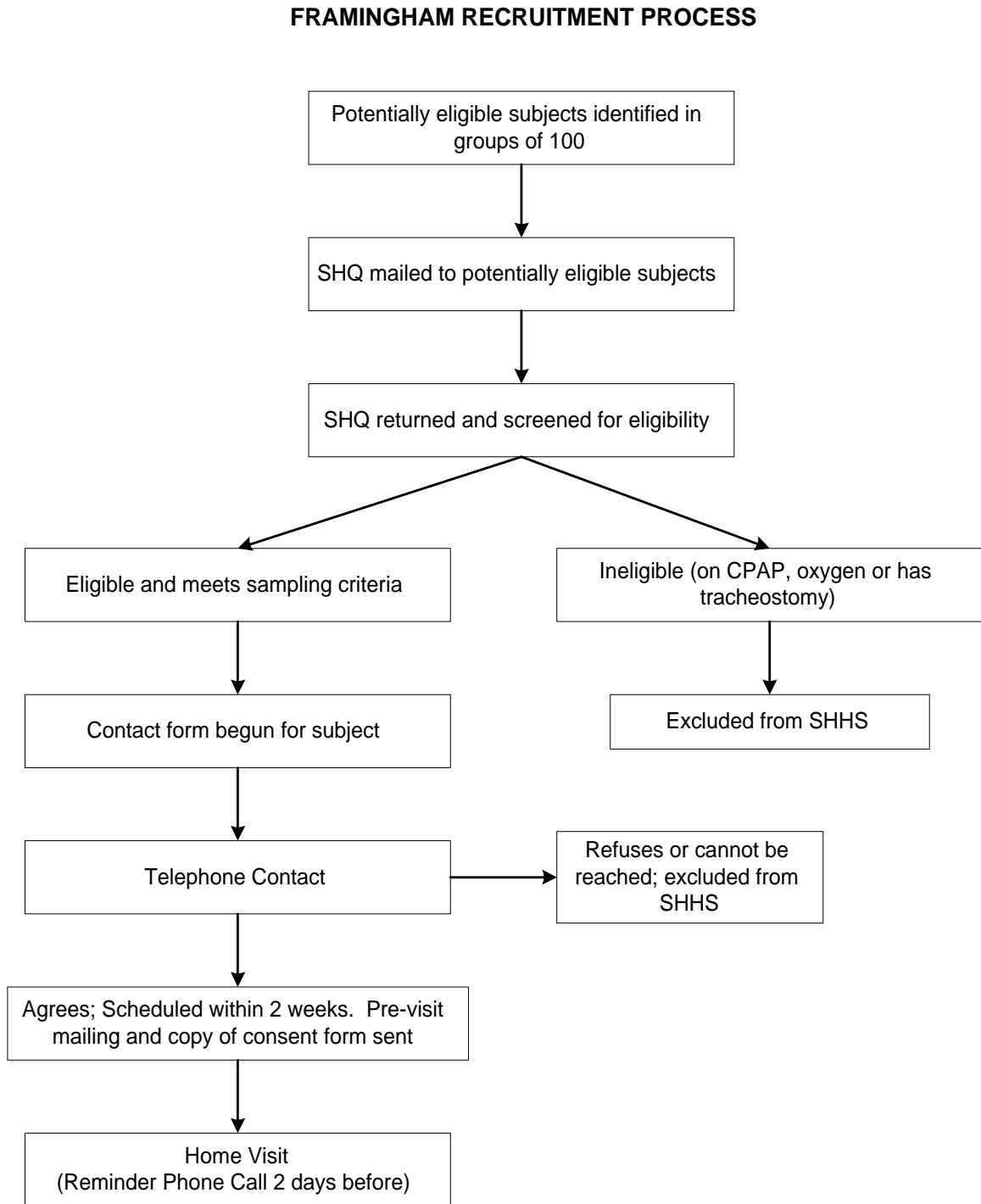


Figure 2.2.1.3.5

2.2.2 Johns Hopkins

2.2.2.1 Time Frame and Time Line for Recruitment

The Johns Hopkins site will recruit approximately 1100 participants, about 750 from ARIC (52 to 73 years old) and 350 from CHS (72 years old or older), with equal numbers of men and women from each parent study.

The following figure outlines our schedule of home visits planned to complete the sleep studies in the first 21 months of the recruitment follow-up period. For the CHS participants, scheduling is assumed to start in October 95. For ARIC, we allow for a 3-month lag period, needed to obtain information on snoring (see below). The estimates in the figure are based on 48 weeks per year, 4 studies per night, 4 nights per week. A fifth night each week will be kept open for rescheduling studies. Allowance has been made for an overall 15% failure rate (including both cancellation and equipment failure).

YEAR 1	YEAR 2		YEAR 3		YEAR 4	
1995	1996		1997		1998	
	Oct	Jan	Oct	Jan	Oct	Jan
CHS	16/wk	6/wk				
ARIC		10/wk	16/wk			
Total per day	4	4	4			

Oct 95 June 97

Weeks: 12 36 36

Total seen				<u>Total</u>	<u>Total - 15%</u>
CHS	192	216		408	346
ARIC		360	576	936	796

The time window for the recruitment of CHS participants overlaps with CHS 7th annual visit (June 95 through May 96). The recruitment of ARIC participants overlaps with the first half of the 4th ARIC clinic visit (3rd follow-up), which will start somewhere between February and March, 1996, and is scheduled to finish in December 1998.

2.2.2.2 Sampling Fractions

2.2.2.2.1 Description of Sampling Fractions

No sampling fractions will be applied to participants recruited from CHS. For ARIC participants, however, the following sampling fractions based on gender, sex, and history of snoring will be applied. Among women, 83 to 97% of those reporting habitual snoring and 15 to 30% of the non-snorers will be invited to participate in the study. Among men, 64 to 92% of the habitual snorers and 20 to 33% of the remainder will be invited to the SHHS. (See Section 2.2.8, Table 2.2.8.2.2.) These sampling fractions were chosen with the goal of ensuring a high prevalence of sleep apnea (AHI5/hr) in the study population (around 25% or higher), while maintaining the general sampling criteria specified above. For each gender-snoring history stratum, a simple random sample will be selected according to the specified sampling fractions from each 3-month block. All African-Americans (approximately, n=30) will be invited to participate, regardless of their snoring history. Likewise, spouses of selected participants will also be invited if they are also participants in the ARIC 4th visit.

2.2.2.2.2 Demographic Data

The Johns Hopkins SHHS cohort will be comprised of 1100 participants, 52 years old or older, 50% male and 50% female. The majority (about 98%) will be white, reflecting the demographic composition of Washington County.

2.2.2.3 Recruitment Procedures

All members of the ARIC and CHS cohorts in Washington County will be sent letters in the summer of 1995 announcing the implementation of the SHHS and giving them information on sleep and sleep disorders. Further, the cohort will be informed of the number of participants who will be recruited for a sleep study and that not all of the current cohort members will be asked to participate. Subsequently, there will be specific approaches to the recruitment of the Hopkins cohort, which will be governed by the current processes for recruitment and retention of the parent cohorts.

2.2.2.3.1 Administering the Sleep Habits Questionnaire, Explaining SHHS, and Scheduling the Home Visit

A. ARIC Component:

All participants scheduled to be contacted for ARIC visit 4 (1996-98) will be sent an introductory letter and the questionnaire on sleep habits with a self-addressed, stamped envelope. The letter will explain the objectives and procedures of the SHHS. Mailings will be conducted in monthly waves according to the scheduled recruitment for the sleep examinations. Even though ARIC visit 4 will not start until around March of 1996, we plan to start recruiting participants in January 1996 for the home sleep study.

The snoring history of the participants who send the questionnaire back will be codified and entered in a database containing the participant's age, race, and gender. From this database, participants who do not meet the exclusion criteria (Section 2.1) will be randomly selected to be invited for the SHHS, according to specified gender and snoring history-specific sampling fractions (see section 2.2.2.2.1).

Recruitment for ARIC Washington County participants will be conducted in two ways:

- The selected participants whose 4th ARIC clinic examination is scheduled to occur before April 97 will be recruited at the time of their scheduled visit 4 examination. This will be done at the time of ARIC exit interview.
- ARIC participants with windows for their 4th visit between April 97 and December 98 will be recruited during a special home visit by a SHHS interviewer. Recruitment during the first 3 months of 1996, before ARIC 4th visit actually starts, will also be conducted at a home visit.

Recruitment through home visit will be initiated simultaneously with the recruitment at the home. At the time of recruitment, the date for the home sleep study will be scheduled. The informed consent form will be signed at the home visit.

B. CHS Component:

One month prior to their year 8 examination (for participants scheduled between October 95 and June 96) and year 9 examination (after July 96), CHS participants will receive a letter explaining the objectives and procedures of the SHHS as well as the Sleep Habits Questionnaire.

At the end of their CHS clinic exam, all participants will be invited to participate in the SHHS. No sampling will be done. An attempt will be made to recruit all minority participants and an equal number of males and females. When the desired number of participants (n=350) is achieved, recruitment will stop.

Participants who agree to participate will sign the informed consent and will be given the Sleep Habits Questionnaire. At that time, the date for the home sleep study will be scheduled.

2.2.2.3.3 Schedule Monitoring

The returned questionnaires from both ARIC and CHS participants will be tracked by the SHHS personnel at the Field Center to determine returns. When a participant does not return the questionnaire, a phone call will be made to the study participant to secure the completed questionnaire or to complete the questionnaire by telephone. ARIC and CHS participants who are interested in participating in the SHHS but unable to schedule the home visit immediately will be recontacted via telephone two weeks later to schedule the home visit at their earliest convenience. Two days before the scheduled home visit, SHHS personnel will call the participants in order to confirm the appointment, answer any questions, and get directions, if necessary.

Adjustments of the sampling fractions will be done depending on the results of interim analysis of the study-wide and Field Center-specific recruitment (see Section 2.1).

2.2.2.3.4 Turnaround

The returned Sleep Habits Questionnaires will be entered into the database as they are received and sent to the Coordinating Center on a weekly basis (via e-mail). (For the ARIC participants, this information will be used to generate the listings of participants to be invited to the study according to the established sampling fractions.) The Field Center will generate weekly reports detailing the number of Sleep Habits Questionnaires mailed and received, the number of studies scheduled, and the number of studies completed.

2.2.2.3.5 Flow Diagram

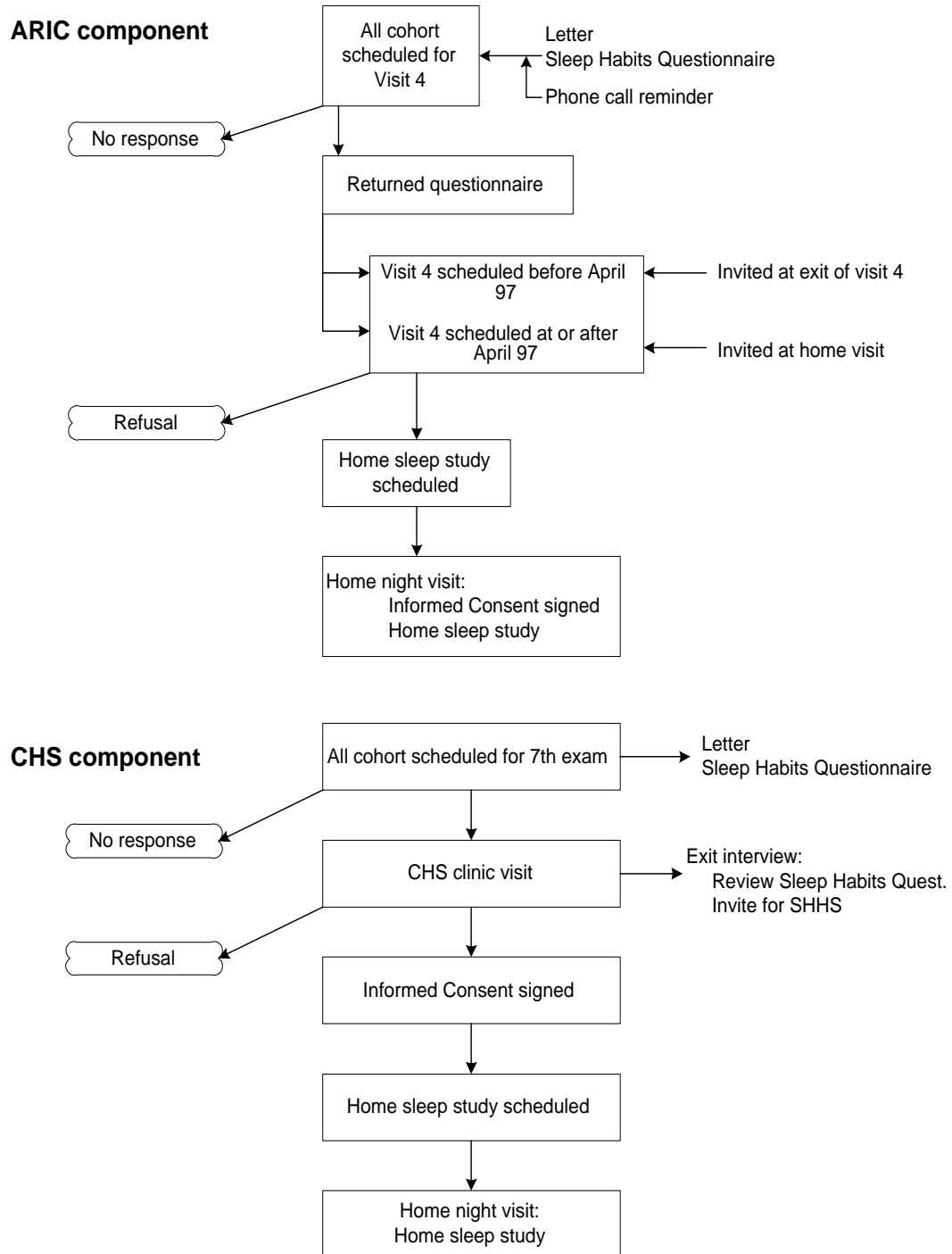
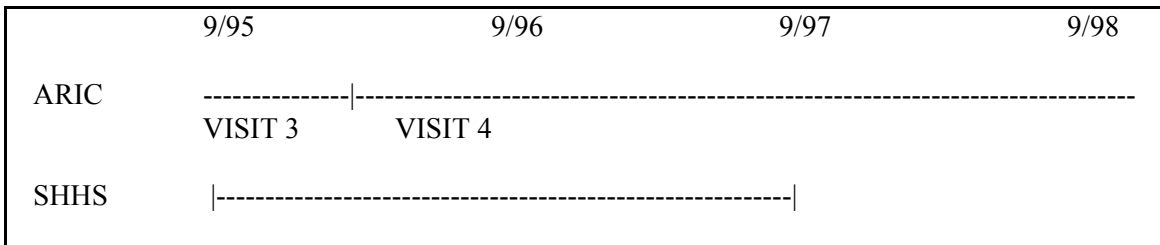


Figure 2.2.2.3.5

2.2.3 Minnesota

2.2.3.1 Time Frame and Time Line for Recruitment

Recruitment will start in September 1995 and be completed within two years, as dictated by the study protocol. The source population for SHHS will be ARIC visit 2 returnees (N=3,828), all of whom will be mailed the Sleep Habits Questionnaire during the two-year recruitment period. Mailing will be conducted in approximately monthly cycles of 100 each until 1,000 successful sleep studies are completed. (At that time a one-time bulk mailing will be sent to the remaining subjects). Based on the pilot study, it is anticipated that each monthly cycle would yield about 60 SHHS participants (or 15 sleep studies per week). Assuming 20% failure rate of multichannel PSG (study-wide pilot data), the anticipated 600 sleep studies per year will yield 500 successful studies (or 1,000 successful studies over two years). The recruitment period for the sleep study will overlap the last few months of ARIC visit 3 (1993-1995) and part of visit 4 (1996-1998). ARIC visit 4 is expected to start in early 1996 (probably March or April).



2.2.3.2 Sampling Fractions

2.2.3.2.1 Description of Sampling Fractions

Equal numbers of men and women will be recruited from each mailing cycle for a home sleep study. Within gender, recruitment will be dependent on habitual snoring status, in line with the study's sampling priorities. Among women, all those reporting habitual snoring will be recruited and 25 to 50% of the remainder, depending on the actual participation rate. Among men, 85 to 100% of those reporting habitual snoring and 15 to 50% of the remainder will be recruited, again, depending on the participation rate. The aforementioned sampling fractions should maximize, within gender, the proportion of subjects having sleep-related breathing disorder (AHI>5). The number of minorities is extremely small (less than 30). All of them will be approached and offered to participate, if eligible. When sampling will be less than 100%, eligible participants will be randomly selected.

The SHHS participation rate and representativeness may be computed with any of the following denominators: 1) ARIC selectees in Minneapolis (N=6,021); 2) ARIC visit 1 participants (N=4,009); 3) ARIC visit 2 returnees (N=3,828); 4) ARIC participants who responded to the SHHS mailing cycles; 5) ARIC participants who responded to the SHHS mailing cycles and were willing to participate in SHHS; 6) ARIC participants who were selected for at-home sleep study. Regardless, ARIC database will allow a comparison of the 1,000 SHHS participants with any of the remaining groups including the original 6,021 ARIC selectees. (Non-respondents to ARIC visit 1 were partially characterized by means of a mailed survey.)

2.2.3.2.2 Demographic Data

The Minneapolis center will contribute 1,000 subjects to the final SHHS cohort: 500 women and 500 men in the age range of 52-74. The cohort will be overwhelmingly white (>98%).

2.2.3.3 Recruitment Procedures

2.2.3.3.1 Administration of Sleep Habits Questionnaire

The questionnaire will be administered, by mail, to all of the source cohort (visit 2 returnees) with the exception of those few who explicitly requested not to be contacted again. The database also contains data about those who died in the interim and those who moved out of the Minneapolis-St. Paul metropolitan area. Mailing will be conducted in monthly cycles, each targeting about 100 ARIC participants. A postcard will be sent one week after the mailing date, thanking respondents and encouraging non-respondents to fill out and return the questionnaire.

2.2.3.3.2 Explaining SHHS

A newsletter to the ARIC participants in the summer of 1995 contained an article about the Sleep Heart Health Study. A cover letter explaining SHHS and its relation to ARIC will be sent with the Sleep Habits Questionnaire. Further information about SHHS will be provided over the phone to those who will be selected for a sleep study. Recruitment materials, tailored to the ARIC cohort, have been developed locally during the pilot phase of SHHS.

2.2.3.3.3 Schedule Monitoring

Each cycle of returned Sleep Habits Questionnaires will yield a list of potential SHHS participants. SHHS selectees (section 2.2.3.2.1) will be contacted by phone in an attempt to schedule a night for the sleep study. The goal will be to complete 15 studies per week (an average of 3 studies per night over 4 weekday nights and one weekend night). Every attempt will be made to fill up the time slots in an efficient manner.

The participant will be informed that the sleep technicians will call 2-3 days before the scheduled night to introduce themselves and answer any remaining questions. A reminder note of the appointment will be mailed about 10 days before the scheduled date. The reminder note will include instructions for the night of the study (preparations).

2.2.3.3.4 Turnaround

Sleep Habits Questionnaire data will be keyed in as they accumulate and used to stratify subjects according to habitual snoring status. It is anticipated that most of the questionnaires from a given mailing cycle will be returned within 21 days of the cycle mailing date. At that time the mailing cycle will be closed and processed to generate a list of subjects for scheduling a sleep study. Attempts to schedule selectees from a given cycle will be terminated two months later. The Minneapolis center has developed a local manual of operations detailing local procedures and communication forms for its three geographical locations (the ARIC Clinic, the University of Minnesota, and the Sleep Laboratory of Hennepin County Medical Center).

2.2.3.3.5 Flow Diagram

MINNESOTA RECRUITMENT PROCESS

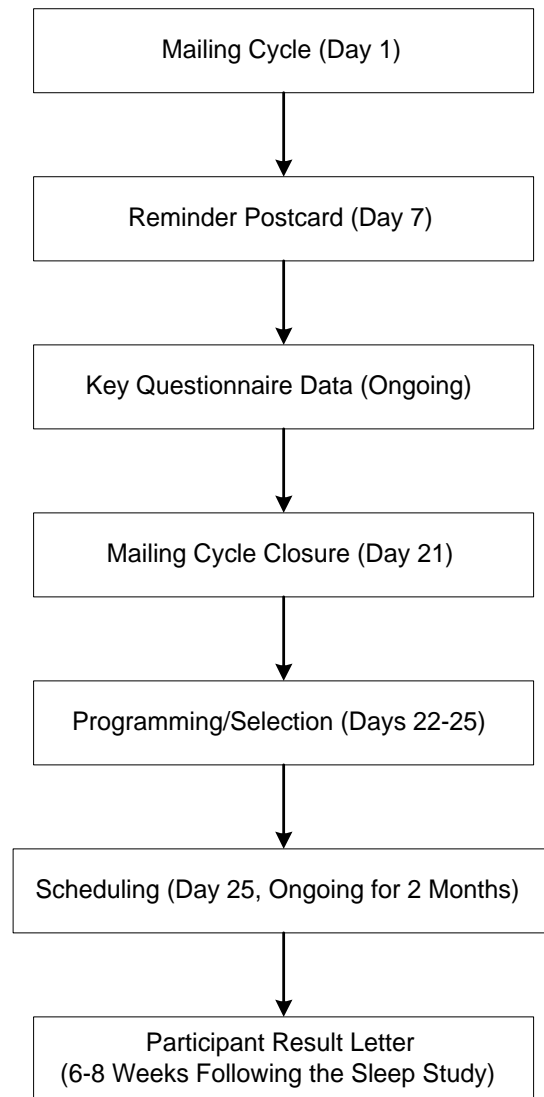


Figure 2.2.3.3.5

2.2.4 NYU/Cornell

As described in Section 1.4.1, the NYU/Cornell field site includes subjects from four cohorts: 1) Pickering's New York Hospital (NYH) clinic sample, 2) the Worksite sample, 3) the Menopause sample, and 4) a Harlem Hospital sample of minorities that is currently being established according to the same general criteria as Pickering's sample. The Worksite and Menopause samples are scheduled for their next data collection point during the next 2-3 years, and the PSG studies will be scheduled to follow shortly after the parent studies' data collection. For most of the participants in the Worksite Study, this will be the fourth evaluation, occurring ten years after the first. For participants in the Menopause Study, this will be their first follow-up, occurring two years (?) after they were initially studied. Follow-up for the Pickering NYH sample and the Harlem Hospital sample has not been performed at fixed intervals, but an attempt will be made to follow-up all subjects who have been seen since 1990 during the period 9/95 - 9/97, and to recruit subjects for the SHHS according to the protocol described below.

2.2.4.1 Time Frame and Time Line for Recruitment

Subjects in each sample will complete the sleep questionnaire at the time they are reevaluated for the parent study. All eligible subjects of the Worksite Study, the Menopause Study, and the Harlem Hospital Clinic sample will be invited to participate in the SHHS. The remainder of the 1000 SHHS subjects from NYU/Cornell, indeed the majority, will be recruited from the Pickering NYH clinic sample. As shown in the following table, subjects will be recruited and scheduled for PSG studies on a continuous basis, at an overall average rate of 9.75 to 10.25 subjects/week during the period of 10/95 to 9/97. In order to recruit as many subjects as possible from the Worksite Study, PSG studies will continue to be performed in this cohort at the rate of 1.5 subjects/week until 6/98 (?).

2.2.4.2 Sampling Fractions

2.2.4.2.1 Description of Sampling Fractions

All eligible subjects of the Worksite Study, the Menopause Study, and the Harlem Hospital Clinic sample will be invited to participate in the SHHS. Thus the sampling fractions will be 1.0 for participants in these three cohorts. The remainder of NYU/Cornell participants in the SHHS will be recruited from Pickering's NYH clinic sample. Estimated sampling fractions for this cohort are based on the study-wide goals of balancing the numbers of males and females recruited at each Field Center, oversampling snorers, and balancing the distribution of those over and under age 65 within this cohort.

2.2.4.2.2 Demographic Data

The resulting sample, pooled across the four Cornell cohorts, should be approximately 50% female. About 24% of the males and 13-15% of the females are expected to have an AHI ≥ 5 . Every eligible minority subject will be invited to participate in the SHHS, and we project that this should result in 20-24% minority participants. Depending on what proportion of all NYU/Cornell subjects are recruited from Pickering's cohort, 25-30% of the final sample will be 65 years of age or older.

2.2.4.3 Recruitment Procedures

2.2.4.3.1 Administration of the Sleep Habits Questionnaire

All participants in the Pickering NYH Clinic sample, the Menopause Study, and the Harlem Hospital Clinic sample will be contacted by mail or phone on a rolling basis. A copy of the Sleep Habits Questionnaire will be mailed to subjects' homes, along with a stamped, self-addressed manila envelope. A postcard will be sent to those who have not returned the questionnaire within two weeks, and up to three phone calls will be made to try to obtain completed questionnaires. [or will subjects be asked to bring their completed questionnaires to NYH at the time of their evaluation?] All Worksite Study subjects will complete the Sleep Habits Questionnaire as part of their regularly scheduled evaluation for the parent study. Returned questionnaires will be checked for completeness, entered into a database and e-mailed to the Coordinating Center at regular intervals.

2.2.4.3.2 Explaining SHHS

Subjects in the Worksite Study will first learn of the SHHS through a project newsletter that is mailed shortly prior to the scheduled recruitment into the parent study. Additional information will be sent to them at the time the results of their cardiovascular work-up are mailed, approximately 2-3 weeks after their evaluation for the parent study. Subjects in the other three cohorts who are selected for a PSG study will be approached, either in person or by phone, after they have been mailed literature describing the SHHS. (For the first six months of data collection, an attempt will be made to recruit all eligible subjects into the SHHS. After evaluating the participation rate by strata within each cohort, sampling fractions for Pickering's NYH clinic sample will be adjusted to achieve the targets specified in the earlier table.) The Cornell SHHS project coordinator will make up to ten attempts to contact each selected subject before declaring him/her a non-participant. The project coordinator will explain the study in detail to the subject and attempt to solicit a verbal agreement to participate in the SHHS.

2.2.4.3.3 Schedule Monitoring

Once a potential subject has verbally agreed to a PSG study, the Cornell project coordinator will enter the relevant data in the ACCESS database and provide his/her name, address and phone number to the NYU project coordinator. The NYU project coordinator will provide this same information to the contact person at the firm that has subcontracted to perform all PSG studies for the NYU/Cornell Field Center. This firm will schedule the PSG study, obtain signed informed consent upon arriving at the subject's home, perform the PSG study, and return the results

(including the completed medication assessment and questionnaires) to the NYU project coordinator. The NYU project coordinator will mail the sleep study files to the Cleveland Reading Center, according to a fixed schedule, enter the questionnaire data into an appropriate database, and regularly provide updates of the data to the Coordinating Center.

2.2.4.3.4 Turnaround

It is anticipated that most PSG studies on subjects from the Pickering NYH clinic sample, the Menopause Study and the Harlem Hospital clinic sample will be performed within 4 weeks of subjects' follow-up evaluation for the parent study. For participants in the Worksite Study, there will typically be a 4-6 week time lag between their diagnostic evaluation and recruitment into the SHHS, with the PSG typically being performed 1-3 weeks later. Data entry will be performed on a continuous basis, as questionnaires are returned, and there should be very little delay associated with transmission of data to the Coordinating Center once the necessary e-mail/internet procedures are established.

2.2.4.3.5 Flow Diagram

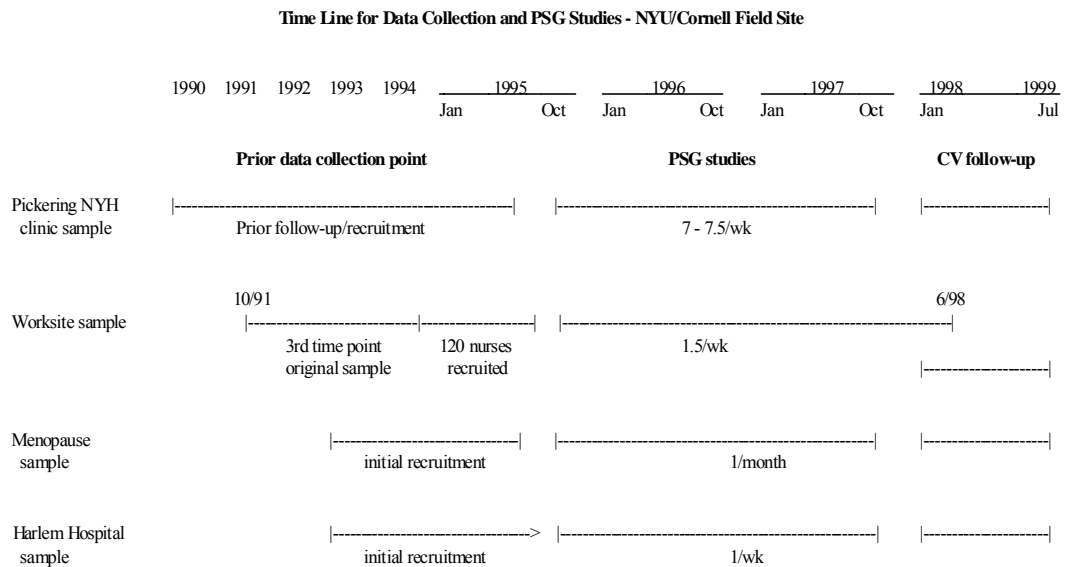


Figure 2.2.4.3.5

2.2.5 Sacramento-Pittsburgh

2.2.5.1 Time Frame and Time Line for Recruitment

CHS runs continually. There is only a down period of about a week between years of the study. We will start recruitment as soon as the study is approved and hope to complete the data collection for SHHS in one year. We will be scheduling 12 in-home PSG studies per week per site (Sacramento and Pittsburgh). With an expected loss of 10% of the studies, last minute refusals, incomplete studies etc., we will finish in one year.

2.2.5.2 Sampling Fractions

2.2.5.2.1 Description of Sampling Fractions

We will contact all CHS participants at Pittsburgh and Sacramento (2,788 individuals). If after the first one hundred individuals have been approached we find that we can project to finish without asking all our minorities to participate or with a sample that is not gender balanced, we will modify our procedures and request participation from fewer of the over represented group.

2.2.5.2.2 Demographic Data

We expect to average a 50% participation rate. With this assumption we should have about 300 minorities participating. We will balance the cohort so we have 50% men and 50% women, +/- 5%. All participants at our sites will be over 68 years of age. The non-minorities will be over 70 years old.

2.2.5.3 Recruitment Procedures

2.2.5.3.1 Administration of the Sleep Habits Questionnaire

The Sleep Habits Questionnaire will be mailed to the entire CHS cohorts at Sacramento and Pittsburgh, along with the usual packet of questionnaires which is mailed to the participants about two weeks before their annual visit. Participants will fill out the questionnaire on their own and have it checked over for completeness at the time of their annual visit.

2.2.5.3.2 Explaining SHHS

All CHS participants at the Sacramento and Pittsburgh sites will receive a letter describing the study or have information about the study included in the CHS Newsletter. At the time of their annual visit the technician working with the participant will explain the study to him or her. This will be supervised by the study coordinator for SHHS.

2.2.5.3.3 Schedule Monitoring

Before the participant leaves the clinic after completing the annual visit, a time for the home visit will be scheduled. Since some participants may need to check at home before scheduling the visit, a time will be arranged for a follow-up phone call to set up the actual visit. This phone call will be scheduled to occur within 48 hours.

2.2.5.3.4 Turnaround

The home visit will be scheduled to occur within two weeks of the annual visit. Those home visits that need to be rescheduled will be rescheduled to occur within the next two weeks following the rescheduling contact.

2.2.5.3.5 Flow Diagram

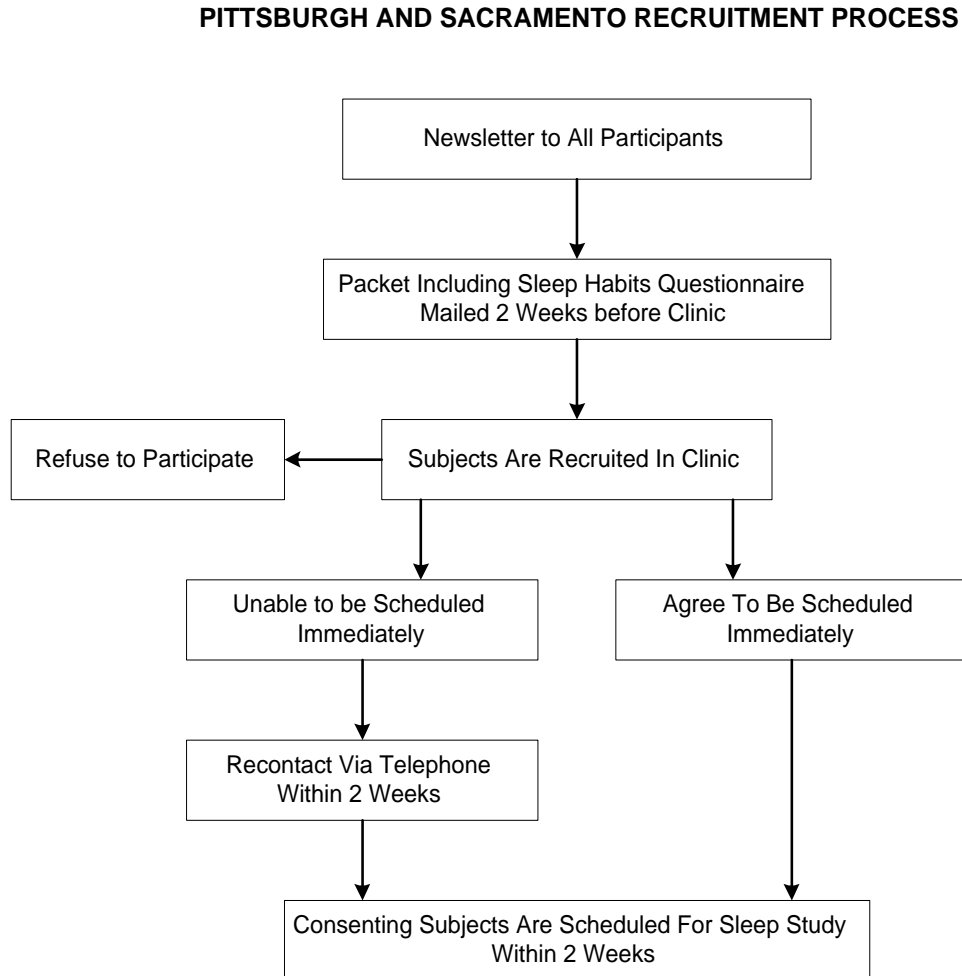


Figure 2.2.5.3.5

men and 22% in women. The prevalence of subjects who ever snored is available. To oversample snorers in this age group, this SHS data will be used to initially select subjects for possible recruitment. In these putative snorers, the presence of snoring will be confirmed by asking them to complete and return the SHHS Sleep Habits Questionnaire before scheduling a sleep study. The actual number of snorers (as determined by the SHHS Sleep Habits Questionnaire) will be tracked in cooperation with the Coordinating Center and may vary significantly from the projected number derived from SHS data. Initially it is projected that all subjects who are approached and agree to participate will be scheduled for a sleep study. However, it is possible that as the study proceeds a SHS Field Center will decline to enroll some subjects who were projected to be snorers based on SHS data, but who are not snorers based on the SHHS Sleep Habits Questionnaire, because of the need to enroll more snorers. Adjustments in recruiting will be made after analysis of data generated pertaining to the age, gender, apnea-hypopnea index and snoring prevalence rates in the first 1000 subjects enrolled in the overall study, after 200 SHS subjects have been enrolled and at 3-month intervals.

2.2.6.2.2 Demographic Data

The following estimates of the demographic characteristics of the final cohort of 600 subjects are based on the following assumptions:

- 1) identical recruitment rates between those over and under 65 years of age;
- 2) equal numbers of men and women.

Table 2.2.6.2.2

Projected Demographic Data for the SHS Cohorts*

<u>Characteristic</u>	<u>Number</u>
Men	300
≤65 years	240
>65 years	60
Women	300
≤65 years	232
>65 years	68

*All 3 SHS field sites will be combined in making sampling fraction adjustments.

2.2.6.3 Recruitment Procedures

2.2.6.3.1 Administration of Sleep Habits Questionnaire

SHS subjects who tentatively have agreed to participate in the SHHS will be asked to complete and return the SHHS Sleep Habits Questionnaire before being scheduled for a home sleep study. Because Exam 2 of SHS participants will be completed by November 1995, it is planned to administer the SHHS sleep questionnaire to the entire remaining SHS cohort during their Exam 3, which is scheduled to occur August-October 1996.

2.2.6.3.2 Explaining SHHS

A SHHS investigator from Tucson (Quan or Enright) will travel to each of the 3 SHS sites during late August or early September to meet with the SHS investigator, clinic coordinator, clinic nurse who will recruit and perform the sleep testing, and the tribal leaders. The goals, benefits, and procedures of the SHHS will be explained and discussed during the full day's visit.

Recruiting of 200 SHHS participants (from a total of about 1500) at each of the 3 SHS clinics will begin during the first week of September 1995. It will proceed in two phases. First, sleep apnea and the SHHS will be the lead article in the Fall 1995 issue of the Strong Heart Newsletter, mailed to all Strong Heart participants. Starting within 2 weeks after the newsletter mailing, selected Strong Heart participants will receive a phone call from the SHHS/SHS coordinator, with an explanation of the SHHS and a request to schedule a home visit. Calls will be targeted to participants needed to fill age, gender, and snoring "cells" (strata). Only one sleep monitor will be available for each SHS state (Arizona, Oklahoma, and South Dakota), but 2 or more geographically separate tribes will participate within each state. Therefore, within each SHS state, for this phase, recruiting and sleep testing will first be done at one site for 6 months and then at the other site for the next 6 months: Eagle Butte and then Pine Ridge in South Dakota, Lawton and then Anadarko in Oklahoma, Salt River then Gila River in Arizona.

The second phase of recruiting, starting in May 1996 for those who do not have a home telephone, will be a recruiting visit "cold call" to their home in the late afternoon. If the SHS participant is not home, the newsletter explaining the study will be left at the door, along with a note requesting that they call the coordinator (using a pay phone) to schedule a visit for the sleep study.

2.2.6.3.3 Schedule Monitoring

Subjects who indicate willingness to participate in the SHHS will sign a consent form and complete the SHHS Sleep Habits Questionnaire. Their responses to the snoring question on the questionnaire will be analyzed, and if appropriate based on sampling priorities for snoring, they will be contacted by the study coordinator to be scheduled for a sleep study.

2.2.6.3.4 Turnaround

If possible, subjects who consent to participate and are appropriate for enrollment based on sampling requirements in the SHHS will be scheduled for a home sleep study by the study coordinator within 2 weeks of their agreement. Those subjects who are not able to have a sleep study performed within 2 weeks will be scheduled at their earliest possible convenience. Any subjects who cancel an appointment or who are postponed by the study staff because of intercurrent illness will be rescheduled at the earliest possible mutually agreeable date. For all consenting subjects, every effort will be made to study bed partners on the same night.

In order to obtain a consistent rate of recruitment into the study, the number of subjects agreeing to participate will be monitored closely with the assistance of the Coordinating Center. If the recruitment rate is suboptimal, additional numbers of subjects will be contacted and/or alternative recruiting strategies will be considered.

Other recruitment and sampling problems will be discussed as they occur during conference calls among the Tucson investigators and the SHS investigators. In addition, Drs. Enright and Quan plan periodic visits to the SHS field sites to assist and monitor recruitment. As necessary, these problems also will be discussed with the Coordinating Center and members of the overall SHHS Steering Committee.

2.2.6.3.5 Flow Diagram

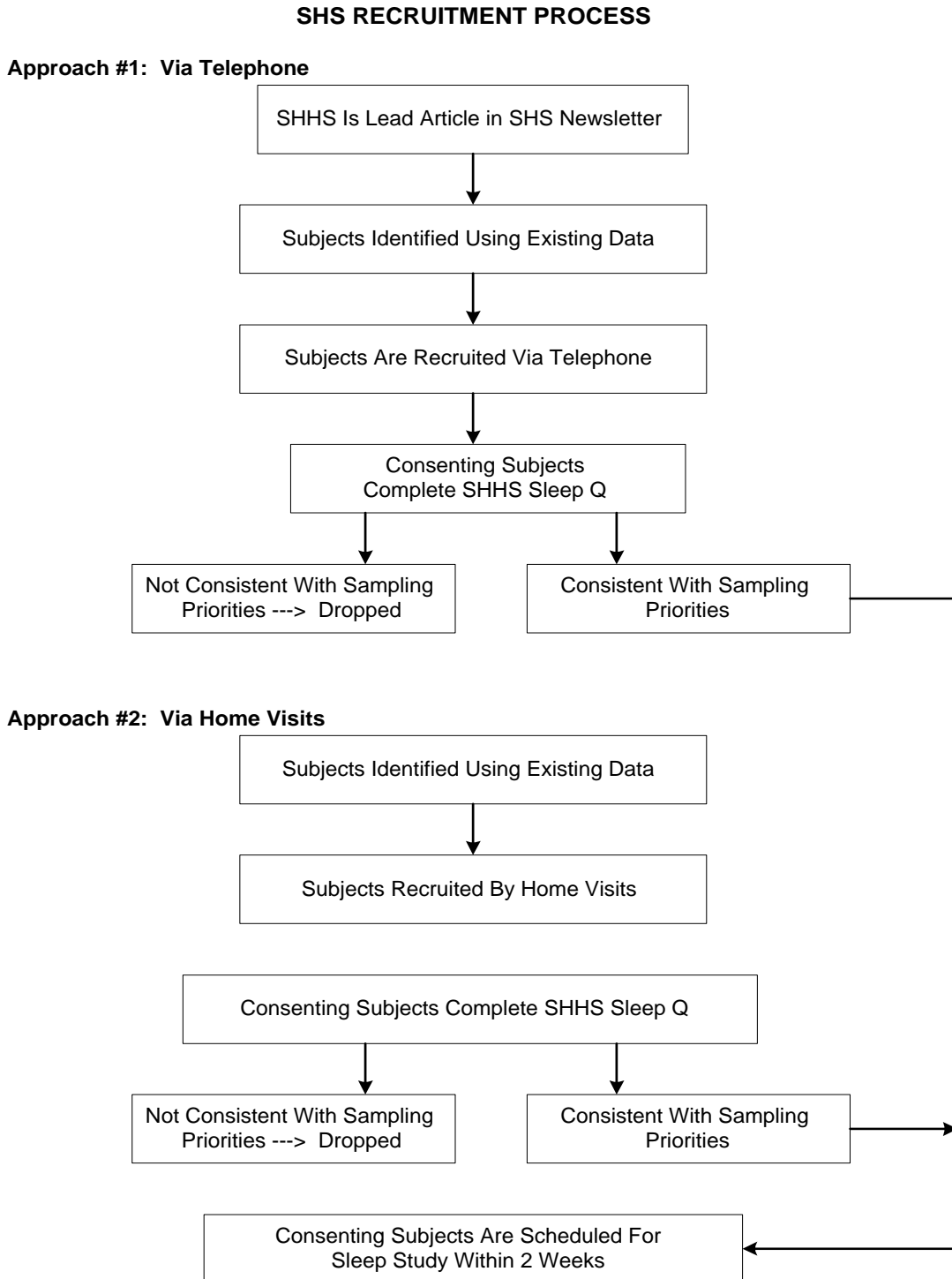
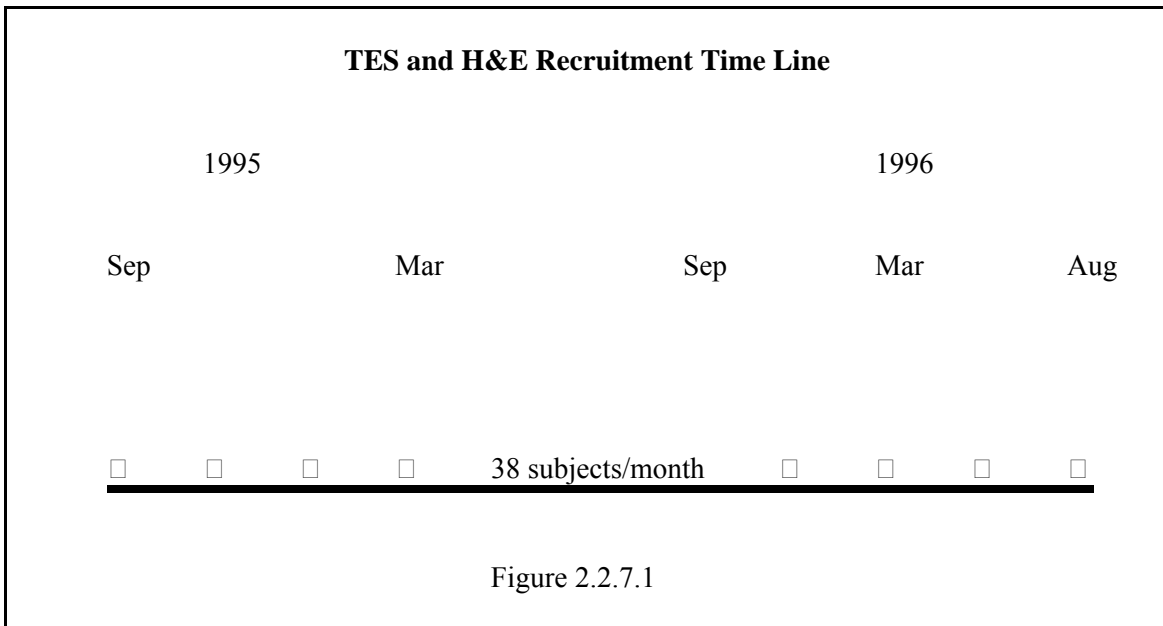


Figure 2.2.6.3.5

2.2.7 Tucson - Epidemiologic Study (TES) and Health and Environmental Cohort (H&E) Field Centers

2.2.7.1 Time Frame and Time Line for Recruitment

The combined TES and H&E Field Centers intend to recruit 900 subjects over a 24-month time frame, a period of time when participants in the TES and H&E will be undergoing cardiovascular evaluations in clinic. Subjects will be enrolled continuously over this period of time in relatively equal monthly increments (~38 subjects/month).



2.2.7.2 Sampling Fractions

2.2.7.2.1 Description of Sampling Fractions

The TES population to be sampled includes 1154 Anglo subjects (495 men and 659 women) who are at least 40 years of age. The H&E population to be sampled includes 938 subjects (449 men and 489 women) who are at least 40 years of age. In the H&E population there are 133 Hispanic men and women (73 men and 60 women). Priority will be given to sampling from this latter minority sub-cohort. From these 2 populations 900 subjects will be recruited for the SHHS.

In order to oversample younger snorers in the TES and H&E populations, snoring data from the 1990-92 survey of these populations will be used. In the TES population, there is a 45.6% prevalence of snoring in the 495 men and a 29.3% prevalence of snoring in the 659 women in the 40-64 year age group. In the H&E population, there is a 51.7% prevalence of snoring in the 449 men and a 36.5% prevalence of snoring in the 489 women in the 40-64 year age group. Initially all of those reporting snoring will be approached for possible participation. Re-evaluation of the sampling fraction will be made as the study proceeds according to the number of subjects found to have sleep apnea.

2.2.7.2.2 Demographic Data

The following estimate of the demographic characteristics of the final cohort of 900 subjects is based on the following assumptions:

- 1) a recruitment rate of 65% in Anglos and a slightly higher recruitment rate of 75% in Hispanics (greater effort will be expended to recruit Hispanics);
- 2) identical recruitment rates between those over and under 65 years of age;
- 3) equal numbers of men and women.

Table 2.2.7.2.2

Projected Demographic Data for the TES and H & E Cohorts

<u>Characteristic</u>	<u>Number</u>
Anglos	800
Men	400
≤65 years	247
>65 years	153
Women	400
≤65 years	222
>65 years	178
Hispanics	100
Men	50
≤65 years	42
>65 years	8
Women	50
≤65 years	45
>65 years	5

2.2.7.3 Recruitment Procedures

2.2.7.3.1 Administration of Sleep Habits Questionnaire

Subjects will be administered the Sleep Habits Questionnaire using the following 3 approaches:

- 1) At the current time, some subjects in the TES and H&E cohorts are undergoing cardiovascular evaluations in the Tucson SCOR research clinic. These subjects will be asked to complete the Sleep Habits Questionnaire at the time of their clinic visit.
- 2) Other subjects who have already undergone their cardiovascular evaluations may be selected for recruitment into the SHHS via telephone. Before telephone contact, they will be sent SHHS introductory material. Enclosed with the introductory materials will be the SHHS Sleep Habits Questionnaire which the subjects will be asked to complete and return, irrespective of whether they elect to participate in the study.
- 3) At end of the 24-month recruitment window, all remaining subjects in the cohorts will be sent SHHS introductory material and asked to complete and return by mail the Sleep Habits Questionnaire.

2.2.7.3.2 Explaining SHHS

Subjects will be recruited using the following 2 approaches:

- 1) At the current time, subjects in the TES and H&E cohorts are undergoing cardiovascular evaluations in the Tucson SCOR research clinic. One to two weeks before their appointment in the research clinic, all subjects will be sent SHHS introductory material. The material will include information defining sleep apnea, its medical consequences and also the reasons for performing the SHHS. The study will be described briefly and the subjects will be told that they will be asked to complete a special questionnaire at the time of their clinic visit and that they may be asked to undergo a home sleep study. At the time of their clinic visit, subjects will be selected for possible recruitment into the SHHS according to the sampling priorities established for this site. However, all subjects will be asked to complete the SHHS Sleep Habits Questionnaire. Those subjects selected for recruitment will be approached by the SHHS study coordinator and asked to consider participating in the SHHS.

Approximately 550 subjects over the course of 24 months will be recruited through personal contact in the clinic. This projection is based on the following assumptions. Approximately 800 subjects will be undergoing cardiovascular examinations in the research clinic over the 24 months of SHHS recruitment. If a recruitment rate of approximately 67% is obtained, 550 subjects will be enrolled.

- 2) An additional 350 subjects will be recruited in the following manner. Every 2 weeks, 25 subjects in the TES and H&E cohorts who have already completed their cardiovascular evaluations will be selected for possible recruitment based on sampling priorities for this site. They will be sent SHHS introductory materials. These materials will include information defining sleep apnea, its medical consequences and also the reasons for performing the SHHS. The study will be described briefly, and the subjects will be told that they will be contacted within 2 weeks and asked to participate. Enclosed with the introductory materials will be the SHHS Sleep Habits Questionnaire which the subjects will be asked to complete and return, irrespective of whether they elect to participate in the study.

It is projected that approximately 1500 subjects over 24 months can be contacted by letter and telephone. Although recruitment may be less efficient when performed in this manner, a 23% recruitment rate will result in another 350 subjects enrolled in the SHHS.

2.2.7.3.3 Schedule Monitoring

Subjects who indicate willingness to participate in the SHHS during a clinic visit will sign a consent form and, if possible, be scheduled for a sleep study at the time of their clinic visit. Other willing subjects will sign a consent form and later be contacted within 2 weeks by telephone. In the follow-up telephone call, the study coordinator will answer questions, provide additional study information and schedule an appointment for a home sleep study.

For those subjects who are sent SHHS introductory materials via telephone, the study coordinator will contact these subjects to enroll them in the study within 2 weeks. If they agree to participate, they will be sent a consent form to be returned and then scheduled for a home sleep study.

2.2.7.3.4 Turnaround

If possible, subjects who consent to participate in the SHHS will be scheduled for a home sleep study by the study coordinator within 2 weeks of their agreement. Those subjects who are not able to have a sleep study performed within 2 weeks will be scheduled at their earliest possible convenience. Any subjects who cancel an appointment or who are postponed by the study staff because of intercurrent illness will be rescheduled at the earliest possible mutually agreeable date. For all consenting subjects, every effort will be made to study bed partners on the same night.

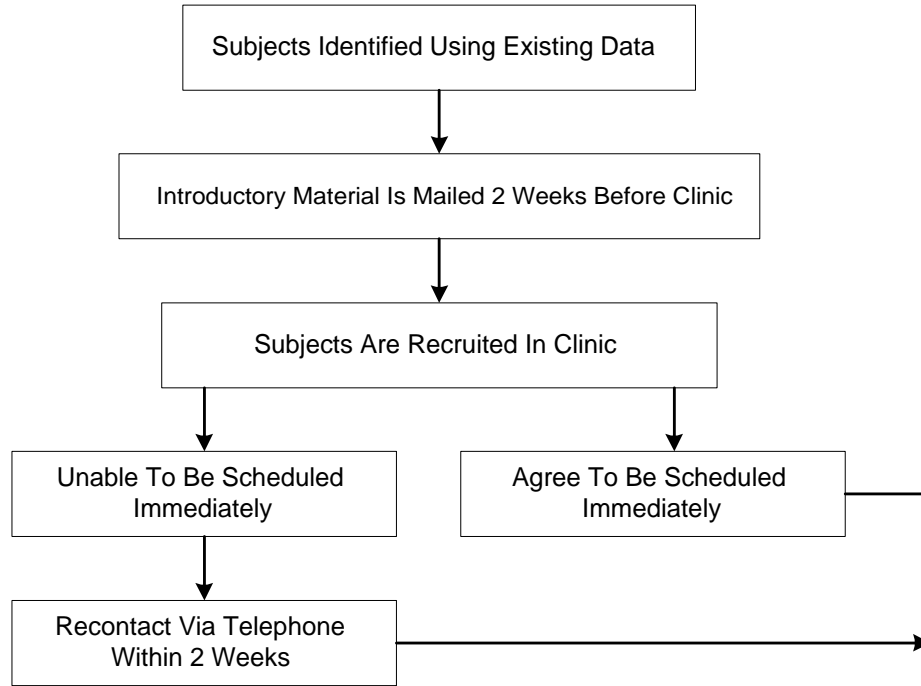
In order to obtain a consistent rate of recruitment into the study, the number of subjects agreeing to participate will be monitored closely with the assistance of the Coordinating Center. If the recruitment rate is suboptimal, additional numbers of subjects will be mailed SHHS materials every 2 weeks so that greater numbers can be approached via the telephone method.

Other recruitment and sampling problems will be discussed as they occur during this investigative center's weekly staff meetings. As necessary, these problems also will be discussed with the Coordinating Center and members of the overall SHHS steering committee.

2.2.7.3.5 Flow Diagram

TES AND H&E RECRUITMENT PROCESS

Approach #1: Via SCOR Clinic



Approach #1: Via Telephone

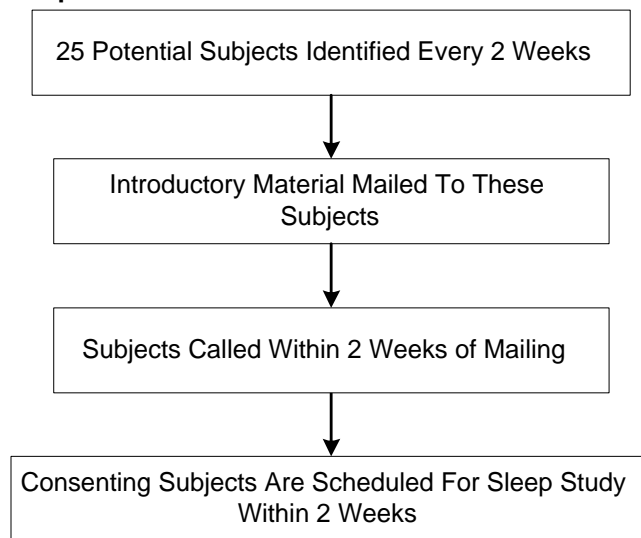


Figure 2.2.7.3.5

2.2.8 Summary of Sampling Fractions by Center

The following tables show the proposed sampling fractions to achieve each center's target N for recruitment under the assumptions of a 50% participation rate and a 75% participation rate. Sampling fractions are stratified by gender, age, and snoring status. For illustration purposes, Table 2.2.8.1 shows the steps for estimating the sample sizes obtained for each strata based on NY/Cornell data. Tables 2.2.8.2 to 2.2.8.7 provide the final sample size results for the other parent cohorts and their Field Centers, except CHS. (All participants in CHS are 65 years of age or older, but many do not know whether they snore.)

Table 2.2.8.1 includes only males (M) and is stratified by study (1=Pickering study; 2=worksite study) and age. The number of individuals eligible, the number of Sleep Habits Questionnaires completed assuming 80% completion, and the expected snoring distribution are presented. Next, the sampling fractions and resultant sample size, N, are given for the two participation rates. For example, the first block of the table labeled "Age < 65" shows there were 856 eligible for recruitment and, based on 80% returning sleep questionnaires, 685 to determine snoring status. The final distribution of snoring was 390 non-snorers and 294 (?) snorers. Thus, if only 50% consent to participate in the study, then 70% of the non-snorers (N=137) and 90% of the snorers (N=133) would be sampled from males less than 65 years of age. If 75% consent to participate, then the sampling fractions drop to 30% of non-snorers and 40% of the snorers.

Tables 2.2.8.2 - 2.2.8.7 present the final sampling fractions and resultant sample sizes (N) by center assuming 50% and 75% participation rates.

Table 2.2.8.1 Steps for Estimating Sampling Fractions and Sample Sizes Based on NY/Cornell's Data

Sex	Study	Age	E(#eligible)	E(# questionnaires)	E(snoring)	If 50% consent		If 75% consent		
						samp frac	N	samp frac	N	
M	1	<65	856	685	No: 390	70%	137	30%	88	
					Yes: 294	90%	133	40%	88	
		≥65	285	228	No: 182	100%	91	65%	89	
					Yes: 46	100%	23	100%	34	
		Harlem minorities	100	80	No: 46	100%	23	100%	34	
					Yes: 79	100%	17	100%	26	
		2	<65	230	184	No: 105	100%	52	100%	79
						Yes: 79	100%	40	100%	59
			≥65	30	24	No: 19	100%	10	100%	14
						Yes: 5	100%	2	100%	4
	Subtotal						527		515	

Table 2.2.8.1 (continued)

Sex	Study	Age	E(#eligible)	E(# ques- tionnaires)	E(snoring)	If 50% consent		If 75% consent		
						samp frac	N	samp frac	N	
F	1	<65	588	470	No: 367	100%	183	40%	110	
					Yes: 103	100%	52	100%	78	
		≥65	376	301	No: 265	100%	132	60%	119	
					Yes: 36	100%	18	100%	27	
	Harlem minorities	100	80	No: 62	100%	31	100%	47		
				Yes: 18	100%	9	100%	13		
	2	<65	140	112	No: 87	100%	44	100%	66	
					Yes: 25	100%	12	100%	18	
		≥65	15	12	No: 11	100%	5	100%	8	
	Yes: 1				100%	1	100%	1		
	3	<65	50	40	No: 31	100%	16	100%	23	
					Yes: 9	100%	4	100%	7	
		Subtotal					508		517	
	TOTAL						1035		1032	

Table 2.2.8.2 Sampling Fractions and Sample Size (N) for CHS Investigator Centers Stratified by Sex and Percent Participation

	Johns Hopkins				Pittsburgh/Sacramento			
	50% Participate		75% Participate		50% Participate		75% Participate	
<u>Sex</u>	Sampling		Sampling		Sampling		Sampling	
	Fraction	N	Fraction	N	Fraction	N	Fraction	N
M	100%	175	65%	175	100%	462	72%	500
	64%	175	43%	175	82%	538	51%	500
F								
Total		350		350		1,000		1,000

Table 2.2.8.3 Sampling Fractions and Sample Size (N) for Framingham by Sex, Age, Snoring Status, and Percent Participation

			Offspring Cohort				Omni Cohort			
			50% Participate		75% Participate		50% Participate		75% Participate	
<u>Sex</u>	<u>Age</u>	<u>Snoring Status</u>	<u>Sampling Fraction</u>	<u>N</u>	<u>Sampling Fraction</u>	<u>N</u>	<u>Sampling Fraction</u>	<u>N</u>	<u>Sampling Fraction</u>	<u>N</u>
M	< 65	No	100%	124	65%	121	100%	39	100%	59
		Yes	100%	102	100%	152	100%	32	100%	48
	≥ 65	No	100%	35	65%	34	100%	11	100%	17
		Yes	100%	29	100%	43	100%	9	100%	14
Subtotal				290		350		91		138
F	< 65	No	100%	178	60%	160	100%	60	100%	90
		Yes	100%	76	100%	114	100%	26	100%	39
	≥ 65	No	100%	50	60%	45	100%	17	100%	26
		Yes	100%	22	100%	32	100%	7	100%	11
Subtotal				326		351		110		166
Total				616		701		201		304

Table 2.2.8.4 Sampling Fractions and Sample Size (N) for Johns Hopkins - ARIC Stratified by Sex, Age, Snoring Status, and Percent Participation

ARIC Cohort						
<u>Sex</u>	<u>Age</u>	<u>Snoring Status</u>	50% Participate		75% Participate	
			<u>Sampling Fraction</u>	<u>N</u>	<u>Sampling Fraction</u>	<u>N</u>
	< 65	No	33%	108	20%	98
M		Yes	92%	227	64%	237
	_ 65	No	32%	24	20%	23
	>	Yes	92%	17	64%	18
Subtotal				376		376
	< 65	No	30%	181	15%	135
F		Yes	97%	165	83%	212
	_ 65	No	30%	21	15%	16
	>	Yes	97%	9	83%	12
Subtotal				376		375
Total				762		761

Table 2.2.8.5 Sampling Fractions and Sample Size (N) for Minnesota Stratified by Sex, Age, Snoring Status, and Percent Participation

<u>Sex</u>	<u>Age</u>	<u>Snoring Status</u>	50% Participate		75% Participate	
			<u>Sampling Fraction</u>	<u>N</u>	<u>Sampling Fraction</u>	<u>N</u>
M	< 65	No	49%	178	16%	86
		Yes	100%	272	85%	344
	_ 65	No	35%	29	31%	39
	>	Yes	100%	21	100%	31
Subtotal				500		500
F	< 65	No	53%	301	27%	226
		Yes	100%	159	100%	238
	_ 65	No	48%	31	23%	23
	>	Yes	100%	9	100%	13
Subtotal				500		500
Total				1,000		1,000

Table 2.2.8.6 Sampling Fractions and Sample Size (N) for Strong Heart Stratified by Sex, Age, Snoring Status, and Percent Participation

<u>Sex</u>	<u>Age</u>	<u>Snoring Status</u>	50% Participate		75% Participate	
			<u>Sampling Fraction</u>	<u>N</u>	<u>Sampling Fraction</u>	<u>N</u>
M	< 65	No	31%	108	21%	110
		Yes	50%	132	33%	130
	_ 65	No	49%	34	33%	35
	>	Yes	50%	26	33%	25
Subtotal				300		300
F	< 65	No	17%	116	11%	116
		Yes	60%	116	40%	116
	_ 65	No	27%	42	18%	42
	>	Yes	60%	26	40%	26
Subtotal				300		300
Total				600		600

Table 2.2.8.7 Sampling Fractions and Sample Size (N) for Tucson by Sex, Age, Snoring Status, and Percent Participation

			H & E Cohort				TES Cohort			
			50% Participate		75% Participate		50% Participate		75% Participate	
<u>Sex</u>	<u>Age</u>	<u>Snoring Status</u>	<u>Sampling Fraction</u>	<u>N</u>	<u>Sampling Fraction</u>	<u>N</u>	<u>Sampling Fraction</u>	<u>N</u>	<u>Sampling Fraction</u>	<u>N</u>
M	< 65	No	100%	69	59%	60	100%	73	53%	58
		Yes	100%	73	100%	110	100%	61	100%	92
	≥ 65	No	100%	17	100%	26	100%	39	75%	59
		Yes	100%	21	100%	34	100%	31	100%	61
Subtotal				180		230		204		270
F	< 65	No	100%	102	51%	79	91%	97	54%	78
		Yes	100%	59	100%	88	100%	44	100%	60
	≥ 65	No	100%	34	100%	50	81%	97	40%	79
		Yes	100%	8	100%	13	100%	32	100%	53
Subtotal				203		230		270		270
Total				383		460		474		540

2.2.9 Summary of Sampling and Recruitment Methods

The following table, Table 2.2.9.1, summarizes the sampling and recruitment strategies used by each of the centers. It indicates the method and time to administer the Sleep Habits Questionnaire, the sampling method adopted, and the method used to actually recruit the subject.

Table 2.2.9.1 Summary of Methods of Sleep Habits Questionnaire Administration, Sampling, and Recruitment by Field Center

Field Center	Sleep Habits Questionnaire (SHQ)	Sampling	Recruitment
Framingham -- Offspring and Omni	Mailed in 3-month waves following their FHS visit.	Initially 100% and then follow sampling fractions as needed.	Letter of invitation followed by a telephone call.
Johns Hopkins -- ARIC	Mailed at monthly cycles according to the scheduled recruitment for the sleep exams.	Randomly selected based on sampling fractions applied to those who responded to SHQ.	At Clinic Visit for those regularly scheduled for an exam. A special Home Visit will be scheduled for those not seen in clinic within the time frame for the SHHS recruitment.
-- CHS	Mailed out 2 weeks prior to regular clinic visit.	All will be invited to participate.	At Clinic Visit.
Minnesota	Mailed out in monthly cycles of 100 each.	SHQ asks if subject is interested in SHHS. Subjects who are interested will be randomly sampled according to sampling fractions.	Telephone call.

Table 2.2.9.1 (Continued)

Field Center	Sleep Habits Questionnaire (SHQ)	Sampling	Recruitment
New York/Cornell -- Pickering -- Work Site -- Menopause	Mailed. (when?) At regularly scheduled clinic visits. Mailed. (when?)	All minorities. All will be invited to participate. All will be invited to participate.	Telephone call or personal visit. At clinic visit. Telephone call or personal visit.
Pittsburgh/Sacramento	Mailed out 2 weeks prior to regular clinic visit.	All will be invited to participate.	At clinic visit.
Tucson (TES and H&E)	By mail or in the clinic.	According to sampling fractions.	At the clinic visit or by telephone call two weeks following mail out of questionnaire.
Strong Heart	At clinic visit or home visit recruitment.	According to sampling fractions.	Telephone call or a home visit for those without a telephone.

2.3 Sample size and power considerations

2.3.1 Assumptions and considerations

The target sample size is set at 6,000 subjects, or approximately 1,000 from each investigative center. This sample size was fixed by the time frame of the study and the resources available to the investigators. It is estimated that approximately one third of this sample will have prevalent cardiovascular or cerebrovascular disease, leaving 4,000 subjects available to test hypotheses regarding incident events.

The primary hypotheses regarding events can be specified as the relationship between two dichotomous variables in a two-by-two table (presence or absence of event by exposure to sleep apnea). The cell frequencies and, hence, the power for these hypotheses are determined by three parameters:

- 1) the prevalence of sleep-disordered breathing (SDB) in the sample: 15%, 20%, 25%, 35%
- 2) the event rates: 0.5%, 1.0%, 1.5%, 2.0%, 2.5%
- 3) the relative risk (RR) of an event (SDB vs. without SDB): 1.5, 1.75, 2.0, 2.25, 2.5, 2.75, 3.0

The rationales for choosing the values listed for each parameter are outlined below.

Review of the literature indicates that the prevalence of sleep-disordered breathing depends on the age, body mass, and race distributions of the populations being studied. A recent study¹⁴ estimated that the prevalence of sleep-disordered breathing (defined as an apnea/hypopnea index > 5) in middle-aged adults is 9% in women and 24% in men. The prevalence was estimated to be even higher in the elderly (20%-62%)⁵. Data from the Cleveland Family Study, an epidemiologic study of more than 800 subjects, further suggested that the prevalence of sleep-disordered breathing may be twice as high in African-Americans as in Caucasians¹⁵.

Event rates were estimated using data from the CHS cohort with an average of 3.5 years of follow-up data (unpublished data). To date, the incidence of myocardial infarction has been 3.7%, or approximately 1% per year. For strokes, the incidence was also 3.7%. All cause mortality to date has been 7.6%, or about 2% per year. Coronary heart disease mortality was 2.6%, or 0.75% per year. Thus, event rates range from 0.75% to 2% for each year of follow-up. While the CHS cohort represents an older cohort (ages 65 years and older), this age group will comprise about 50% of the SHHS study. Assuming none of the younger group (40-64 years) experienced an event, then the yearly event rate in SHHS would be less than 0.4% up to 1%. If the event rate in the younger group is half the rate in the older group, then the yearly event rate would range from .6% to 1.5%. For the average follow-up of two years expected for SHHS, these assumptions could yield event rates ranging between 0.8% to 3%. Thus power calculations used event rates between 0.5% and 2.5%.

Most of the evidence relating sleep-disordered breathing and myocardial infarction is based on studies of snoring, not specifically documented sleep apnea. For these studies relative risks ranged between 1.8 and 4.4^{4,6,9}. Those few studies which considered sleep apnea specifically only evaluated the presence of apnea shortly after an MI had occurred and not longitudinally. The few studies relating stroke to sleep apnea found odds ratios of 2 to 3.2 for snoring^{10,11}. For hypertension, marked increases in systolic (>200 mm Hg) and diastolic (>100 mmHg) have been observed with apneas^{1,7}. The prevalence of sleep apnea in hypertensives is estimated to be at least three-fold higher than in subjects without hypertension^{2,3,8}.

2.3.2 Power calculations

The EGRET program SIZ¹² was used to estimate power, assuming the logistic regression model for cohort data. Power curves were estimated for each combination of event rates and prevalence of SDB over the range of relative risks. Power curves were determined using Method 1 of SIZ. This is an analytic method, based on asymptotics, which seeks to approximate the distribution of the test statistic, the likelihood ratio test (LRT), under the alternative hypothesis¹³.

Within each value of the prevalence of SDB, the values are separated by two lines. These lines separate the tabulated powers into three categories: power less than 60%, power ranging from 60% to 79%, and power greater than or equal to 80%.

The primary hypotheses regarding incident events (coronary heart disease or stroke) will be based on the smaller sample size of 4,000 participants without prevalent CVD at enrollment. Hypotheses which can be tested including prevalent cases (e.g., all-cause mortality) will be based on the 6,000 subjects. Power was determined for all 140 combinations of the three parameters, assuming sample sizes of N=4,000 subjects and 6,000 subjects, as well as an intermediate value of 5,000 subjects. The alpha level was specified at 5%. The following tables provide the power for the various parameter combinations. The lines in the table partition the tabulated values of power into those less than 60%, 60-79%, and 80% or better.

As the table shows, power increases with increasing prevalence, event rate, relative risk, and/or sample size. For a sample size of N=4,000, the power is limited for the lowest event rate of 0.5% or a relative risk of 1.5. For a mid-range event rate of 1.5% and a RR of 2.0 or greater, the power is at least 59% for a prevalence of 15% SDB and at least 71% for a prevalence of 25%. The power for a prevalence of 35% is only a few points higher than those for 25%. For all parameter combinations considered, a power of at least 80% can be achieved for 40% of the parameter combinations, with an additional 16% demonstrating power in the 60-79% range.

For a sample size of N=6,000, the power is still somewhat limited for an event rate of 0.5% , but is higher than those estimates for N=4,000 with power of at least 60% at the highest relative risks. For the mid-range event rate of 1.5%, there is approximately 80% power to detect a relative risk of 2.0 or greater. Again, the power for a prevalence of 35% is only a few points higher than a prevalence of 25%. For all parameter combinations considered, a power of at least 80% can be achieved for 59% of the parameter combinations, with an additional 15% demonstrating power in the 60-79% range. Thus, the power is sufficient (at least 80%) at this sample size for more than half of the parameter space considered.

2.3.3 References

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Estimated Power based on N = 4,000

<i>Event rate:</i>		<i>.5%</i>	<i>1%</i>	<i>1.5%</i>	<i>2%</i>	<i>2.5%</i>
<i>Prevalence of SDB RR</i>						
<i>15%</i>	<i>1.5</i>	11	17	23	29	34
	<i>1.75</i>	17	29	41	51	60
	<i>2</i>	25	43	59	71	81
	<i>2.25</i>	33	57	72	85	92
	<i>2.5</i>	42	69	85	93	97
	<i>2.75</i>	50	79	92	97	99
	<i>3</i>	58	86	96	99	100
<i>20%</i>	<i>1.5</i>	12	20	27	34	40
	<i>1.75</i>	20	34	47	59	68
	<i>2</i>	28	50	68	78	86
	<i>2.25</i>	38	64	81	90	95
	<i>2.5</i>	47	76	90	96	98
	<i>2.75</i>	56	84	95	98	99
	<i>3</i>	63	90	98	99	100
<i>25%</i>	<i>1.5</i>	13	22	30	38	45
	<i>1.75</i>	21	37	52	64	73
	<i>2</i>	31	54	71	83	90
	<i>2.25</i>	41	68	84	93	97
	<i>2.5</i>	50	79	92	97	99
	<i>2.75</i>	59	87	96	99	100
	<i>3</i>	67	92	98	99	100

35%	1.5	14	24	33	42	50
	1.75	24	41	57	64	79
	2	33	58	75	84	92
	2.25	43	72	87	94	98
	2.5	52	83	94	98	99
	2.75	61	88	97	99	100
	3	68	93	99	100	100

- 1) Prevalence = prevalence of sleep-disordered breathing (SDB) at baseline
- 2) RR = relative risk of event in those with SDB compared to those without SDB
- 3) Power calculations were done for logistic regression analyses.

Estimated Power based on N = 5,000

<i>Event rate:</i>		<i>.5%</i>	<i>1%</i>	<i>1.5%</i>	<i>2%</i>	<i>2.5%</i>
15%	RR 1.5	12	20	27	35	41
	1.75	20	35	49	61	70
	2.0	29	52	68	80	88
	2.25	39	65	82	92	96
	2.5	50	79	92	97	99
	2.75	59	87	96	99	100
	3.0	68	92	99	100	100
20%	RR 1.5	14	23	32	41	48
	1.75	23	41	56	69	78
	2.0	36	60	76	87	92
	2.25	44	73	88	95	98
	2.5	56	83	95	98	99
	2.75	65	91	98	100	100
	3.0	73	95	99	100	100
25%	RR 1.5	15	26	36	45	54
	1.75	26	45	62	74	83
	2.0	39	63	80	90	95
	2.25	48	77	91	97	99
	2.5	58	88	96	99	100
	2.75	69	93	99	100	100
	3.0	76	96	100	100	100
35%	RR 1.5	17	29	40	51	59
	1.75	29	49	66	79	87
	2.0	40	67	84	92	97
	2.25	53	80	93	98	100
	2.5	62	88	97	99	100
	2.75	71	94	99	100	100
	3.0	77	97	100	100	100

- 1) Prevalence = prevalence of sleep-disordered breathing (SDB) at baseline
- 2) RR = relative risk of event in those with SDB compared to those without SDB
- 3) Power calculations were done for logistic regression analyses.

Estimated Power based on N = 6,000

<i>Event rate:</i>		<i>.5%</i>	<i>1%</i>	<i>1.5%</i>	<i>2%</i>	<i>2.5%</i>
<i>Prevalence of SDB RR</i>						
<i>15%</i>	<i>1.5</i>	13	23	31	40	47
	<i>1.75</i>	22	40	54	66	76
	<i>2.0</i>	37	63	79	89	94
	<i>2.25</i>	46	74	88	94	97
	<i>2.5</i>	58	86	96	99	99
	<i>2.75</i>	67	92	98	99	99
	<i>3.0</i>	75	96	99	99	99
<i>20%</i>	<i>1.5</i>	16	27	37	47	55
	<i>1.75</i>	26	47	62	75	83
	<i>2.0</i>	42	70	86	93	97
	<i>2.25</i>	52	81	93	97	99
	<i>2.5</i>	64	90	98	99	99
	<i>2.75</i>	73	95	99	99	99
	<i>3.0</i>	80	97	99	99	100
<i>25%</i>	<i>1.5</i>	17	30	41	52	61
	<i>1.75</i>	29	51	67	80	87
	<i>2.0</i>	46	74	89	95	98
	<i>2.25</i>	56	84	95	98	99
	<i>2.5</i>	68	93	98	99	99
	<i>2.75</i>	76	96	99	99	100
	<i>3.0</i>	83	98	99	99	100
<i>35%</i>	<i>1.5</i>	10	24	37	50	67
	<i>1.75</i>	33	56	74	85	92
	<i>2.0</i>	49	75	90	96	99
	<i>2.25</i>	60	87	97	99	100
	<i>2.5</i>	70	94	99	100	100
	<i>2.75</i>	78	97	100	100	100
	<i>3.0</i>	84	99	100	100	100

- 1) Prevalence = prevalence of sleep-disordered breathing (SDB) at baseline
- 2) RR = relative risk of event in those with SDB compared to those without SDB
- 3) Power calculations were done for logistic regression analyses.

2.4 Human Subjects

The study was specifically designed to have a balanced number of men and women and adequate representation of minority populations (Section 2.3.1). Subjects will only be excluded for a limited number of well-justified scientific reasons, as described earlier.

The study is purely observational and therefore poses minimal risks to the participants. Data from the pilot study indicated that about one-quarter to one-third of the subjects report moderate to great deal of discomfort sleeping with a multi-channel sleep monitor; a rate considered acceptable by the Steering Committee. The chosen monitor (Compumedics) is battery-operated and therefore risk-free. Although Compumedics is not an FDA-approved device, its use for research purposes is permissible because the study will not provide a final clinical diagnosis of sleep apnea. (Alert values for subject referral for medical work-up are detailed in section 6.10).

2.4.1 Informed consent

IRB approval for the full protocol will be obtained locally. Site-specific consent forms will be used to meet the specific requirements of the IRB committee at each institution. The consent form will be signed either at the time of recruitment or on the night of the sleep study.

The attached consent form was developed to assist sites in preparation of their own forms.

SUBJECT'S CONSENT FORM

STUDY TITLE: Sleep Hearth Health Study

INVESTIGATORS: [Insert Names of Investigators]

SPONSORS: **National Heart, Lung and Blood Institute and the National Sleep Center**

I AM BEING ASKED TO READ THE FOLLOWING MATERIAL TO ENSURE THAT I AM INFORMED OF THE NATURE OF THIS RESEARCH STUDY AND OF HOW I WILL PARTICIPATE IN IT. IF I CONSENT TO DO SO, SIGNING THIS FORM WILL INDICATE THAT I HAVE BEEN SO INFORMED AND THAT I GIVE MY CONSENT. FEDERAL REGULATIONS REQUIRE WRITTEN INFORMED CONSENT PRIOR TO PARTICIPATION SO THAT I CAN KNOW THE NATURE AND THE RISKS AND CAN DECIDE TO PARTICIPATE OR NOT PARTICIPATE IN A FREE AND INFORMED MANNER.

PURPOSE

I am being asked to participate in the [**FILL IN YOUR SITE'S NAME**] Sleep Heart Health Study. The purpose of this project is to learn more about how breathing disturbances during sleep affect a person's risk of developing heart disease or stroke. The results of this study will allow us to determine whether people with breathing disturbances during sleep are at greater risk for developing heart disease or stroke.

SELECTION CRITERIA

I am being asked to participate because I am currently enrolled as a subject in the [**FILL IN YOUR PARENT COHORT**] and because I have completed a sleep questionnaire administered as part of the [**FILL IN PARENT COHORT**]. I am at least 40 years of age. Approximately 6000 subjects will be enrolled nationwide. Approximately [] subjects will be enrolled at [**YOUR SITE**].

PROCEDURE

If I agree to participate, I will be asked to agree to the following. I will undergo a home sleep study and complete additional brief questionnaires. I understand that a home sleep study involves being connected to a special battery-operated monitoring device by several wires and sensors. Technicians will visit my home on the evening of the home sleep study. They will ask me to fill out additional questionnaires and then connect me to the sleep monitoring device. Wires using washable paste will be connected to the surface of my scalp, on the sides of my forehead and underneath my chin in order to record how well I am sleeping. Wires will be connected over the front of my chest using easily removable adhesive disks to monitor my heart rhythm and rate. Light-weight belts will be fitted around my chest and abdomen and a sensor will be taped under my nose to assess my breathing efforts. An additional sensor will be taped on one of my fingers to measure the oxygen level in my blood during the night. All of these wires and sensors will be connected to the sleep monitor which will be located at my bedside. The technicians will leave my home after they have finished connecting me to the sleep monitor. They will leave with me a brief questionnaire to complete after I awaken in the morning. I will attempt to sleep in my usual manner. I understand that I will be able to get up and move about during the night. Furthermore,

if absolutely necessary, I will be able to disconnect myself completely from the device before the night is over. After I awaken in the morning, I will disconnect myself from the device. I understand that at a mutually agreeable time, a technician will return to my home to collect the device and the questionnaire.

After completion of the home sleep study, I will be periodically contacted over the next several years to inquire about my health. It may be necessary for me to sign a release so that the investigators can obtain some of my medical records for review.

RISKS AND DISCOMFORT

I understand that there is no known medical risk to the home sleep study which currently is used to diagnose sleep disorders. Approximately 33% of subjects report a moderate degree of difficulty sleeping during the night of the monitoring. Adhesive disks and tape are used to attach sensors and wires to the skin; when removed, they may cause some very temporary pain, may remove some hair, and may leave a small area of red skin which is painless and resolves within a few days. The paste used to attach the wires to the scalp, adjacent to the eyelids and underneath the chin will require removal with simple soap and water.

BENEFITS

Information about my sleep [**ADD IF YOU INTEND TO SEND REIMBURSEMENT** and a check for (amount)] will be mailed to me 4-6 weeks after the study. In addition, this information will be provided to my physician if I so desire.

CONFIDENTIALITY

My participation in this study will be treated as confidential. Any records or results relating to the study will be used only by the investigators for scientific purposes, and my name will not be used in any reports that might be published.

PARTICIPATION COSTS

There are no costs to me for participating in this study.

LIABILITY

I understand that side effects or harm are possible in any research program despite the use of high standards of care and could occur through no fault of mine or the investigator involved. Known side effects have been described in this consent form. However, unforeseeable harm may also occur and require care. I understand that money for research-related side effects or harm, or for wages or time lost, is not available. I do not give up any of my legal rights by signing this form. Necessary emergency medical care will be provided without cost. If I should withdraw voluntarily from the study or am asked by the doctor to leave the study, I must return all equipment used by the study. For further information or in the event of research related injury, I can contact [**INVESTIGATOR'S NAMES**] at [**PHONE NUMBERS**]. If I have questions concerning my rights as a research subject, I may call the Human Subjects Committee office at [**PHONE NUMBER**].

AUTHORIZATION

BEFORE GIVING MY CONSENT BY SIGNING THIS FORM, THE METHODS, INCONVENIENCES, RISKS AND BENEFITS HAVE BEEN EXPLAINED TO ME AND MY QUESTIONS HAVE BEEN ANSWERED. I UNDERSTAND THAT I MAY ASK QUESTIONS AT ANY TIME AND THAT I AM FREE TO WITHDRAW FROM THE PROJECT AT ANY TIME WITHOUT CAUSING BAD FEELINGS OR AFFECTING MY MEDICAL CARE. MY PARTICIPATION IN THIS PROJECT MAY BE ENDED BY THE INVESTIGATOR FOR REASONS THAT WOULD BE EXPLAINED. NEW INFORMATION DEVELOPED DURING THE COURSE OF THIS STUDY WHICH MAY AFFECT MY WILLINGNESS TO CONTINUE IN THIS RESEARCH PROJECT WILL BE GIVEN TO ME AS IT BECOMES AVAILABLE. I UNDERSTAND THAT THIS CONSENT FORM WILL BE FILED IN AN AREA DESIGNATED BY THE HUMAN SUBJECTS COMMITTEE WITH ACCESS RESTRICTED TO THE INVESTIGATORS: **[INVESTIGATORS' NAMES]**. I UNDERSTAND THAT I DO NOT GIVE UP ANY OF MY LEGAL RIGHTS BY SIGNING THIS FORM. A COPY OF THIS CONSENT FORM WILL BE GIVEN TO ME.

Subject's signature: _____

Signature of Witness: _____

Date: _____

INVESTIGATOR'S AFFIDAVIT

I have carefully explained to the subject the nature of the above project. I hereby certify that to the best of my knowledge the person who is signing this consent form understands clearly the nature, demands, benefits and risks involved in participation, and the signature is legally valid. A medical problem or language or educational barrier has not precluded this understanding.

Investigator: _____

Date: _____

2.4.2 Confidentiality of Data

Each subject will be identifiable by a unique ID number, the one assigned by the parent cohort. Personal identifiers will be kept at the corresponding Field Center. Only ID numbers will occur on paper forms, PSG data files, and all data files created from the paper forms or covariate data obtained from the parent cohort. Paper forms will be kept locked in file cabinets at the Field Centers. Only authorized study personnel will have access to the study data. The CC will only maintain data files and none of the data collection forms. Results will be reported in an aggregate form without personal identifiers.

The CC is located in an office building that has very good external security. The building has a 24-hour manned security desk, and key-cards keyed for a particular floor of the building are required in order to use the elevators outside of regular working hours. For internal security, only staff working on SHHS will have access to the CC computers. Passwords are required to access the databases maintained at the CC. Data files are backed-up on a regular basis with an extra set stored off-site in a locked office. Only authorized users will have access to back-up files.

All study personnel will sign a statement of confidentiality (See 2.4.3).

2.4.3 Employee Statement of Confidentiality

The Sleep Heart Health Study (SHHS) maintains privileged and confidential information regarding health history and cardiovascular disease on all of its participants. As an employee of the SHHS it is my responsibility to ensure the confidentiality of all data collected and maintained by the study. This responsibility includes active support and maintenance of the procedures listed below at all times. No information which identifies a specific participant or physician is released to, or discussed with, anyone other than staff members of the reporting source, unless specific prior arrangements have been made.

My signature on this form is my personal assurance that I will actively follow the procedures described below. I also understand that should I violate any of these procedures at any time, I will immediately forfeit my position as a staff member of the SHHS.

1. All confidential information is kept in locked files after office hours.
2. All confidential documents which are no longer needed are shredded by a forms shredder. These documents are never placed in waste baskets.
3. Diskettes containing confidential information are to be stored in locked cabinets outside of normal working hours.
4. Caution will be exercised to maintain participant confidentiality in the presence of visitors and others who are not SHHS staff.
5. Conversations that take place outside SHHS offices will not include information that identifies a specific person, hospital, or physician.

- 6. All confidential information including participant data forms, medical release forms, and informed consent forms shall be kept in a closed container (accordion folder, briefcase, or the like) after completion in the home. These forms shall be returned to the clinic as soon as possible after they are completed, usually the morning after the sleep study is completed, and placed in a central location for data entry and filing.
- 7. When traveling to and from the participant's home, precautions to prevent theft or accidental loss of information will be observed. For example, completed forms should not be left in a vehicle overnight.
- 8. I will show respect to participants I meet, and their home and lifestyle. Both at and outside of work I will not discuss, comment upon, or share any such knowledge I may have of a participant.

As a staff member of the SHHS, I offer my personal assurance that I will follow and support these procedures at all times.

Date

Staff Member

Date

Supervisor



SLEEP HEART HEALTH STUDY MANUAL OF OPERATIONS

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CHAPTER 3 - PARENT COHORT DATA

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3.1 Overview

SHHS is designed to use existing data collected by the parent studies regarding health history, cardiovascular risk factors, and cardiovascular events. The Comparability Subcommittee was responsible for examining the comparability of data collected in the various cohorts, and reviewing and revising the prioritization list of covariates. The main goal was to identify the need for additional information to be collected in some or all the SHHS sites regarding variables that are considered important for the study. These variables included those that could potentially be confounders or modifiers of the association between sleep disorders breathing and cardiovascular disease. In addition, the subcommittee also considered variables involved in the assessment of the secondary hypotheses.

3.2 Parent and Site Databases

Each parent study was asked to provide copies of all questionnaires. Methods of data collection were compared for all data that were deemed critical (see Section 3.3). In addition, parent studies were asked to send the SHHS Coordinating Center actual data from study participants on key variables. These data will be used for comparison of distributions across studies, in order to assess the need for statistical adjustment in future analyses of study results.

3.3 Essential covariate information

Variables were classified in ranks of priority as follows:

- (A) Variables that are considered critical for the study. These are major risk factors for cardiovascular disease and may impact the relationships of events to SRBD. If any of the cohorts do not have comparable data in any of these variables, additional data are collected.
- (B) Variables that could be important in specific or subset analysis: an attempt to achieve comparability will be made, but is not required that all cohorts have comparable information.
- (C) Other variables that could be used in cohort-specific analyses, or in ancillary studies, but no specific attempt to achieve comparability will be made.

The following table shows the list of variables according to the rated priority. The A-variables include those needed to define prevalent clinical and subclinical cardiovascular disease, in order to identify participants at risk of incident disease, as well as the main cardiovascular risk factors previously described as strong correlates of SRBD (hypertension, smoking, anthropometric indices). Other cardiovascular risk factors that have not been clearly identified as correlates of SRBD are also included, in order to study their role as possible confounders or effect modifiers. Finally, the list of A-variables included medications and other strong correlates or indicators of

respiratory or sleep disorders (self-reported history of SRBD and respiratory symptoms, caffeine and alcohol intake, spirometry).

For the A-variables, a maximum acceptable time window between the time of the home sleep study and the closest measurement is specified.

3.4 Methods of Evaluation of Parent Study Data

The first phase of the comparability study focused exclusively on comparing methods of data collection for the A-category variables. The comparability subcommittee members examined the information available for the methods for the collection of category A variables in each cohort, including the wording of specific questions for interview data, the measurement methodology for procedures such as blood pressure and anthropometry, and the laboratory methods for the determination of physiologic parameters (see Section 3.5).

In addition, requests for data for certain category A variables were sent to the coordinating centers of the parent studies, in order to carry out a formal statistical comparison of the actual distribution of continuous and categorical variables in the source cohorts. These analyses are conducted at the CC and are aimed at developing a strategy for statistical adjustment of the data for final data analyses. The data that was collected from the parent studies were:

- ID
- Date of Birth
- Gender
- Race
- Seated systolic and diastolic blood pressure
- Use of anti-hypertensive medications
- Supine ankle and arm blood pressures
- Height, Weight, Waist, Hip
- Cholesterol, HDL, LDL, Triglycerides
- FEV1, FVC

In a second phase, the subcommittee will also examine the data collection procedures and distributions of category B variables, in order to establish a set of recommendations for statistical analyses, should these variables be used in specific analyses in subsets of the SHHS participants.

The following paragraphs summarize the results of the assessment of comparability. Appendix A.1 contains tables with the specific wording of questionnaires and instruments for the collection of the A-variables. All relevant forms and questionnaires from the parent studies have been compiled and are available at the SHHS Coordinating Center upon request.

In addition to the assessment of comparability, the following sections also outline the additional information being collected for each variable. With few exceptions, this information is collected the night of the home visit, prior to the sleep exam, using an interviewer administered instrument called the Health Interview (see Section 6.5). Some variables are collected at all sites; some are site-specific.

3.5 Comparability of A-Category Variables

3.5.1 Prevalent Cardiovascular Disease

History of cardiovascular disease (CVD) must be assessed at the baseline exam of the SHHS in order to identify incident CVD and the temporal relationship of CVD with sleep apnea. Some of the parent studies have assessed their participants for prevalent CVD at baseline and follow-up exams; others have not. A study of the comparability of the methods of assessment shows that the studies vary both in the types of CVD assessed, as well as the degree to which self-reported disease is validated. Because the cohorts are at various stages of recruitment and follow-up, both baseline data and follow-up data may be used to define whether a subject is at risk of incident CVD.

For this study, we have defined the following variables as those critical to obtain at baseline or from the parent study database in order to address the hypotheses of the SHHS:

- Myocardial Infarction (MI)
- Angina
- Coronary Artery Bypass Surgery (CABG)
- Coronary Angioplasty
- Stroke
- Congestive Heart Failure (CHF)

For stroke and myocardial infarction, all studies except one (New York) collect self-reported history of diagnosis and surgical procedures at baseline and at each follow-up. For angina, two centers use versions of the Rose Questionnaire, two centers use reported history and one center uses both. For CHF, one center uses symptom questions, one uses reported history and symptoms, one uses reported symptoms and physical exam, two centers do not assess CHF. The time-frame varies considerably (6 months to 2 years prior to the sleep exam), definitely outside the maximum permissible time window (3 months).

Because of these differences in assessment of prevalent CVD status, the comparability subcommittee developed a brief self-reported history check-list to be administered to each participant during the home visit prior to the sleep exam in order to ensure comparability in the type of data and the time frame of assessment (see Section 6.5). These questions will be asked in all cohorts except New York, which will include them as part of the participant's parent study assessment immediately (within 3 months) prior to the home sleep study.

3.5.2 Self-Reported History of Hypertension and Diabetes

All studies except Framingham have collected self-reported history of hypertension and diabetes within three years of the planned sleep studies. Thus, in order to achieve comparable information regarding awareness of these key risk factors, these questions will be added to the Health Interview (on the night of the sleep study) to the Framingham participants (see Section 6.5.3).

3.5.3 Self-Reported History of Respiratory Diseases and Symptoms

The parent studies use diverse methods and criteria to assess history of respiratory conditions and symptoms. In order to obtain comparable baseline information about respiratory disorders from all participants within the desirable time window, a series of questions on history of physician diagnosis of chronic bronchitis, asthma, and emphysema will be asked as part of the Health Interview to participants from all cohorts (see Section 6.5). In addition, questions assessing the presence of respiratory symptoms (cough, phlegm, hay fever, sinusitis, runny nose, see Section 6.5) will be asked. The asthma questions are from the IUATLD Bronchial Symptoms Questionnaire¹. The cough & phlegm questions are shortened versions of the ATS-DLD-78-A questions², which allow a diagnosis of chronic bronchitis; they are very similar to the questions asked in the TES, where the phrase used is “phlegm, sputum, or mucus from your chest”. The hay fever question is from the ATS-DLD-78-A. The stuffy nose question is asked at the Normative Aging Study³, where it was found to correlate with sleep symptoms.

3.5.4 Self-Reported History of SRBD

Sleep related breathing disorders symptoms have only been assessed in the CHS, Tucson, and SHS cohorts. A uniform assessment in terms of instrument and timing is required in all participants in the SHHS. This information will be collected in the Sleep Habits Questionnaire to be sent to all participants from the source cohorts (see Section 4.1).

3.5.5 Cigarette Smoking

All studies have comparable information regarding assessment of current cigarette smoking status and dosage. All studies but New York have information that would allow the calculation of cumulative exposure (cigarette or pack-years). The timing with respect to the sleep study varies from study to study and even between participants in any given study. In participants from all studies on whom cigarette smoking status has not been assessed within three months from the home sleep study, a series of questions to update current cigarette status (including cigarettes per day and pack-years) will be asked as part of the Health Interview (see Section 6.5). Questions that will permit the calculation of pack-years will be added to the Health Interview in all New York participants.

3.5.6 Educational Level

All sites except Framingham have assessed Years of Education. The coding for ARIC and CHS includes years of Vocational School and whether the subject obtained a GED; Cornell and Tucson are ambiguous about this, probably leaving it up to subjects to decide whether or not to count vocational training as “formal education.” The ARIC/CHS approach can be made quite comparable to the Cornell/Tucson data by ignoring vocational training and counting GED as 12 years. Thus, a question about education will be added to the Framingham Health Interview (see Section 6.5.3).

3.5.7 Usual Alcohol Intake

All studies have the information to characterize present alcohol consumption and number of drinks per day. There are some differences regarding timing with respect to the home sleep study as well as the algorithms for the calculation of the amount (i.e., cc of ethanol) consumed per week that will need to be taken into account. The NY assessment is particularly limited for this purpose, since the frequency of different types of drinks is reported as ranks rather than actual quantities. Thus, questions to assess weekly alcohol intake will be added to the Health Interview among New York participants (see Section 6.5.4).

3.5.8 Usual Caffeine Intake

All studies but Tucson seem to have the information to characterize present caffeine consumption and number of cups of caffeinated beverages consumed per day. There are some differences that need to be taken into account when calculating the amount consumed per day, particularly for ARIC (does not distinguish caffeinated/decaf sodas) and New York (ranks). Thus, three questions regarding usual caffeine intake will be included in the Health Interview in all cohorts (see Section 6.5).

3.5.9 Seated Blood Pressure

Seated blood pressure is obtained in all parent studies. There are a few differences in the protocol that could produce minor differences in the values obtained. The most significant differences are the use of a random zero sphygmomanometer in ARIC, and an aneroid manometer in Tucson (all other parent studies use a standard mercury sphygmomanometer). ARIC and New York do 3 consecutive determinations (the average of the last two measurements are routinely used in ARIC reports), whereas CHS does only 2 determinations. Framingham and Tucson's protocols do not specify the number of measurements. Otherwise, all studies take the measurements in seated position after 5 minutes rest, using a bell stethoscope, and reading 1st and 5th Korotkoff phases.

An additional problem with the blood pressure determinations in the parent studies is the fact that the timing in relation to the sleep examination differs across studies (from within weeks to more than one year). Thus, a seated blood pressure will be measured in all SHHS participants at the night of the sleep exam following a common protocol. Blood Pressure will be taken by the sleep technician with the subject in a seated position after 5 minutes rest, using a standard mercury sphygmomanometer and a choice of four cuff sizes. The observer should listen with the bell of a Littman stethoscope and record the pressures corresponding to the first and fifth Korotkoff sounds. The average of the last two of three readings taken with at least 30 second intervals is used to describe the blood pressure.

See Section 6.2 for detailed instructions regarding measuring blood pressures.)

3.5.10 Anthropometric Indices

Some generic adjustments will be necessary for all anthropometric measurements:

- Those that are systematically rounded down:
 - ARIC: add .5 units.
 - CHS: add .25 units.
- Transform all measurements to the metric system.

3.5.10.1 Height

Assessed in all cohorts. No action needed.

3.5.10.2 Weight

Given the strong association between body weight (obesity) and SRBD and the possibility that some participants may had experienced important weight changes immediately prior to the home sleep study, it was considered necessary to have a measurement of current weight, as close as possible to the night of the study. A maximum window of one month was considered acceptable. Thus, for participants whose parent study has measured their weight within the month prior (or subsequent) to the home sleep study, that measurement will be used to estimate body mass index. Participants measured outside a one-month window will be measured on the night of the sleep study using a portable scale (see protocol in Section 6.3). Participants will be weighed in their night clothes (but no bathrobes) before they are connected to the sleep monitor. In addition, participants from the New York cohort who are weighed in the clinic will have a constant subtracted from their weight measurement, to adjust for subject being dressed.

3.5.10.3 Waist Girth, Hip Girth

All cohorts measure waist and hip within the 3-year window considered acceptable. Thus no action is needed.

3.5.10.4 Neck Girth

Neck girth was not measured in all cohorts. Those that did, did so using slightly different protocols. In particular, whether the measurement is made perpendicular to the long axis of the neck versus in a horizontal plane could cause important differences in accuracy of the measurement. Thus, in the night of the sleep study, subsequent to the head measurements needed for the correct placement of the EEG electrodes, the neck circumference will be measured using a common protocol in all sites. The protocol will be based on the method described in Lohman, Roche and Martorell, Anthropometric Standardization Reference Manual, Human Kinetics Books, Champaign IL, 1988, pp. 41-42. Neck circumference is measured with the subject upright, head in the Frankfort Horizontal Plane. An inelastic tape measure is applied around the neck just inferior to the laryngeal prominence. The minimal circumference of the neck is measured to the nearest cm, rounding up. The measurement is made perpendicular to the long axis of the neck (which is not necessarily in the horizontal plane). The pressure on the tape

should be the minimum required to maintain skin contact, and the measurement should be completed in less than 5 seconds, to avoid subject discomfort.

3.5.11 Serum Lipid Levels

The following tables summarize the methods used in the different parent studies to assess total cholesterol and HDL cholesterol.

TOTAL CHOLESTEROL

Study	Method	Characteristics/comments
ARIC	Enzymatic method with absorbance readings ¹	Materials brand: Cobas Fara II Analyzer (Rocher), Standard cholesterol reagent Boehringer (Cat No. 236691) Method is linear up to 500 mg/dl, otherwise dilutions have to be made Validity of the method in the presence of bilirubin or hemoglobin is not specified
SHS	Enzymatic method with absorbance readings ¹	Materials brand: Cholesterol System Pack for HITACHI 717 Method is valid with bilirubin levels up to 12 mg/100ml and hemolysis up to 200 mg/ml.
Framingham	Enzymatic method with absorbance readings ¹	Materials brand: ABBOTT SPECTRUM Cholesterol Reagent Method is linear up to 500 mg/ml, otherwise dilutions have to be made No hemoglobin interferences. Icteric specimens should not be used.
Tucson	Spectrophotometry	Materials brand:
New York	Enzymatic method with absorbance readings ¹	Materials brand: Technicon Omnipak reagents, Technicon Dax System
CHS	Enzymatic method with absorbance readings ¹	Materials brand: KODAK ECTACHEM Clinical chemistry products

¹Cholesterol esters are hydrolyzed to free cholesterol by cholesterol esterase. The cholesterol produced is oxidized by cholesterol oxidase in a reaction that results in the formation of hydrogen peroxide. Hydrogen peroxide reacts with 4- aminoantipyrine and phenolin the presence of peroxidase to yield a quinonimine dye which absorbs at 500 nm.

HDL-CHOLESTEROL

Study	Method	Characteristics/comments
ARIC	Dextran sulfate-Mg ¹	If supernate after precipitation is cloudy respun or filter before proceeding.
SHS	Heparin-Manganese precipitation ²	If supernate after precipitation is cloudy respun or filter before proceeding.
Framingham	Dextran sulfate-Mg	
New York	Dextran sulfate-Mg	
CHS	Dextran sulfate-Mg	

¹Mixtures of dextran sulfate and magnesium cause precipitation of LDL and VLDL while the HDL remain in solution. The supernate containing HDL is analyzed for cholesterol content.

²Mixture of manganese chloride with heparin is used to cause LDL and VLDL precipitation.

3.5.12 Spirometry

With the exception of New York, all centers have performed spirometry following ATS standards⁴. This procedure will be added to New York's participants as part of their parent study clinic examination.

3.5.13 Ankle-Arm Index

The ratio of the ankle to arm systolic blood pressure (ankle-arm index) is a component of non-invasive testing of lower extremity arterial circulation. In most cases, a reduced ankle systolic pressure results in a reduced ratio indicating obstruction to flow due to atherosclerosis. It is a much more sensitive measure of lower extremity arterial disease than symptoms of intermittent claudication or the Rose Questionnaire for intermittent claudication. It is correlated with atherosclerosis in other vascular beds and is a strong predictor (relative risks of 3.0 to 4.0) of mortality in population studies. Because it is very easy to measure this ratio in non-invasive studies using a relatively inexpensive Doppler stethoscope, and because it identifies a subgroup with established atherosclerosis, the AAI has been incorporated into the SHHS protocol.

In the SHHS, four of the parent studies already had an AAI protocol in the parent protocol. The manual of operations for the parent studies were reviewed in detail. All centers obtain the measurement with the participant lying down, using a Doppler stethoscope, following standard blood pressure measurement technique. The ARIC protocol only measures the pressures in one arm and leg (selected at random). Because the legs are so highly correlated, the parent study data for all parent cohorts will be analyzed using one leg selected at random to classify participants. The only center not using a protocol for the ankle arm index (New York) is adopting the protocol used in CHS.

3.5.14 Medications

3.5.14.1 Background and Rationale

The SHHS medication inventory is designed to assess current medication use. It is adapted from the protocols used for CHS, ARIC and Strong Heart Study. The methods used across all SHHS field Centers were either too widely variable in time, or not comparable in method. The comparability committee recommended assessing current use with the same method at the time of polysomnography for all centers.

At the baseline home polysomnography visit, the participant provides the technician with all prescription medications used during the two weeks prior to the visit, as well as recent selected over-the-counter medications and supplements. The technician transcribes information from the container onto the data collection form. After the information is transcribed, the interviewer queries the participant about each medication and asks several additional questions regarding the use of medications for sleep, caffeine, and other selected over-the-counter medications.

The medication form has several important purposes.

1. Medication use will be used to better define those reporting prevalent heart disease, hypertension, diabetes and other conditions. For example, a person taking nitroglycerin will generally have coronary heart disease. Diabetes may be insulin-requiring or not.
2. Medications may be prescribed for sleep or may have side effects of sedation.
3. Medication use may be an essential covariate in the analysis of the primary effects of sleep apnea on cardiovascular disease.

3.5.14.2 Definitions

Time frame--All prescription medications, and selected over-the-counter medications taken within the two week period prior to the interview (home or clinic) are included.

Prescription medication--CHS Definition: a medication for which a prescription was written by a physician, dispensed by a pharmacist or physician, and taken by the participant during the two weeks prior to the interview. This includes prescription:

- * Eye drops
- * Pills or tablets
- * Creams/salves
- * Dermal patches
- * Injectables (such as insulin)

Non-Prescription Medications--one that may be purchased without a physician prescription.

Note: Physicians sometimes write prescriptions for medications which can be purchased without a prescription (over-the-counter medicines). For example, the participant may take one aspirin a day. When the physician wrote a prescription for the aspirin, it is considered a prescription medication. When the physician recommended that the participant take aspirin, but did not write a prescription for it, the aspirin is not considered a prescription medication.

One question regarding nitroglycerine prescriptions will be added to the Health Interview form, since information from medication bottles is collected only for medications taken within the previous two weeks, and thus some use of nitroglycerin could be missed. In addition, one question regarding use of sleeping pills will be added to the Morning Survey (see Section 6.7).

(See Section 6.6 for detailed instructions regarding collecting medication data.)

3.5.15 Electrocardiography

Baseline ECG is performed in all parent study clinic visits preceding the PSG. All sites perform a standard resting 12-lead ECG with the participant supine. Ten seconds of data are acquired simultaneously from each lead (I, II, III, aVR, aVL, aVF, V1-V6) to a Marquette MAC PC or MAC II system. At each site, a paper copy of the ECG is produced and filed. Minnesota coding of the ECG data is performed on all participants in ARIC, CHS, and SHS. Minnesota coding may be performed for other sites as well. Currently, NYCC ECG data is interpreted by a clinical cardiologist, and FHS ECG data is interpreted by the clinic physician. Some minor differences in lead placement and electrode type among sites are not considered critical to hamper the comparability of ECG examination across centers.

3.5.16 Other A-Variables

3.5.16.1 Age

Birth date data has been sent to the SHHS CC by all parent studies, so age can be calculated for any relevant time points (e.g., age at recruitment into SHHS, age at subsequent events)

3.5.16.2 Marital Status

All parent studies use the same categories. Some studies separate Divorced and Separated into two categories, but some combine this as one category. Therefore for SHHS these will be considered one category. The following coding convention will be followed:

- 1 = Married
- 2 = Widowed
- 3 = Divorced/Separated
- 4 = Never Married
- 8 = Unknown/Refused to answer

3.5.16.3 Gender

Coding will be standardized to 0 = Female, 1 = Male

3.5.16.4 Race/Ethnicity

The major difference between cohorts is that some consider Hispanic or Mexican American as a race, others do not. For SHHS purposes, Hispanic will be considered a race. The following codes will be used:

- 1 = Caucasian
- 2 = African-American
- 3 = Native-American/Alaskan Native
- 4 = Asian/Pacific Islander
- 5 = Hispanic/Mexican-American
- 6 = Other

3.6 References

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SLEEP HEART HEALTH STUDY MANUAL OF OPERATIONS

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CHAPTER 4 - PRE-ENROLLMENT DATA COLLECTION

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4.1 Sleep Habits Evaluation

4.1.1 Purpose and Method of Development

The Sleep Habits Questionnaire was developed to serve 4 main purposes:

1. To survey the source populations on key sleep and breathing questions for weighted sampling to construct the SHHS sample with adequate variance in sleep disordered breathing. For this, the key questions must have known predictive value in community populations. Data from The Wisconsin Sleep Cohort survey (an instrument based on most screening questions commonly asked in sleep clinics) of a source population of employed middle aged men and women (n=6000) and subsequent laboratory polysomnography data on a sample (n=1100) were used to determine the key weighting variables. The data were considered by the Sampling and Design Committee. The candidate variables were self-reported frequency of snoring and breath pauses, loudness of snoring, and self-perception of snoring. The single question on snoring frequency was determined to be sufficient for the sampling scheme.
2. To identify people who should not be included in the SHHS sample. The exclusions were: people treated for sleep apnea on a nightly basis (CPAP or dental device), but not by surgery, and people on home oxygen therapy. Although individuals with a tracheostomy will be excluded, the prevalence of this exclusion factor did not warrant inclusion on the Sleep Habits Questionnaire. Questions were devised to identify such people.
3. To characterize the SHHS sample participants and assess selection bias on key variables that would not otherwise be available from parent cohorts (sleepiness, snoring, etc).
4. To collect data from a very large sample (~20,000) for analysis of self-reported data on sleep problems and conditions and cardiovascular endpoints and other data routinely collected on the parent cohorts. Because the questionnaire length was limited, the items included for this purpose needed to have established validity and should address an *a priori* hypothesis (of Steering Committee agreed-upon scientific importance).

Important domains in view of the 4 purposes were identified, and existing instruments with questions on these domains were gathered. Proposals for each domain were drafted by the Q and I Committee and discussed at Steering Committee meetings. Data from the Cleveland Family Study and the Sleep Cohort Study were used to examine the validity and variance of some questions in order to select wording and scales. In most cases, the exact wording of previously used questions was retained. However, for the Epworth Sleepiness Scale, several changes were desired for clarity and grammatical correctness. To investigate the effect of new language, a pilot study of three versions of the Epworth was conducted at the Tucson field site. The clarified version did not produce significantly different answers and was consequently adopted.

A draft of the Sleep Habits Questionnaire incorporating all changes from the Steering Committee was created and formatted by the Coordinating Center. The draft was tested in two ways: purposeful scrutiny by 43 volunteers (administered by Q and I committee members to adults who were asked to fill out the questionnaire and to NOTE anything they had problems answering), and by cohort participants who were pilot testing the sleep monitors at 8 field sites (n=96). The comments, distributions, missing data, etc. were considered for the revisions and the final version.

4.1.2 Procedures and Methods for Data Collection

4.1.2.1 Method of Data Collection

The Sleep Habits Questionnaire is designed to be self-administered. Depending on the Field Center, participants may complete this form by mail, at a clinic exam, or during a personal visit from one of the parent study personal recruitment visits. See Section 2.2 for summary of methods of collection by Field Center.

4.1.2.2 Completion of Questionnaires

The letter that accompanies the questionnaire should not advise or otherwise encourage participants to consult with others as they complete the questionnaire. The following sentence should be included in the letter: *Please read and fill out this questionnaire by yourself, without discussing questions with anyone.*

- a) Participants' queries about how to answer the items.

Participants will vary in their access to help in filling out the questionnaire, and this may introduce a bias in the completeness and validity of the questionnaire data by site. Participants who receive the questionnaire by mail will need to call the study office for help, while those who are given the questionnaire during a study visit will have ample opportunity to ask for clarification and get other kinds of help. As a counter measure, participants should not be encouraged to ask for help in the in-person settings, and staff in all settings should adhere to the permitted clarifications below. Fortunately, most items are self-explanatory and are unlikely to raise questions. However, if clarification is needed, see clarification instructions in coding and editing instructions (see Section 4.1.3).

- b) Participants with problems: illiterate, poor eyesight, other handicaps that preclude reading and writing. Another person is permitted to read the items and mark the answers if necessary. For the mailed-questionnaire setting, it is most likely that participants will find someone else to help them. For the in-person setting, a staff member should be identified who will assist such participants if they do not already have someone to help them.

4.1.3 Interview and Coding Instructions

4.1.3.1 Introduction

If the questionnaire is returned by mail, respondents will not be called for missing or incorrect information. If the questionnaire is completed in the presence of SHHS study personnel, the questionnaire can be checked for completeness/accuracy by the study personnel and any missing data or discrepancies can be double-checked with the study participant.

The instructions that follow outline the permissible clarifications and coding instructions on a question by question basis. This protocol should be consistently adhered to. Any deviations from protocol should be referred to the study coordinator. Any proposed changes in protocol should be referred to the Operations Subcommittee.

4.1.3.2 Review for Completeness

Questionnaires should be examined for completeness and accuracy prior to data entry. See question by question specification of codes to clarify or correct data on questionnaire. Any questions regarding how data are coded that are not covered in this document should be reviewed with the study coordinator.

4.1.3.3 General Instructions

1. Indicate responses clearly and neatly.
2. Complete paper form with black pen.
3. Using a red pen or pencil, make corrections on interview, "X-ing" out the discrepancy and writing next to it the corrected response. Stray marks on the forms should be scratched out using red as well.
4. Leading zeros are not required to fill in all fields of a variable.
5. Missing data.
 - a) By type of Administration
 - i) On self-administered forms, data not completed by the participant will be left as blanks.
 - ii) On interviewer-administered forms, all questions should be marked with a response except those that are SKIPPED as a result of a SKIP pattern. Items SKIPPED by a SKIP pattern should be left blank on the form.

b) Coding Specifications

The following guidelines specify how to deal with coding “don’t know” and “blank” data. However, there may be exceptions to these rules, so please consult the question-specific details provided for each form.

- iii) If a participant explicitly responds “don’t know” to a question, the interviewer should fill the field with 8’s. For example: If someone can’t remember what year they stopped smoking, code the month as 88 and year as 8888.

Thus, 8’s imply that data are missing because the participant explicitly responded “Don’t Know” or “Unsure.”

- ii) If a participant refuses to answer or does not give a valid response, the interviewer should fill the field with 9’s. For example: If someone refuses to answer the questions regarding “alcohol” consumption, then code the data as 99.

If on a self-administered form the participant responds by writing in an involved response, this should be coded as 9’s. Some questions on self-administered forms purposely do not include a “Don’t Know” option. If the participant writes in “Don’t Know,” code as 9.

Thus, 9’s indicate that data are missing because of some kind of error in the response or a refusal.

6. If a range of values is given, take the midpoint. If data are collected only as integer values, then find the midpoint and round up to nearest integer. For example, 6-8 cups a day is 7 cups. The midpoint of the range 6-7 cups a day is 6.5 and should be rounded up to 7 cups as the final answer.
7. The year in a date is to be entered as a 2-digit number without the “19” prefix. Exception to this rule is when the response is “don’t know” or question is left blank by the respondent and is not part of a SKIP pattern. Since 1988 and 1999 may be valid responses in this study, year will have to be filled with a 4-digit number, 8888 or 9999, respectively.
8. For questions where “hours” and “minutes” are to be specified, convert fractional hours to minutes. Both hours and minutes fields must be completed, even if the response is 0. For example, if a respondent indicates 3/4 of an hour, then neatly “X-out” in red the 3/4 and recode data to 0 “hours” and 45 “minutes.”
9. By definition, midnight is 12:00 A.M.
10. Record your ID number at the appropriate spot on the interview form.

11. If 2 responses are given for a question, choose the response closest to the “normal” response and X-out the other response. “Normal” is defined on a question-by-question basis. For example, the question regarding “How loud is your snoring?” is coded on a scale of 1 to 4. If the respondent has circled a 2 and 3 or has put a mark between 2 and 3, then code final response as 2.

4.1.3.4 Question by Question Specifications

Prequestion data

The participant information and Field Center ID at the top right of page 1 should be complete before the form is given or sent to the participant.

“What is Today’s Date” should be coded in the MM/DD/YY format, two-digits for each component of the date. For example, December 7, 1995 should be coded as 120795. If the participant codes the date in some other way (e.g., writing “Dec” instead of 12 for the month), the person reviewing the form should convert the date to the proper format before giving the form to the data entry staff.

1. A. At what time do you usually FALL ASLEEP on weekdays or workdays?
B. At what time do you usually FALL ASLEEP on weekends or your non-work days?

Clarification:

If an individual has a job, they report the usual time they FALL ASLEEP on their work days for Part A and for their non-work days for Part B.

If an individual does not work, then the individual should report the usual time for weekdays (Monday through Friday) for Part A and the usual time for weekends (Saturday and Sunday) for Part B.

Coding:

Hours and minutes are 2-digit fields.

AM or PM designation needs to be checked.

Hours permissible range: 1 to 12

Minutes permissible range: 0 to 59

If no AM/PM designation is checked, look at other questions with sleep and wake up times (Questions 1 and 3) to determine, if possible, if the missing data are AM or PM.

Data for Questions 1.A. and 1.B. should be visually compared to data for time usually WAKE UP (Questions 3.A. and 3.B., respectively) for consistency. Inconsistencies must be rectified. It is possible that someone may actually sleep during the day so care must be taken when checking for consistencies between FALL ASLEEP time and WAKE up time.

NOTE: Midnight is 12:00 AM by definition. A major point where inconsistencies will occur is when the respondent misspecifies 12 midnight as PM instead of AM.

2. How many minutes does it usually take you to fall asleep at bedtime?

Coding:

A 3-digit field is allowed for specification of minutes.
Permissible range: 00 to 480.

Any hour specification must be converted to minutes.

If a range is given, take the midpoint. If midpoint is a fraction of a minute, the midpoint should be rounded up to nearest minute.

Example: 10-20 minutes should be coded as 15 minutes.
10-15 minutes should be coded as 13 minutes.

If two times are given, a usual time and a special circumstances time, code the usual time.

Example: "Usually it takes 10 minutes but if my spouse is snoring it takes 30 minutes."
Code as 10 minutes.

3. A. At what time do you usually WAKE UP on weekdays or workdays?
B. At what time do you usually WAKE UP on weekends or your non-work days?

Clarification:

If an individual has a job, they report the usual WAKE UP time on their work days for Part A and for their non-work days for Part B.

If an individual does not work, then the individual should report the usual time for weekdays (Monday through Friday) for Part A and the usual time for weekends (Saturday and Sunday) for Part B.

Coding:

Hours and minutes are 2-digit fields.
AM or PM designation needs to be checked.
Hours permissible range: 1 to 12
Minutes permissible range: 0 to 59

If no AM/PM designation is checked, look at other questions with sleep and wake up times (Questions 1 and 3) to determine, if possible, if the missing data are AM or PM.

Data for Questions 3.A. and 3.B. should be visually compared to data for time usually WAKE UP (Questions 1.A. and 1.B., respectively) for consistency. Inconsistencies must be rectified. It is possible that someone may actually sleep during the day so care must be taken when checking for consistencies between FALL ASLEEP time and WAKE up time.

NOTE: Midnight is 12:00 AM by definition. A major point where inconsistencies will occur is when the respondent misspecifies 12 midnight as PM instead of AM.

4. How many hours of sleep do you usually get at night (or your main sleep period) on weekdays or workdays?

Clarification:

If an individual has a job, they should report the usual number of hours of sleep they get on their work days.

If an individual does not work, then the individual should report the usual number of hours of sleep on weekdays (Monday through Friday).

Coding:

Number of hours is a 2-digit field with two digits for the hours.

Permissible range: 00 to 24

If a range is given, take the midpoint. If midpoint is a fraction of an hour, the midpoint should be rounded to the nearest hour.

Example: 8 to 9 hours should be coded as 9 hours.

8 and a half hours is coded as 9 hours

8 to 8 and a half hours is coded 8 (8.25 rounds to 8)

If two times are given, a usual time and a special circumstances time, code the usual time.

Example: "Usually 8 hours except if I have business travel and then it's only 4 to 5 hours."
Code as 8 hours.

5. How many hours of sleep do you usually get at night (or your main sleep period) on weekends or your non-workdays?

Clarification:

If an individual has a job, they should report the usual number of hours of sleep they get on their non-work days.

If an individual does not work, then the individual should report the usual number of hours of sleep on weekends (Saturday, Sunday).

Coding:

Number of hours is a 2-digit field with two digits for the hours.

Permissible range: 00 to 24

If a range is given, take the midpoint. If midpoint is a fraction of an hour, the midpoint should be rounded to the nearest hour.

Example: 8 to 9 hours should be coded as 9 hours.

8 and a half hours is coded as 9 hours

8 to 8 and a half hours is coded 8 (8.25 rounds to 8)

If two times are given, a usual time and a special circumstances time, code the usual time.

Example: "Usually 8 hours except if I have business travel and then its only 4 to 5 hours." Code as 8 hours.

6. During a usual week, how many times do you nap for 5 minutes or more? Write in "0" if you do not take any naps.

Coding:

Number of times is a 2-digit field.

Permissible range: 0 to 50

If a range is given, take the midpoint. If midpoint is a fraction, round to nearest integer value.

Example: 6 or 7 naps should be coded as 7 (6.5 rounded up to 7).
10 to 12 naps should be coded as 11 naps.

If respondent describes napping pattern in words, convert to an integer value, if possible.

Example: "I usually fall asleep in front of the TV after dinner."
Code as 7 naps per week.

7. Please indicate how often you have each of the following. (Check one box for each item.)

Coding:

Parts A. through G. are all coded the same.

Permissible codes: 1, 2, 3, 4, 5

If someone writes in a comment such as Not Applicable, code a value of 1 (NEVER).

If two boxes have been marked and it is not clear which is the intended single response, code the value marked that is closest to 1 (RARELY).

8. Have you ever snored?

This is a lead-in question for questions 9 through 13.

Clarification:

"Ever" refers to 1 or more times at any time in the past, regardless of whether it was recent.

Coding:

Permissible codes: 0, 1, 8

If answer is YES (code =1), then participant should have answers coded for questions 9 - 13.

If answer is NO (code=0) or Don't Know (code=8), then participant should have SKIPPED out of questions 9 - 13. However, if responses are given for any of questions 9 - 13, enter data as given on the form.

EXCEPTION: If a valid response is given for any of questions 9 through 13, then the "No," "Don't Know," or missing on question 8 is to be changed to a "Yes" on the questionnaire and

entered into the database as "Yes." Valid responses are defined as -- Q9: values 0 to 4; Q10: values 1 to 4; Q11: any # of years, except 0 or 88 (Don't know); Q12: values 1 to 3; and Q13: only the value of 1.

9. How often do you snore? (Check one)

Clarification:

"How often" refers to the number of nights per week that any snoring is thought to occur. (Not how many times per night or how much of the night).

Coding:

Permissible codes: 0, 1, 2, 3, 4, 8

If answer is "Do not snore anymore" (code=0), then SKIP to question 13. SKIPPED data are to be left blank. However, if a response is given, enter data as given.

If two boxes have been marked and it is not clear which is the intended single response, code the value marked that is closest to 1 (Rarely).

10. How loud is your snoring? (Check one)

Coding:

Permissible codes: 1, 2, 3, 4, 8

SKIPPED data are to be left blank. However, if a response is given, enter data as given.

If two boxes have been marked and it is not clear which is the intended single response, code the value marked that is closest to 1 (Only slightly louder than normal breathing).

11. For how many years have you been snoring?

Number of years is a 2-digit field.

Permissible range: 0 to 80

SKIPPED data are to be left blank. However, if a response is given, enter data as given.

If a range is given, take the midpoint. If midpoint is a fraction, round to nearest integer value.

Example: 5 or 6 years should be coded as 6 (5.5 rounded up to 6).

10 to 12 years should be coded as 11 years.

12. Is your snoring: (check one)

Clarification:

In comparison to a few years ago, do you think you now snore more, less or about the same?

Coding:

Permissible codes: 1, 2, 3, 8

SKIPPED data are to be left blank. However, if a response is given, enter data as given.

If two boxes have been marked, the data will have to be coded as invalid (code=9).

13. Have you ever had surgery as treatment for your snoring?

Clarification:

Has a physician ever used a laser to tighten your throat tissue (“LAUP”), or have you ever had tissue in your throat or airway removed by cutting, specifically to reduce your snoring?

Coding:

Permissible codes: 0, 1

SKIPPED data are to be left blank. However, if a response is given, enter data as given.

Code treatment as YES (code=1) even if the respondent indicated that it was not effective, or that they still snore.

14. Are there times when you stop breathing during your sleep?

This is a lead-in question to question 15.

Coding:

Permissible codes: 0, 1, 8

If answer is YES (code =1), then participant should have answered question 15.

If answer is NO (code=0) or Don't Know (code=8), then participant should have SKIPPED out of question 15.

15. How often do you have times when you stop breathing during your sleep?

Clarification:

How often do you have times when it seems like you are holding your breath or have a pause in your breathing, or have an “apnea” for about 10 seconds or so?

Coding:

Permissible codes: 1, 2, 3, 4, 8

SKIPPED data are to be left blank. However, if a response is given, enter data as given.

If two boxes have been marked and it is not clear which is the intended single response, code the value marked that is closest to 1 (Rarely).

16. Part A. Have your ever been told by a doctor that you had sleep apnea (a condition where breathing stops briefly during sleep)?

This is a lead-in question to the exclusion criteria contained in Parts B and C.

Coding:

Permissible codes: 0, 1, 8

If answer is YES (code =1), then participant should have answered questions 16.B. and 16.C.

If answer is NO (code=0) or Don't Know (code=8), then participant should have SKIPPED out of 16.B. and 16.C.

16. Part B. Do you sleep with either a pressure mask ("CPAP") or a mouthpiece as treatment for your sleep apnea?

Clarification:

A mouthpiece may include: tongue retaining device or dental device.

Coding:

Permissible codes: 0, 1

SKIPPED data are to be left blank. However, if a response is given, enter data as given.

Code as YES (code=1) if the respondent indicated another term for positive pressure system, such as BiPaP or trade name.

Code as YES even if respondent indicated they feel the treatment is not effective.

Anyone who responds YES (code=1) is not eligible for the sleep study

16. Part C. Have you had surgery as treatment for your sleep apnea?

Clarification:

Surgery includes "UPPP" (UvuloPalatoPharyngoPlasty), mandible or jaw advancement, or "trach", hole in windpipe, or "tracheotomy"

Coding:

Permissible codes: 0, 1

SKIPPED data are to be left blank. However, if a response is given, enter data as given.

If "trach"/tracheostomy, tracheotomy, or hole in windpipe is indicated, the questionnaire should be flagged for exclusion from SHHS

17. Do you usually use oxygen therapy (oxygen delivered by a mask or nasal canula) during your sleep?

Coding:

Permissible codes: 0, 1

If respondent indicates that use is sporadic, or only a few nights a month, or, says "just when I need it" code as ??????

Anyone who responds YES (code=1) is not eligible for the sleep study.

18. In the past year, how often, on average, have you been awakened with the following?

Coding:

All nine questions in this section are coded the same.

Permissible codes: 1, 2, 3, 4, 5

If someone writes in a comment such as Not Applicable, code a value of 1 (NEVER).

If two boxes have been marked and it is not clear which is the intended single response, code the value marked that is closest to 1 (NEVER).

19. Over the past year, how often have one or more members of your household been in or near the room where you have slept?

Clarification:

A location is considered as "near" if the person can hear you talking loudly from that location.

Coding:

Permissible codes: 1, 2, 3

20. What is the chance that you would doze off or fall asleep (not just "feel tired") in each of the following situations? Check one box for each situation. If you are never or rarely in the situation, please give your best guess for that situation.

Clarification:

If the participant never does the activity in the question, prompt "Try to imagine (activity) what do you think the chance of dozing or falling asleep would be on a usual day if you did (activity)?"

Coding:

Parts A. through J. are all coded the same.

Permissible codes: 1, 2, 3, 4

Not Applicable is not a valid response. If someone writes in a comment such as Not Applicable, code as missing (9).

If two boxes have been marked and it is not clear which is the intended single response, code the value marked that is closest to 1 (NO CHANCE).

Post-question Data -- Field Center Use Only questions

Indicate whether the questionnaire was self-administered (code=0) or if it was administered by an interviewer.

If interviewer administered, indicate which language the interview was administered in. Permissible codes are: 1, 2, 3, 4, 5, 6. Enter the ID of the interviewer or reviewer and the date of the interview or review.

4.1.4 Instruments

4.1.4.1 English Version



SLEEP HEART HEALTH STUDY

SLEEP HABITS QUESTIONNAIRE

Instructions

Thank you for taking time to fill out the enclosed Sleep Habits Questionnaire. Please fill out the form **completely**. You may use either pen or pencil. If you have any questions or problems while filling out the form, please call (appropriate name) at (phone number).

When answering a question, put a checkmark (✓) in the box in front of the correct answer. Ignore the little numbers by the boxes. They are there to help us enter the information on the form into our computer.

If you make a mistake, put an "X" over the checkmark. Then put a checkmark in the correct box and draw a circle around that box.

If the question provides space to write an answer, write your response in that space. If necessary, continue your answer on a separate sheet of paper.

Below are examples of how to mark an answer, and how to change an answer if you make a mistake. Depending on your answers to some of the questions, you may be asked to skip other questions or parts of questions. When this occurs, instructions will be printed in *italics*, indicating which question to go to next.

Again, thank you for your time.

Examples

1 Have you ever snored (now or at any time in the past)?

1 YES 0 NO 8 DONT KNOW

If you wish to change an answer (in this example, change a "NO" answer to a "YES" answer):

1 Have you ever snored (now or at any time in the past)?

1 YES 0 NO 8 DONT KNOW

SLEEP HABITS QUESTIONNAIRE,
six pages, inserted after this page



SLEEP HEART HEALTH STUDY

SLEEP HABITS QUESTIONNAIRE

ID#:

Field Center: _____

Today's date: _____
month day year

Please complete as thoroughly as possible and to the best of your knowledge.

1 A. At what time do you usually FALL ASLEEP on weekdays or your work days?

_____ : _____ 1 A.M. (Midnight is 12:00 A.M.)
 2 P.M.

B. At what time do you usually FALL ASLEEP on weekends or your non-work days?

_____ : _____ 1 A.M. (Midnight is 12:00 A.M.)
 2 P.M.

2 How many minutes does it usually take you to fall asleep at bedtime?

_____ (Number of minutes)

3 A. At what time do you usually WAKE UP on weekdays or your work days?

_____ : _____ 1 A.M.
 2 P.M.

B. At what time do you usually WAKE UP on weekends or your non-work days?

_____ : _____ 1 A.M.
 2 P.M.

4 How many hours of sleep do you usually get at night (or your main sleep period) on weekdays or workdays?

_____ (Number of hours)

5 How many hours of sleep do you usually get at night (or your main sleep period) on weekends or your non-work days?

_____ (Number of hours)

6 During a usual week, how many times do you nap for 5 minutes or more? (Write in "0" if you do not take any naps.)

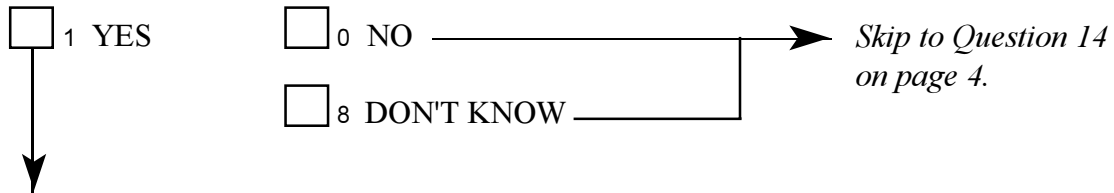
_____ (Number of times)

7 Please indicate how often you experience each of the following. (Check one box for each item.)

	NEVER (0)	RARELY (1/month or less)	SOMETIMES (2-4/month)	OFTEN (5-15/month)	ALMOST ALWAYS (16-30/month)
A. Have trouble falling asleep.	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
B. Wake up during the night and have difficulty getting back to sleep.	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
C. Wake up too early in the morning and be unable to get back to sleep.	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
D. Feel unrested during the day, no matter how many hours of sleep you had.	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
E. Feel excessively (overly) sleepy during the day.	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
F. Do not get enough sleep.	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
G. Take sleeping pills or other medication to help you sleep.	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5

Questions 8 through 16 are about snoring and breathing during sleep. To answer these questions, please consider both what others have told you AND what you know about yourself.

8 Have you ever snored (now or at any time in the past)?

- 1 YES
 0 NO
 8 DON'T KNOW
- Skip to Question 14 on page 4.
- 

9 How often do you snore now? (Check one.)

- 0 Do not snore any more. —————→ Skip to Question 13 on page 4.
- 1 Rarely - less than one night a week.
- 2 Sometimes - 1 or 2 nights a week.
- 3 Frequently - 3 to 5 nights a week.
- 4 Always or almost always - 6 or 7 nights a week.
- 8 Don't know.

10 How loud is your snoring? (Check one.)

- 1 Only slightly louder than heavy breathing.
- 2 About as loud as mumbling or talking.
- 3 Louder than talking.
- 4 Extremely loud - can be heard through a closed door.
- 8 Don't know.

11 For how many years have you been snoring?

_____ (Number of years) OR Don't know 88

12 Is your snoring: (Check one.)

1 Increasing over time?

2 Decreasing over time?

3 Staying the same?

8 Don't know.

13 Have you ever had surgery as treatment for your snoring?

1 YES

0 NO

14 Are there times when you stop breathing during your sleep?

1 YES

0 NO

8 DON'T KNOW

→ *Skip to Question 16
on page 5.*

15 How often do you have times when you stop breathing during your sleep?

1 Rarely - less than one night a week.

2 Sometimes - 1 or 2 nights a week.

3 Frequently - 3 to 5 nights a week.

4 Always or almost always - 6 or 7 nights a week.

8 Don't know.

16 A. Have you ever been told by a doctor that you had sleep apnea (a condition in which breathing stops briefly during sleep)?

1 YES

0 NO

8 DON'T KNOW

→ Skip to Question 17 below.

B. Do you sleep with either a pressure mask ("CPAP") or a mouthpiece as treatment for your sleep apnea?

1 YES

0 NO

C. Have you had surgery as treatment for your sleep apnea?

1 YES

0 NO

17 Do you usually use oxygen therapy (oxygen delivered by a mask or nasal cannula) during your sleep?

1 YES

0 NO

18 In the past year, how often, on average, have you been awakened with the following?

	NEVER (0)	RARELY (1/month or less)	SOMETIMES (2-4/month)	OFTEN (5-15/month)	ALMOST ALWAYS (16-30/month)
A. Coughing or wheezing.	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
B. Chest pain or tightness.	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
C. Shortness of breath.	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
D. Sweats or hot flashes.	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
E. Noise in your surroundings.	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
F. Pain in your joints, muscles, or back.	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
G. Heartburn or indigestion.	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
H. Leg cramps or leg jerks.	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
I. Need to go to the bathroom.	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5

19 During the past year, how often have one or more members of your household been in or near the room where you have slept?

1 NEVER 2 SOMETIMES 3 USUALLY

20 What is the chance that you would doze off or fall asleep (not just "feel tired") in each of the following situations? (Check one box for each situation. If you are never or rarely in the situation, please give your best guess for that situation.)

	NO CHANCE	SLIGHT CHANCE	MODERATE CHANCE	HIGH CHANCE
A. Sitting and reading.	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4
B. Watching TV.	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4
C. Sitting inactive in a public place (such as a theater or a meeting).	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4
D. Riding as a passenger in a car for an hour without a break.	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4
E. Lying down to rest in the afternoon when circumstances permit.	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4
F. Sitting and talking to someone.	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4
G. Sitting quietly after a lunch without alcohol.	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4
H. In a car, while stopped for a few minutes in traffic.	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4
I. At the dinner table.	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4
J. While driving.	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4

Thank you for your participation in the Sleep Heart Health Study.

Field Center Use Only

0 Self administered

Interviewer administered, in:

1 English 4 Pima

2 Spanish 5 Other, specify: _____

3 Lakota 6 Unknown

Interviewer or Reviewer _____ Date: _____
month day year

4.2 Recruitment Forms and Reports

4.2.1 Overview

Because of site-specific needs and conventions, a uniform set of participant recruitment material (invitation, explanatory brochures, etc) will not be feasible. A set consisting of the following will serve as a resource for the sites (see Appendix A.2 for documents):

- (1) A first-contact letter to request participants (~20,000 all sites combined) to complete the sleep habits questionnaire. This will introduce SHHS and will explain that some participants (~6000 all sites combined) will be asked to participate in the home sleep study protocol.
- (2) A letter or card to follow (1) by a week or so, with “thank you for sending back the questionnaire” or “a reminder in case you have forgotten”
- (3) A letter requesting participation in the home sleep study protocol.
- (4) A brochure to explain in a user-friendly format what a sleep study is all about, answers to the most common questions, etc.
- (5) A “newsletter”: may be used as a SHHS newsletter alone, or used to draw articles to incorporate into parent study newsletters.

Each site will complete a Contact Form for each individual contacted for a home sleep study, regardless of whether they agree to participate. For the recruitment of the first 25 people per site, a copy of their contact form containing the final result of the contact will be sent to the Coordinating Center to assess quality control.

From the contact form data and the clinic data maintained at the Coordinating Center (e.g., age, race, gender, etc.), weekly recruitment progress reports will be generated and distributed to the clinics (example attached). As PSG data are obtained by the Coordinating Center, this information will be integrated into the reports.

4.2.2 Sample Letter

Dear _____ *parent study volunteer*,

A few days ago we mailed you a "SLEEP HABITS SURVEY" as part of a new national study on how sleep affects heart health. The ----*parent study*---- is one of the participating centers.

If you have already completed and returned the survey, we thank you very much for your help. We sincerely appreciate the time you have spent answering the questions.

If you have not completed the survey yet, we hope you will take a few minutes and do so at this time. If you did not receive the survey in the mail for some reason, or need another one, please call us at

_____ and we will send you another. Your help is extremely important in this new study of sleep and health.

Thank you!

title

4.2.3 Time Table

Recruitment will begin in October of 1995 and will be completed within 24 months. In some sites recruitment may be completed sooner, depending on site-specific logistics and the necessary coordination with the ongoing efforts of the parent study. Analysis of the SHHS cohort demographic characteristics will be done after 1,000 studies have been completed. Results will be compared to recruitment protocol specified for age, race, and gender. Cross-sectional composition analyses will be performed in the subsequent two years as well.

4.2.4 Contact Form and Instructions for Completing

4.2.4.1 Summary

The contact form collects data on whether or not the person will participate in the study and facilitates clinic contact by providing a section for recording the sequence of contacts until the person has been finally reached and participation status determined. The first part of this form is to be completed and data entered for each person at the time he/she is first sampled. The rest of the form will be completed and final data sent to the Coordinating Center only after the "Result of final contact" has been established, indicating whether or not the person will participate. If the person agreed to participate, the form will include the date of the scheduled sleep study; if not, the form will include the reason for non-participation. If the "sequence of contacts attempted" exceeds 10 contacts, these may be continued on the back of the form.

4.2.4.1 Contact Form

Sleep Heart Health Study
Contact Form

Field Center: _____ Recruiter ID: _____
Participant ID number: _____

1. Date of Final Recruitment Contact: _____

2. Method of contact:

- (1) Telephone
- (2) In-person, at clinic
- (3) In-person, at home
- (4) Mail

3. Result of Final Recruitment Contact

- (1) Scheduled sleep study for (date) _____
- (2) Refused. Reason: _____
- (3) Unable to participate due to illness
- (4) Participant out of area for extended time; may call back later, after (date) _____
- (5) Unable to locate
- (6) Participant deceased
- (7) Did not respond to mail contact
- (8) Other, specify: _____

4. Number of contacts attempted: _____
(Count of 5, below)

5. Sequence of contacts attempted:

Date	Result*	Comments	Recruiter
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____

- *Result codes: (1) - No answer (phone)
 (2) - Bad number
 (3) - Busy
 (4) - Left Message
 (5) - Call back later
 (6) - No one home (visit)
 (7) - Unavailable, call back after _____
 (8) - I'll call back after _____

4.2.4.2 Coding and Edit Specifications for Contact Form

These specifications provide for the completion and editing of the contact form data in preparation for data entry. Once the final recruitment contact has been obtained, all items on the

form should be reviewed for discrepancies, and edited in accordance with these specifications prior to data entry.

1. Field Center code: Each Field Center has been assigned a two-digit site ID number. These numbers will automatically appear on the contact form and in the data base. The center IDs are:

<u>Investigative Center</u>	<u>Field Center</u>	<u>Field Center IDs</u>
1. Framingham	Framingham	11
2. Johns Hopkins	ARIC	21
	CHS	22
3. Minnesota	ARIC	31
4. NYU/Cornell	Project 1	41
	Project 2	42
	Project 3	43
5. Pittsburgh/Sacramento	Pittsburgh	51
	Sacramento	52
6. Strong Heart/Tucson	SHS S. Dakota	61
	SHS Oklahoma	62
	SHS Phoenix	63
	University of Arizona (Tucson)	64

2. Recruiter ID: The recruiter ID number is a three-digit number, which will be assigned to each recruiter locally. The first digit of the recruiter ID is the same as the first digit of the Field Center ID, and the other 2 digits can be any number between 01 and 99. The recruiter ID number entered into the data base should correspond to the staff person who made the final participant contact and established the code under "results of final recruitment contact." This provides identification of the last person to complete the form should questions arise regarding the data. Other ID numbers may appear on the form but should be crossed out to minimize confusion for the data entry person. The recruiter whose ID appears on the form is also responsible for the final edit of the form (see number 8, below).

3. Date of Final Recruitment Contact: This is the date that the final recruitment contact was made and final participation status was determined. All other dates can be maintained under the section for "contacts attempted." The Final Recruitment Contact Date is to be coded month, day, and year (MMDDYY). For example, September 4, 1995 would be coded as 090495.
4. Method of contact: The primary method used to contact the selected participants for participation should be coded:
 - (1) Telephone
 - (2) In-person seen at the clinic
 - (3) In-person seen at their home
 - (4) By mail
5. Result of final recruitment contact: Under this section, specify whether the individual has agreed to participate, refused, or provides some other reason for nonparticipation. Missing data are not allowed for this item.
 - (1) Scheduled sleep study for (date) _____
If the individual has agreed to participate, fill-in the code of (1) and write in the date the sleep study is scheduled for. Date to be coded MMDDYY.
If study cannot be scheduled at the time the participant agrees to participate, code as "scheduled sleep study" but leave date blank. At the time the visit is actually scheduled, enter date and send to Coordinating Center. If participant ultimately refuses, then recode this form as "refused."
 - (2) Refused. Reason: _____
If the person has stated that they refuse to participate fill in the code of (2) and write the reason for refusal in the blank. Note that there may be overlap between code (2) refused, (3) unable to participate due to illness, and (4) participant out of the area for extended period of time. If the reason for refusal corresponds to either of these latter categories, then codes (3) and (4) should override a code of (2). If both (3) and (4) are given as reasons for refusal, code the reason which appears primary. If it is still unclear how to code the reason, consult your site coordinator.
 - (3) Unable to participate due to illness
 - (4) Participant out of area for extended time; may call back later, after (date) _____
If the person is interested in participating but will be out of the area for an extended period of time, then request a new contact date (MMDDYY) after which they may be contacted again.

If the person will be out of the area but is not interested in participating, then code as (2) Refusal.

Code (3) and (4) should be used if the recruiter is reasonably sure that: 1) this will be the final code; or 2) there is an extended time period before there is any chance of the code changing. If a person is too ill, too busy, or out of the area but agrees to be recontacted regarding the study within 6 weeks (?), this should not be considered a final code but should be recorded under number 5 on the form (Sequence of attempted contacts).

(5) Unable to locate

If the person cannot be located after a reasonable effort including using all contact information available from the parent study, the individual should be coded as (5) unable to locate and additional contacts terminated.

(6) Participant deceased

(7) Did not respond to mail contact

Some of the sites are making initial recruitment contacts by mail. If mail is not responded to in a reasonable amount of time (site specific?), then this code is the final recruitment contact. If at a later date a response is received, then the recruitment process continues and the contact form can be updated and retransmitted to the Coordinating Center.

(8) Other, specify: _____

This code should only be used after all other choices have been exhausted. If coded, then during the edit process the specified reason should be re-evaluated to determine if the response could have been better classified using other codes. If so, the code should be changed.

6. Number of contacts attempted: This is a count of the number of contacts required to obtain the final recruitment contact. This number should count the final contact.
7. Sequence of contacts attempted to reach participants: This section of the form is designed for the recruiters to record their attempts to contact participants. The date is to be coded in a MMDDYY format. The "Result" codes are provided at the bottom of the page and space is provided for comments. If the number of lines are insufficient, contact attempts may be recorded on the back of the page. This section is for local use and will not be data entered except for the total number of contacts attempted.
8. Editing: When final recruitment status is determined, the recruiter whose ID appears on the form is responsible to review the form for the following:
 - 1) completeness - are all required items present, including number of contacts;
 - 2) accuracy - is the final recruitment status shown on the form the most accurate representation for that participant?

4.2.5 Recruitment Progress Report

Attached is an example of a recruitment progress report. The progress report will indicate the outcome of the most recent contacts sent to the Coordinating Center and the cumulative contacts to date. The reports will indicate the final results of the contacts, the progress of the PSG studies, and the distributions of the contacts, PSG completed, and the refusals by race, gender, and age. The number of expected participants to date will also be included.

This report will be completed on a weekly basis by the Coordinating Center and sent to the reporting site. On a monthly basis the same report will be generated for all SHHS recruitment sites to describe the study-wide recruitment progress.

EXAMPLE OF RECRUITMENT PROGRESS REPORT

Weekly Recruitment Progress Report:

for {Site name}

Current Reporting Period: 9/1/95 - 9/8/95

	<u>Current</u>		<u>Total to Date</u>
	<u>Number</u>	<u>Percent</u>	<u>Number</u> <u>Percent</u>
Contacts			
Refuse to participate in SHHS			
Agree to participate in SHHS			
- PSG completed			
- PSG pending			
Agree but PSG never done			
- PSG never scheduled			
- PSG scheduled but refused			
Unable to participate due to illness			
Cannot locate			
Participant deceased			
Expected recruitment			

Characteristics of participants:

Contacts
 (#, % white to nonwhite)
 (#, % male to female)
 (#, % age ≤ 64 to age 65+)

PSG completes
 (#, % white to nonwhite)
 (#, % male to female)
 (#, % age ≤ 64 to age 65+)

Refusals
 (#, % white to nonwhite)
 (#, % male to female)
 (#, % age ≤ 64 to age 65+)

4.3 Alternative Sites for PSG Studies

The intent of the SHHS is to collect data on participants in the home setting. However, it may occasionally become necessary to consider alternative sites for testing in order to not lose participants or to maximize the chances of obtaining usable data. Some examples of the problems in the usual home setting would include:

- unacceptable sleeping arrangements (many people/pets in bedroom)
- dangerous environment (for equipment or technician)
- tribal/cultural taboos against equipment in the bedroom
- strongly stated patient personal preference not to be monitored at home

The following is the policy for use of alternative sites:

It is strongly urged that in all cases maximum efforts be made to obtain a quality recording in the participant's bedroom at home. However, if this is not possible or if the participant is likely not to participate in the study if recording is done in the home, alternative sites may be considered. In descending order of priority, these could include:

- a friend or relative's house (e.g., for a single woman who wishes to be tested in the company of a friend)
- a hotel room
- a clinic
- a hospital/sleep lab bed (but with Compumedics setup) - e.g., in General Clinical Research Center

Rationale:

It is not clear that data recorded in the participant's bedroom is more definitive at establishing the presence of SRBD than data obtained in other settings. The critical element of the data collection is the presence of sleep, which will be documented by the EEG data. While the amount of sleep may differ in different settings (first-night effect), this is equally true in the home during PSG monitoring, and does not seem likely to change the categorization of SRBD when sleep is present.

It is estimated that in the Tucson and NY cohorts, less than 5% of participants would be monitored in such alternative locations, primarily to ensure participant participation.

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SLEEP HEART HEALTH STUDY MANUAL OF OPERATIONS

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CHAPTER 5 - HOME VISIT IMPLEMENTATION AND CONDUCT

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5.1 Overview

At the time of recruitment, a home visit is scheduled to conduct the sleep study. A few days prior to the home visit, the participant is contacted to confirm the visit date, time, place, and traveling directions, and to determine if any recent event, such as illness or a family emergency, has occurred which would impact their typical sleep pattern and, hence, require rescheduling of the PSG study. In addition, the participant's chart at the parent study clinic is reviewed to determine whether any A-variables have been collected within the acceptable time window, and packets are prepared for data collection labeled with appropriate ID numbers. The packet will include a token of appreciation to be given to the participant.

The home visit is the key data collection point. The majority of the baseline data will be collected at that time. The home visit is conducted by a team of two individuals (one sleep technician and one helper) who have been specifically trained and certified to set up the Compumedics sleep monitor, obtain the necessary vital measurements, to conduct Health and Medication interviews, and collect and review for completeness the other paper forms that are completed by the participant. The field team will be trained to be courteous, respecting the participant's home, family, and privacy, and to make their visit as unobtrusive as possible. They are also trained on how to deal with medical alerts and emergencies.

In the home, one member of the team will set up the Compumedics monitor, while the other begins the data collection process. The sleep monitor is battery operated so the participant is not potentially in connection with electrical outlets. Electrodes will be glued to the hair, face, and chest; a thermistor is attached above the lip to monitor respiration; and an oximeter will be attached to one finger. During the evening visit, the participant's blood pressure is taken, he/she is weighed, neck circumference obtained, and Health and Medication interviews are administered. In addition, a Morning Survey is left for the participant to complete in the morning after the monitoring is completed. At some Field Centers the self-administered SF-36 quality of life survey will also be left with the participant. This process should take approximately 1.5 to 2 hours.

The next morning a technician returns to the participant's home at a pre-arranged time to collect the sleep monitor and self-administered surveys. The technician thanks the participant for participating and indicates that a summary of the results of their sleep study will be sent to them in two weeks. This process will take approximately 10 to 15 minutes.

Upon returning to work, the sleep technicians log in all data collected and evaluate the overall completeness and quality of the sleep study. The PSG data are then sent to the Reading Center for processing and the paper forms submitted for local data entry. If the study was inadequate, a repeat study request is initiated.

A few days following the home visit, the study coordinator will personally call the participant to obtain feedback on how their home visit went and determine if there were any problems with the study personnel, paper form completion, or the sleep monitor. At centers where telephone calls are not feasible, an evaluation postcard will be left with the participant when the monitor is collected.

5.2 Preparation

5.2.1 Pre-visit confirmation call

Shortly before the scheduled PSG, a call is placed to the participant by one of the two technicians who will actually visit the participant. In addition to a reminder, this call will serve several purposes: the technicians can introduce themselves and thereby establish rapport and increase the participant's comfort level about the visit, ask needed directions, allow the participant to ask last-minute questions, and to make sure that the PSG should remain scheduled for that date.

During the phone call use the following instrument to screen for conditions which may warrant postponement of sleep study:

I. Introduction

Hello, I am a member of the Sleep Heart Health Study staff. I will be one of the two people helping set up the equipment for your home sleep study scheduled for _____. It is important for the purposes of our Study to measure your typical night's sleep. I would like to ask a few questions to learn if there is anything unusual that might disrupt your normal sleep pattern on the night of your sleep study?

II. Questions

1. Do you feel as well as usual, or have you been sick or injured?

If they have been sick or injured, "could you please describe the problem?"

2. Has anything unusual happened that may affect your sleep?

Yes____ No____

If yes, "could you please describe the problem?"

III. Guidelines for telephone interviewer

The purpose of this call is to assess if the volunteer is having any new problems which are severe enough to disrupt their usual sleep pattern on the night of the study. This will be done by asking the set of questions listed above. Again, we are looking for new or significantly worsened conditions rather than stable chronic problems. If a condition which fits these criteria is present, the sleep study will be postponed to a later date. The following is a partial list of conditions which could fit these criteria:

1. Respiratory illness
(cold, acute sinusitis or bronchitis, pneumonia)
2. Acute Systemic Illness
(febrile illness, viral syndrome)
3. Acute physical condition which is significantly altering usual sleep pattern.
(pain due to recent injury, worsening of pre-existing medical problem)
4. Psychological distress disrupting usual sleep
(extremely upset over recent loss)
5. New disruptions in sleep environment
(any noises, noxious stimuli, or night time responsibilities
which would preclude a usual night's sleep)
6. Time zone or sleep shift changes within three days of scheduled sleep study.

5.2.2 Prepare the Participant

Remind the participant to have showered within the last 24 hours, and to have shampooed, shaved, and refrained from using hairsprays, gels, mousse, and/or oils in the hair. (Explain that this is not an issue of cleanliness, but that the special procedures require the skin to be as free from oils as possible.) Ask participant to remove nail polish (to prevent interference with a finger probe used for detecting oxygen levels).

Ask the participant to be dressed in a t-shirt, tank top, or bed clothes (or a SHHS night shirt, if available). Find out what position the patient sleeps in to configure the vest properly (headbox placement).

Ask participant to gather all prescription medications taken in the 2 weeks prior to the home visit.

5.2.3 Packet of Data Collection Forms

Table 5.2.3.1 shows the forms to be completed, data to be collected, and the corresponding acceptable data collection "windows." Prior to the home visit all data collection forms should be assembled and labeled with the participant's ID number and Field Center ID number. The participant's chart should be pulled to check if any of the data to be collected at the home visit have already been ascertained within the data collection "window" allowed for that variable. Such data would include weight, smoking, alcohol, etc. Record the information that falls within the acceptable window on the form and check the box indicating that the data are from a clinic visit. Record the date of the clinic visit as well.

Table 5.2.3.1 Data Collected at Home Visit

Content	Data Collection Window
1. Informed Consent	If not previously obtained
2. Blood pressure	Night of home visit
3. Weight	1 month
4. Neck circumference	Night of home visit
5. Health Interview (interviewer-administered)	
a. History of heart disease: Angina, myocardial infarction, stroke, heart failure	3 months
b. History of hypertension	3 years
c. History of diabetes	3 years
d. History of heart or cardiac surgery, or the insertion of a pacemaker	3 months
e. History of emphysema, chronic bronchitis, chronic obstructive pulmonary disease, or asthma	No window
f. Current respiratory problems: coughs, chest congestion, runny or stuffy nose, sinus problems	3 months
g. Typical amount of caffeine consumed (coffee, tea, colas)	3 months
h. Years of education	No window
i. Cigarette smoking history and current habits	3 months
j. Typical alcoholic beverage consumption	3 years
6. Medications taken in the past two weeks	Night of home visit
7. Morning Survey (self-administered)	
a. Medications taken in the four hours prior to bedtime or during the night	Morning - immediately following PSG study
b. Assessment of previous night's sleep	Morning - immediately following PSG study
c. Caffeine, alcohol, and tobacco use in the four hours prior to bedtime	Morning - immediately following PSG study
8. Quality of Life survey (self-administered)	Night of home visit if not previously completed

5.2.4 Equipment Check

Check that all equipment and supplies are available, clean and in working order (e.g., wires intact). **Perform “15 Minute QA Check”** (see below). Replace any defective parts with parts supplied by or approved by Compumedics. (See Reference Section in the PSG Training Manual for details regarding equipment configuration.) The Compumedics System and its accessories should not be modified.

You should have the following equipment and accessories:

1. Equipment carrying case
2. Recorder with **fully charged** battery (>7V)
3. PCMCIA card
4. Communication cable to connect headbox to recorder
5. Patient sleep vest with attached headbox and sensors:
 - Head box
 - (2) non-disposable electrode leads and snaps
 - (10) gold cup electrodes with attached lead wires
 - (2) thoracic/abdominal belts
 - (1) thermocouple cable and disposable thermocouple
 - (1) body position sensor
 - (1) mic/snoring sensor
6. Oximeter cable/disposable oximeter

Try to have back-up supplies, including spare electrodes and cables, disposable oximeters and thermocouples, and an extra battery.

Each monitor and headbox has been assigned a two digit ID. Check that monitor ID labels affixed directly to the monitor match labels affixed to the monitor's leather casing (the latter will be the only one visible when you check the initialization of your card.)

NOTE: Once a PIB has been configured correctly, there will not be a need to change electrodes or respiratory bands between participants **unless a problem with electrode impedances or adjusting OFFSETS are noted**. Repeated attaching/detaching electrodes and bands is discouraged to minimize trauma to the PIB.

5.2.4.1 QA Equipment Check (To be performed prior to every study)**Suggest copying this form and maintenance of a log of all QA checks.****SHHS Technician 15-minute QA Procedure: Pre-study****The following procedure should be completed successfully before every study**

NOTE: Before using any monitor, check that previous study yielded good quality data on all channels. If not, check with your local PSG Resource person and/or the Reading Center to determine whether the monitor needs to be repaired, electrodes replaced, etc., before it is used again.

- 1. Ensure sensors, leads, vest, and leather case are clean, tidy and in good condition.
Leads should be free of tape adhesive.
Gold cup electrodes should be free of gel/paste/tape, a shiny gold color, and not distorted.
Re-usable oximeter probe should be free of dirt and adhesive.
Vest should be washed in warm soapy water or dry-cleaned. Foam padding & extension straps included.
Leather case should be wiped with a damp cloth.
- 2. Ensure that all electrode wires and connecting cables are securely attached to PIB.
(Check by tugging firmly.) Pack an extra set of all leads, thermistry cable/probes, oximeter.
- 3. 2 batteries fully charged (>7 V).
- 4. Insert one battery in monitor and keep second battery in briefcase as a backup.
- 5. Memory card set-up with correct montage (e.g. SHHS.MON), participant name, tech name, monitor ID, site ID.
- 6. Insert memory card into portable unit. Ensure button pops out and is flush with card and card protector.
- 7. Enclose portable unit within leather case. Check that the leather case is labeled with same ID as the monitor.
- 8. Connect headbox to main unit. Listen for double-click when connecting cable to headbox and main unit. Pull cable with moderate force to ensure it does not disconnect easily at both ends.
- 9. Connect oximeter probe to main unit. Pull firmly on cable and ensure it is secure.
- 10. Switch main unit ON, listen for "BEEP" and observe the 3 OKs:
A/D1.....OK A/D2.....OK Realtime Clock.....OK

Occasionally the realtime clock may say RESET, but this is not a problem. If any other message appears notify Compumedics and:

-
- turn OFF, replace battery with spare battery, and turn on again. If still a problem:
- turn OFF, remove memory card and turn ON again. If still a problem:
- contact Compumedics immediately.
- 11. With memory card inserted, check for the READY message.
- 12. Check for correct information on card (Main Menu, PATIENT....)
- 13. Time and Date correct
- 14. Automatic START and END times correct

- 15. Battery voltage of each battery indicate full charged: 8.0±I.0 Volts (Main Menu, OPTIONS...)
- 16. Settings correct (Main Menu, OPTIONS, SETTINGS...):

EMG NOTCH	60
OXIMETER ALARM	OFF
REMOTE	ON
AUTO RECORD	ON
- 17. Oximeter
 - red light shining brightly from probe, even when cable moved (as a patient would)
 - surface of probe clean
- 18. Check Offset of Thorax and Abdomen

(Adjusting offset for the respiratory bands may be more difficult than for the other channels, and therefore, it is suggested that this be done BEFORE and at the time of hook-up; adjustment at hook-up will be sufficient for the other channels.)

- a. Select OPTIONS from the MAIN MENU
- b. Select ADJUST OFFSET
- c. Use NEXT until THORAX (or ABDOMEN) is displayed
- d. Press OFFSET button
- e. Press Next to go to Abdomen (or Thorax)

You should see a flat line, centered in the electronic display. If the channel remains off-center, detach the thorax (or abdomen) cable from the PIB and repeat the procedure (this allows the unit to “discharge” more freely). Then reattach the cables and confirm the line is centered. If it remains a problem, contact the Reading Center.

- 19. Calibrate Position and Light Sensors.

These channels are most accurately calibrated in the home**, with the PIB in place on the subject (in vest). However, because of difficulties moving the participant in different positions, or in adjusting the lights in the participant’s home, the following may be done beforehand:

- a. Lights

Find a room near your clinic/lab with light conditions most similar to that found in a typical bedroom (no fluorescent lights, medium brightness, windows in room). Try to do calibration in the late evening, if possible (after sunset).

- i. Move the UP button to CALIBRATION
- ii. Press LIGHT
- iii. Click OK
- iv. Use the down pointer to LIGHTS ON
With lights on, press OK
- v. Turn off lights. Click OK for LIGHTS OFF
- vi. Click DONE

- b. Position

You may place the PIB in your palm, trying to approximate the plane that the PIB will lie on a participant. Remember that most people lie on one or more pillows, and that the PIB will not lie parallel to the floor in heavier people and in women.

- i. Move the UP button to POSITION and hit OK
- ii. Move the cursor to FRONT
- iii. Turn/rotate PIB to be in the position that it would be in with the participant lying on his/her stomach
- iv. Hit OK -- note the number in the upper right corner
- v. Wait 10 seconds and hit OK again. Compare the number in the upper right corner to the previous number.
- vi. Repeat until the numbers are consistent.
- vii. Hit CAL
- viii. Repeat for all other positions (BACK, R SIDE, L SIDE)

**Note: This procedure may be modified with further software modifications by Compumedics.

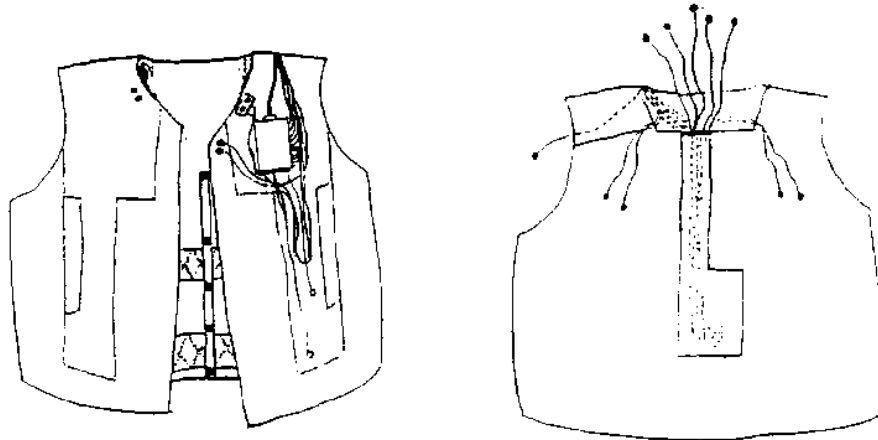
_____ (initials/date)

_____ (monitor ID)

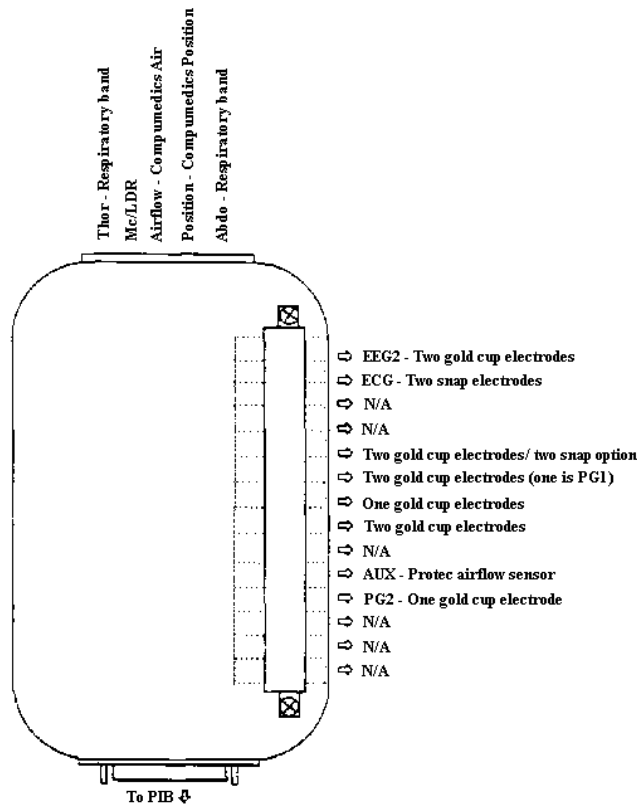
5.2.5 Vest Preparation

(If using the Prototype Vest--longer version, if using Bib design, skip this section)

1. Place the headbox in the flap on the upper back of the vest, or in the right or left front flap.
2. Ascertain that all leads are connected to the headbox in the order described below.
3. Run the EMG and EOG leads down the back and then back up to the neck, leaving enough slack to reach around to the front of the patient's head.
4. Run C3 and A1 wires over the left shoulder.
5. Run C4 and A2 wires over the right shoulder.
6. Run the ECG leads over the left shoulder and down to the opening in the middle of the front left side.
7. Run the airflow lead over the right shoulder and down to the opening in the middle of the front right side.
8. Place the effort belts in the slots inside the vest, and run their leads up the left side of the vest, over the shoulder and into the headbox.
9. Attach thermistor to cable.



The Diagram below shows the complete headbox configuration:



Use small pieces of color coded tape, or marker, to label each electrode wire at several points, visible to you during electrode placement. Be sure to use consistent labels to mark electrode wires as “negative” or “positive”.

TIP: You may want to separately gather all right sided electrodes (C4, A2, R EOG) and all left sided electrodes (C3, A1, L EOG) and secure them through a styrofoam cup that has had a hole punched into its bottom. This may prevent tangling, and help with easier identification during placement.

5.2.6 Supplies

Once the sleep vest and the sensors are neatly in place, make sure all your supplies are ready to use.

Below is a list of supplies for single person use (however, make sure you pack extras):

- 1 tube of Elefix EEG paste
- 1 tube EC-2 paste
- 4 X 4 gauze pads
- 1 tape measure
- precut 1 x 1 gauze squares
- 1 scissors
- Alcohol swabs or Electrode Prep pads
- 1 small bottle acetone or acetone prep pads
- 2 cotton tip applicators
- 1 roll Transpore tape
- 1 roll Hypafix or Medipore tape (cut into 1x1 squares)
- 2 hair pins
- 1 bottle Omniprep or NuPrep
- 2 disposable snap ECG pads (Medtronics Cleartrace)
- 1 wax pencil (Do not use red, if possible)
- 1 disposable oximeter (attached to cable connected to recorder)
- 1 disposable thermistor (attached to cable in vest)
- (2) towels
- 1 tray
- soap solution
- small cup
- latex gloves
- head nets
- drinking straws
- plastic bag (collect trash)
- face mirror

5.2.7 Prepare the PCMCIA Flash (Memory) Card

Before leaving for the home visit, you must prepare the PCMCIA Card that will store the sleep data that will be collected. This is called the initialization procedure.

1. Insert flashcard into PCMCIA slot in computer
2. Begin Portable Manager program (at C:> prompt type "portable")
3. Press F2 (or click on it) to Setup Card
4. Dialog box will appear. Type the following information, clicking "OK" after each correct entry, or "Cancel" after an error
 - Type **participant ID**
 - Type **technician ID**
 - Type **monitor ID** (enter four digit ID, the first 2 digits consisting of the monitor ID, and the second 2 digits consisting of the PIB ID)
 - Type **Site ID**
5. Press "Enter" to accept the setup
6. Select F3 for Montage Manager (or click on it)

7. Be sure SHHS.MON shows as the selected montage file. The SHHS.MON must have the following settings. Pay special attention to Channels 12 and 17, which should both be set at Sample Rate 10, and OX Status which should be set at 1.

SAMPLING RATES SHOULD MATCH THE FOLLOWING TABLE:

Channel	Label	Sampling Rate	Sensitivity
1	SaO ₂	1	
2	H.R.	1	
3	EEG2	125	250uV
4	ECG	125	2.5mV
5	LEG/L	-	2.5mV
6	LEG/R	-	2.5mV
7	EMG	125	62.5uV
8	EOG/L	50	250 uV
9	EOG/R	50	250 uV
10	EEG	125	250 uV
11	SOUND	10 (optional)	x1
12	OLDAIR	10	x1
13	THOR	10	x1
14	ABDO	10	x1
15	POSITION	1	
16	LIGHT	1	
17	AUX/AIRFLOW/NEW	10	250 uV
18	CPAP	-	
19	OX STATUS	1	

If you need to change the SHHS.MON settings:

While in Montage Manager:

- Select File from the menu bar and choose Open.
- Click on the symbol and select the SHHS.MON file.
- Click on the field you wish to change. A dialog box will appear with options for the settings. Select the appropriate setting. Note: In order to change the OX status you must press the <enter> key to toggle between options.
- From the File option on the menu bar choose Save.
- Enter the name of the file "SHHS" click OK.
- From the File option on the menu bar choose Exit.

** If for some reason a channel is missing from the layout, select Polygraph from the menu bar, click add, and then click OK. Configure the new channel as needed.

(See Reference Section in PSG Training Manual for additional instructions on Montage Changes and Polygraph Configuration.)

8. Remove flashcard and insert it into the recorder.

[**WARNING:** The memory card can only be inserted in one direction. It should slide into the slot easily. Insert carefully; never force in. This may damage the card and the recorder. The eject button will pop if inserted incorrectly.]

5.2.8 Battery Charging and Care

1. Charging
 - a. Be sure that the battery charger is plugged in. When you first plug it in, both lights will flash simultaneously as the charger performs a self-test.
 - b. Insert the battery into the charger gently, with the main label facing the LEDs on the charger.
 - c. The yellow light will come on, indicating that the battery is charging. About three hours is the normal charging time, much less can be expected for an already charged/partially charged battery. Be sure that each has been charged for at least three hours, and has a minimum voltage of 7V.
 - d. When the battery is fully charged, the green light will come on. The battery should be left in the charger until it is needed.

*Note: If both LEDs remain lit upon powering up the charger, disconnect power and reconnect. If both LEDs continue to remain lit, the charger is defective and should be returned/replaced.

2. Care
 - a. The battery can leak or explode if exposed to flames or extremely high temperatures. The battery should never be left in direct sunlight in a car or other vehicle.
 - b. A battery loses its charge at colder temperatures (<40° F). Always store or transport at temperatures above 40° F.
 - c. Do not drop, crush, or pierce the battery. Never try to open or otherwise tamper with the battery casing.

5.3 The Home Visit

Upon arrival at the participant's home, identify yourself and show identification. Be professional and courteous to your participant at all times. Help the participant feel at ease and comfortable. Explain all procedures before and as you do them.

Listed below are some features that will assure a successful visit.

1. Be courteous, professional, have ID
2. Be sensitive to participant's needs
3. Ask participant what location would be best to "set up" equipment (usually kitchen)
4. Provide overview of the purpose of the Sleep Study
5. Be patient/be interested
6. Make sure he/she understands all aspects of study; have participant demonstrate or repeat critical areas
7. Provide participant with telephone number to call for "help"
8. Schedule morning pick-up according to participant's needs
9. Keep a positive attitude

Sequence of events at the home visit:

1. Explain the purpose of the study
2. Obtain informed consent, if not already obtained
3. Measure blood pressure
4. Weigh the participant
5. Measure neck circumference
6. Conduct health interview
7. Gather medications, complete medication form
8. Distribute and explain self-administered questionnaires (morning survey and quality of life survey)
9. Attach sensors and vest
10. Check impedances and signal quality
11. Confirm that the participant knows how to make any needed connections and move about with the equipment
12. Make arrangements for answering questions; provide with telephone number
13. Schedule a time for morning visit which is convenient for the participant
14. Inform participant of exactly who will be picking things up in the morning.
15. Clean up, taking rubbish with you.
16. Thank participant.

Details of procedures are contained in Chapter 6, Home Visit Data Collection.

5.4 Morning Visit

Be prompt and courteous. Many participants have busy schedules and will become distressed if you are delayed. They have the option of removing the equipment prior to technician's arrival.

At the morning visit:

1. Inquire about any problems
2. Remove electrodes from participant.
3. Pack up all equipment; disconnect wires at clinic or office.
4. Collect the morning survey
5. Provide letter to participant detailing when results will be sent to them.
6. Clean up
7. Thank them for their time and participation.
8. Indicate to participant, study coordinator will make a follow up telephone call inquiring about the visit or leave feedback postcard (see Section 5.5).

5.5 Follow-up with Participants

After the home visit, feedback will be obtained from the participant. The purpose of obtaining this feedback is to identify any problems with the study personnel, paper form completion, or the sleep monitor equipment. Some Field Centers will be using a postcard to obtain feedback and others will have the study coordinator personally call the participant within a week of the home visit. All comments will be recorded and acted upon.

5.6 Summary Report to the Participants

Within 10 days of the sleep study, a report summarizing the findings of the study will be generated by the Reading Center and sent to the Field Center for distribution.

If the Reading Center identifies an "urgent" referral (see Section 6.10), the Field Center is contacted. The Field Center sends out referral letter and sleep study results to the participant and their physician (if participant requests it).

If the PSG data is insufficient or of poor quality, a "repeat study" request will be initiated. See Section 7.3.



SLEEP HEART HEALTH STUDY MANUAL OF OPERATIONS

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6.1 Overview

The home visit is the major source of data collection for SHHS. There are several data collection activities that occur during this visit. The PSG technician will be involved in all these activities, either directly or indirectly.

The night of the PSG study the technician(s) will:

1. Obtain informed consent (if necessary).
2. Measure and records blood pressure
3. Measure weight (if necessary)
4. Measure neck circumference
5. Complete Adverse Events Form
6. Conduct "Health Interview" to collect comparability data items.
7. Collect "Medication Inventory" by administering CHS medication program
8. Leave "Morning Survey"
9. Leave "Quality of Life Survey" to be self-administered (if necessary)
10. Set up PSG monitor
11. Collect all data forms that have been administered and check for completeness.

The morning after the PSG study a technician will:

1. Pick up PSG monitor
2. Pick up "Morning Survey" and "Quality of Life Survey"
3. Check for completeness of surveys.

Step-by-step instructions for each procedure and data collection forms are described in this chapter. These instructions should be rigorously adhered to.

6.2 Seated Blood Pressure

6.2.1 Overview

6.2.1.1 Background and Purpose

Level of blood pressure is subject to biologic and observer variations, the latter being due to errors in measurement. The purpose of a specific protocol for the measurement of BP and a stringent certification procedure for technicians who measure BP in SHHS is to minimize error in measurement.

6.2.1.2 Definitions and Alerts

The seated BP reading for a SHHS participant is the average of the second and third systolic and diastolic BP's, calculated by computer at the Coordinating Center. When either blood pressure reading is elevated, it will trigger an "alert" and subsequent participant/ physician notification.

For SHHS, the alert levels used by the parent study are to be implemented by SHHS personnel as well. If the parent study does not have formal alert levels, the following levels are to be used:

Alert levels requiring IMMEDIATE referral are:

Diastolic BP > 120
Systolic BP > 200

Alert levels requiring URGENT referral within the week are:

Diastolic BP > 100
Systolic BP > 170

The presence or absence of a medical alert should be indicated on the Signal Verification Form (see Section 6.9). The Adverse Events Form is used to document the details of the medical alert (see Section 6.10).

6.2.1.3 Blood Pressure Measurement

Blood pressure measurements are taken using a conventional mercury sphygmomanometer. The design and operation of the conventional mercury sphygmomanometer are based upon the combined principles of compression of the brachial artery under an elastic, inflatable cuff, and direct registration of pressure levels by a mercury manometer. The observer inflates the cuff, listens for the first (systolic) and the last (diastolic) Korotkoff sounds, reads the mercury level in the column, deflates the cuff, and records the readings.

Once the cuff and device are connected as required for determination of the maximal inflation level, the steps in measurement with the conventional device are as follows:

- If a blood pressure measurement has been taken, wait at least 30 seconds after complete deflation of the cuff. (It is not necessary to wait 30 seconds after determination of the maximal inflation level.)
 - Ask the participant to hold his/her arm as close to vertical as possible for a full 5 seconds. Examiner may assist if needed.
 - Wait at least 25 seconds before proceeding with any additional reading.
- Place the earpieces of the stethoscope, with the tips turned forward, into the ears.
- Apply the bell of the stethoscope over the brachial artery with light pressure, insuring skin contact at all points. Bell should be placed just below but not touching the cuff or tubing. The brachial artery is usually found at the crease of the arm, slightly toward the body.

- Close the thumb valve and squeezing the bulb to inflate the cuff at a rapid but smooth, continuous rate to the maximal inflation level

NOTE: The eyes of the technician should be level with the mid-range of the manometer scale and focused at the level to which the pressure will be raised.

- Open the thumb valve slightly and maintain a constant rate of deflation at approximately 2 mm per second to allow the cuff to deflate, listening throughout the entire range of deflation from the maximum pressure past the systolic reading (the pressure where the first regular sound is heard) to 10 mm Hg below the level of the diastolic reading (that is, 10 mm Hg below the level where the last regular sound is heard). NOTE: Phase V diastolic BP is that point at which the last sound is heard. At least two beats must be heard to record Phase I systolic BP.
- Deflate the cuff fully by opening the thumb valve, and disconnect the tubing from the cuff. Remove stethoscope earpieces from the ears and enter the systolic and diastolic readings in the spaces provided on the form.
- Remove the cuff and store the equipment safely after the last reading.

Criteria for Systolic and Diastolic Blood Pressure

To correctly identify the 1st-phase (systolic) and 5th-phase (diastolic) Korotkoff values, listen carefully via the stethoscope while reading and interpreting the mercury column.

- The systolic value is the pressure level where the first of two or more sounds are heard in appropriate rhythm.
- The diastolic value can be identified as the pressure level where the last of these rhythmic sounds is heard.
- The mercury should be made to drop at 2 mm Hg per second, from the maximum pressure until 10 mm Hg below that of the last regular sound heard. The control of the deflation rate is essential for accurate readings and depends on handling of the bulb and its control valve.

NOTE: A single sound heard in isolation (i.e., not in rhythmic sequence) before the first of the rhythmic sounds (systolic) or following the last of the rhythmic sounds (diastolic) does not alter the interpretation of the blood pressure.

Equipment

- Two or more conventional mercury sphygmomanometers
- Two standard stethoscope tubings and earpieces (suggest Litman) with bell, with tubing to be a **maximum** of 14 inches long
 - One double headed stethoscope
 - BP cuffs in four sizes:
 - 2 large adult cuffs
 - 1 thigh cuff
 - 1 pediatric cuff
 - 2 regular adult cuffs
- Hand towel

6.2.2 Methods

Blood pressure measurements are done prior to the hookup of the sleep monitoring equipment. Following this procedure will provide data comparable to that collected in other studies.

Measurements are recorded on the form which also contains weight and neck circumference.

Blood pressure is usually measured on the right arm. Exceptions are those who have been taking shots, had a mastectomy, or some other condition that precludes using the right side.

Please indicate in the comment field if the blood pressure was measured on the left arm instead of the right (and the reason), or if the participant had been engaging in an activity that could affect his/her blood pressure (e.g., smoking, drinking coffee).

6.2.2.1 Cuff Size

Proper cuff size must be used to avoid under-or-over-estimation of the correct blood pressure. Cuff size is the size of the cuff's bladder, not the cloth. A copy of the chart below should be attached to the sphygmomanometer for easy reference.

Use the instructions below to measure the arm and determine the appropriate cuff size.

The directions for the Arm Measurement Procedure are as follows:

- Ask participant to bare the upper arm.
- Instruct participant to stand holding forearm horizontal to the floor.
- Measure arm length from the acromion (bony extremity of the shoulder girdle) to the olecranon (tip of the elbow), using a metric tape.
- Mark the midpoint on the dorsal surface of the arm.

- Tell participant to relax arm along side of the body.
- Draw the tape snugly around the arm at the midpoint mark.

NOTE: Keep the tape horizontal. Tape should not indent the skin.

- Use the criteria below for determining cuff size. Round up to nearest cm. (Do not use the markings on the blood pressure cuff for reference, as these do not match the protocol given below.)
- CUFF SIZE INDICATED BY MEASURED ARM CIRCUMFERENCE

<u>ARM CIRCUMFERENCE (cm)</u>	<u>CUFF'S BLADDER SIZE (cm)*</u>
Up to 5.9	2.5 ("newborn")
6.0 to 15.9	6.5 ("infant")
16.0 to 22.5	9.0 ("pediatric")
22.6 to 30.0	12.0 ("regular adult")
30.1 to 37.5	15.0 ("large adult")
37.6 to 43.7	17.5 ("thigh")

- * Bladder widths shown are at least 40% of the largest corresponding arm circumferences.
- Record the cuff size used on the form.

6.2.2.2 Application of Blood Pressure Cuff

- Place the appropriate cuff around the upper right arm so that:
 - The midpoint of the length of the bladder lies over the brachial artery, and
 - The mid-height of the cuff is at heart level.

If a thigh size cuff is required by measurement, but the participant is short, use the thigh size and touch the cuff with the bell.

- Place the lower edge of the cuff, with its tubing connections, about 1 inch above the natural crease across the inner aspect of the elbow.
- Wrap the cuff snugly about the arm, with the palm of the participant's hand turned upward.
- Secure the wrapped cuff firmly by applying pressure to the locking fabric fastener over the area where it is applied to the cuff.
- Do not wrap the cuff too tightly around the arm. Observer should be able to insert the first joint of two fingers under the cuff. The cuff should be snug but not tight.

6.2.2.3 Rest Period

The participant should be allowed to rest for a full five minutes prior to measuring his/her blood pressure. Instruct the participant on correct posture, with his/her back supported, both feet flat on the floor and arm resting on the table. The participant should also be instructed not to talk until after the BP measurements are completed. The work station should be free of excessive noise.

6.2.2.4 Determining the Maximal Inflation Level

For each participant determine the maximal inflation level, the pressure to which the cuff is to be inflated for systolic blood pressure measurement. This assures that the cuff pressure at the start of the reading exceeds the systolic blood pressure and thus allows the first Korotkoff sound to be heard. The sphygmomanometer should be at eye level of technician.

The procedures for determining Maximal Inflation Level are as follows:

- Attach the cuff tubing to the conventional mercury sphygmomanometer.
- Palpate the radial pulse.
- Inflate the cuff until the radial pulse is no longer felt (palpated systolic) by inflating rapidly to 70 mm Hg, then inflating by 10 mm Hg increments.
- Deflate the cuff quickly and completely.
- Inflate the cuff to 30 mm Hg above the palpated systolic pressure for all readings.

6.2.2.5 Guidelines for Blood Pressure Readings

- All readings are made to the nearest even digit, rounding up.
- Any reading which appears to fall exactly between markings on the mercury column should be read to the next higher marking i.e., 2, 4, 6, 8 or 0.
- All readings are made at the top of the meniscus, or rounded surface of the mercury column.
- When the pressure is released quickly from a high level, a vacuum is formed above the mercury and the meniscus is distorted. Allow a few moments for it to reappear before reading the manometer.
- If sounds are heard immediately after the cuff is inflated, start the procedure over, including the 30 second rest period (5 seconds vertical.)
- Keep stethoscope in ears during the entire time the three readings are being taken.

6.2.2.6 Blood Pressure Measurement - First Reading

Detailed instructions are given below for measuring blood pressure with a conventional sphygmomanometer.

- Connect the cuff to the sphygmomanometer.
- If a blood pressure measurement has been taken, wait at least 30 seconds after complete deflation of the cuff. (It is not necessary to wait 30 seconds after determination of the maximal inflation level.)
 - Ask the participant to hold his/her arm as close to vertical as possible for a full 5 seconds. Examiner may assist if needed.
 - Wait at least 25 seconds before proceeding with any additional reading.
- Place the earpieces of the stethoscope, with the tips turned forward, into the ears.
- Apply the bell of the stethoscope over the brachial artery, just below but not touching the cuff or tubing. The brachial artery is usually found at the crease of the arm, slightly toward the body.
- Inflate cuff to the previously determined maximal inflation level.
- Deflate the cuff at 2 mm HG per second by carefully controlling the thumb valve, until the mercury level is 10 mm below the diastolic reading (that is, 10 mm below the level where the last regular sound was heard).
- Open the thumb valve fully and disconnect the tubing from the cuff, allowing the mercury to fall rapidly to the zero level.
- Record this reading on the form. (It will not be included in the official study average blood pressure values.)

6.2.2.7 Second and Third Readings

- Ask the participant to hold his/her arm as close to vertical as possible for a full 5 seconds. Examiner may assist if needed.
- Wait at least 25 seconds before proceeding with second readings.
- For the second reading, repeat the steps shown above for the first readings. Record the systolic and diastolic readings on the paper form.
- Repeat all of the steps again for the third reading. Record the systolic and diastolic readings on the paper form.
- The official SHHS blood pressure is calculated from the average of the second and third readings.
- Inform participant of the average readings.

6.2.3 References

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2. Working Group on Hypertension in the Elderly, Statement on Hypertension in the Elderly. JAMA, 1986, 256, No. 1, pp. 70-74.
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6. Atherosclerosis Risk in Communities Study (ARIC) Protocol, Manual 2: Cohort Component Procedures, Version 2.0 1/88. ARIC Coordinating Center, Suite 203 NCNC Plaza, 137 E. Franklin St, Chapel Hill, NC 27514.

Seated Blood Pressure – Weight – Neck Circumference form (12/6/95)

One page inserted after this page.



SLEEP HEART HEALTH STUDY

**SEATED BLOOD PRESSURE
WEIGHT
NECK CIRCUMFERENCE**

ID#:

Field Center: ____ ____

PART I: BLOOD PRESSURE

Cuff Size:

regular 1 pediatric 3
large arm 2 thigh 4

Arm Circumference	Cuff Size
16.0 - 22.5 cm	Pediatric
22.6 - 30.0 cm	Regular (adult)
30.1 - 37.5 cm	Large arm
37.6 - 43.7 cm	Thigh

Pulse Obliteration Pressure

Palpated Systolic: ____ ____ ____

Add 30: + 3 0

Max inflation level: ____ ____ ____
(palpated + 30)

Seated Blood Pressure:

	systolic	diastolic
First reading:	_____	_____
Second reading:	_____	_____
Third reading:	_____	_____

PART II: WEIGHT (1 month)

Weight:

____ ____ ____ . ____ (kg)

₁ Measured tonight

₂ Measured at clinic

Date: ____ / ____ / ____

PART III: Neck Circumference

Neck circumference:

____ ____ ____ . ____ (cm)

Technician ID: ____ ____ ____

Date: ____ / ____ / ____
 month day year

COMMENT: _____

6.3 Weight Measurement

6.3.1 Background and Purpose

Obesity is the strongest known risk factor for obstructive sleep apnea (OSA). In clinic samples, approximately two-thirds of patients with OSA have a BMI > 28 kg/m²¹. In more general samples, obesity increases risk of OSA 8-10 fold². Obesity is also a strong risk factor for hypertension. In fact, much of the controversy concerning a potential causal relationship between OSA and hypertension relates to concerns about confounding with obesity. Thus, measurement of weight will be important for providing data on a key confounder in the relationship between CVD and OSA.

6.3.2 Equipment

- SECA Integra 815 digital scale (other scales are acceptable. See Section 6.3.3)
- A piece of plexiglass

6.3.3 Methods

Record measurement on the Blood Pressure, Weight, and Neck Circumference form. Indicate whether measurement was obtained the night of the home visit or at the clinic. If measured at the clinic, indicate date of measurement.

Any scales may be used but must be calibrated according to quality control specifications. The following guidelines are to be used when weighing the participant using the SECA Integra 815 digital scale:

- Check the scale prior to the visit to verify that the batteries are operational. If necessary, remove the digital display head from the base to open the battery compartment underneath, and replace with a new standard 9 volt alkaline battery. After connecting the battery terminals, insert the battery and close the cover. Replace the head on the base of the scale.
- In the home, place the scale on a hard floor surface rather than on a carpet. If not available, use plexiglass sheet under scale.
- The participant should be wearing lightweight sleeping attire. Remove slippers, robe, or other heavy clothing prior to the weighing.
- Weigh the participant before any of the sleep equipment has been connected to him/her.

To weigh the participant:

- Select “kgs” measurement using the switch on the underside of the digital display.
- Switch on the scale by pressing the ON button. The number 888.8 will appear on the digital display.
- The participant may step onto the scale as soon as the number 0.0 appears on the display.
- Wait about four seconds for the numbers to stabilize. Record the weight viewed on the digital display onto the Blood Pressure, Weight, and Neck Circumference form. This scale is accurate to 0.5 kilograms over the entire weighing range.
- If two values are displayed alternately in the 0.5 kilogram range, then the exact weight is between these values. Round to the nearest whole number. If the scale shows “0.5,” round up.
- The scale switches off automatically after 30 seconds.

Problems:

- If no weight display appears under the load: Remove the person from the scale, press the ON button, and wait for the display to read 0.0.
- If “----” appears in the display: Press the ON button and wait for the display to read 0.0.
- If “ERR” appears on the display: Remove the person from the scale, press the ON button, and wait for the display to read 0.0.
- If “BAT” appears on the display: Change the battery.

6.3.4 References

1. Guilleminault C, Dement WC. Sleep apnea syndromes and related disorders. Williams RL, Katanan I, eds. Sleep Disorders: Diagnosis and Treatment. New York: Wiley; 1978.
2. Redline S, Kump K, Tishler PV, Browner I, Ferrette V. Gender differences in sleep disordered breathing in a community-based sample. Am J Respir Crit Care Med 1994; 149:722-726.

6.4 Neck Circumference

6.4.1 Background and Purpose

Recent data suggest neck circumference, as a measure of central obesity, is better correlated with obstructive sleep apnea (OSA) than is BMI¹. In particular, among subjects with a BMI < 28 kg/m², an increased neck size may identify those with OSA². An increased neck size, as a marker for upper airway compromise, may be a direct risk factor for OSA. As an indicator for hyperlipidemia, an increased neck size may be a marker for altered lipid/glucose metabolism, and thus be another confounder in the relationship between OSA and CVD.

6.4.2 Equipment

Use narrow tape measure from sleep kit.

6.4.3 Definitions

Frankfort Horizontal Plane - head parallel to the floor looking straight ahead

Laryngeal prominence - also known as the Adam's apple, located in the throat.

6.4.4 Method

The method of Lohman, Roche and Martorell³ will be used to measure the circumference of the neck.

Record measurement on same form with blood pressure.

Measure the neck as follows:

1. Participant sits upright with the head in the Frankfort Horizontal Plane.
2. An inelastic tape is applied around the neck just below the laryngeal prominence.
3. The measurement is made perpendicular to the long axis of the neck (which is not necessarily in the horizontal plane).
4. The pressure on the tape should be the minimum required to maintain skin contact.
5. The measurement should be completed in less than 5 seconds, to avoid participant discomfort.
6. The circumference of the neck is measured to the nearest 1/2 cm, rounded up.

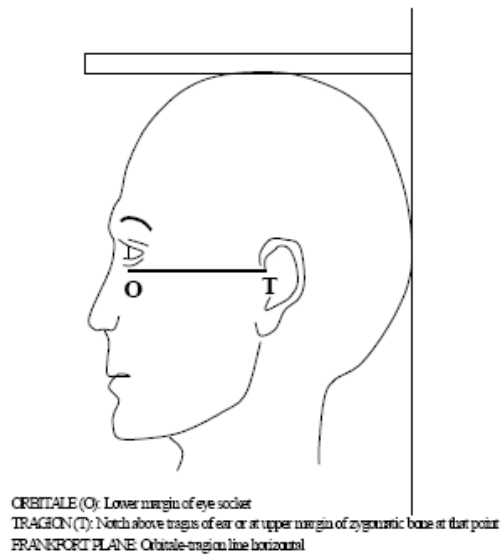


Illustration of The Frankfort Plane

6.4.5 References

1. Stradling JR, Crosby JH. Predictors and prevalence of obstructive sleep apnea and snoring in 1001 middle-aged men. Thorax 1991; 46:85-90.
2. Carlson JT, Hedner JA, Ejnell H, Peterson LE. High prevalence of hypertension in sleep apnea patients independently of obesity. Am J Respir Crit Care Med 1994; 150:72-77.
3. Callaway CW, Chumlea WC, Bouchard C, et al. Circumferences. pp 41-42 in Lohman TG, Roche AF, Martorell R, eds, Anthropometric Standardization Reference Manual, Human Kinetics Books, Champaign, IL, 1988.

6.5. Health Interview

6.5.1 Introduction

The Health Interview is conducted to collect comparable data across cohorts on cardiovascular and respiratory history and other items to obtain needed data.

The interview is administered to the participant the evening of the Home Visit. The technician interviews the participant and completes the form. For questions with a list of choices to choose from, a special card with choices listed on it is shown to the participant.

There are three different versions of the Health Interview. The version that is used by your field center depends on the parent cohort to which it belongs. The three interviews are labeled as follows:

1. ARIC, CHS, Tucson/Strong Heart (Section 6.5.2)
2. Framingham (Section 6.5.3)
3. New York (Section 6.5.4)

See respective sections for interview and coding instructions. Forms follow the instructions.

6.5.2 Interview and Coding Instructions for ARIC, CHS, Tucson/SHS

The instructions that follow outline the permissible clarifications and coding instructions on a question by question basis. This protocol should be consistently adhered to. Any deviations from protocol should be referred to the study coordinator. Any proposed changes in protocol should be referred to the Operations Subcommittee.

6.5.2.1 Review for Completeness

Questionnaires that are interviewer administered should be checked for completeness and accuracy as the questionnaire is administered. If questions arise that are not covered here, make note on survey and review with the study coordinator.

6.5.2.2 General Instructions

1. Indicate responses clearly and neatly.
2. Complete paper form with black pen.
3. Using a red pen or pencil, make corrections on interview, "X-ing" out the discrepancy and writing next to it the corrected response. Stray marks on the forms should be scratched out using red as well.
4. Leading zeros are not required to fill in all fields of a variable.

5. Missing data.

a) By type of Administration

- i) On self-administered forms, data not completed by the participant will be left as blanks.
- ii) On interviewer-administered forms, all questions should be marked with a response except those that are SKIPPED as a result of a SKIP pattern. Items SKIPPED by a SKIP pattern should be left blank on the form.

b) Coding Specifications

The following guidelines specify how to deal with coding “don’t know” and “blank” data. However, there may be exceptions to these rules, so please consult the question-specific details provided for each form.

- i) If a participant explicitly responds “don’t know” to a question, the interviewer should fill the field with 8’s. For example: If someone can’t remember what year they stopped smoking, code the month as 88 and year as 8888.

Thus, 8’s imply that data are missing because the participant explicitly responded “Don’t Know” or “Unsure.”

- ii) If a participant refuses to answer or does not give a valid response, the interviewer should fill the field with 9’s. For example: If someone refuses to answer the questions regarding “alcohol” consumption, then code the data as 99.

If on a self-administered form the participant responds by writing in an involved response, this should be coded as 9’s. Some questions on self-administered forms purposely do not include a “Don’t Know” option. If the participant writes in “Don’t Know,” code as 9.

Thus, 9’s indicate that data are missing because of some kind of error in the response or a refusal.

6. If a range of values is given, take the midpoint. If data are collected only as integer values, then find the midpoint and round up to nearest integer. For example, 6-8 cups a day is 7 cups. The midpoint of the range 6-7 cups a day is 6.5 and should be rounded up to 7 cups as the final answer.
7. The year in a date is to be entered as a 2-digit number without the "19" prefix. Exception to this rule is when the response is "don't know" or question is left blank by the respondent and is not part of a SKIP pattern. Since 1988 and 1999 may be valid responses in this study, year will have to be filled with a 4-digit number, 8888 or 9999, respectively.
8. For questions where "hours" and "minutes" are to be specified, convert fractional hours to minutes. Both hours and minutes fields must be completed, even if the response is 0. For example, if a respondent indicates 3/4 of an hour, then neatly "X-out" in red the 3/4 and recode data to 0 "hours" and 45 "minutes."
9. By definition, midnight is 12:00 A.M.
10. Record your ID number at the appropriate spot on the interview form.

6.5.2.3 Question by Question Specifications

Pre-questionnaire Data

Affix a participant label at the top right of page 1 before going to the home. Write your 2-digit Field Center ID number in the indicated space.

PREVALENT DISEASE QUESTIONS

In the box provided indicate whether the data for questions 1 and 2 are being collected today at the home visit or were collected in the clinic within 3 months of the home visit date.

If data were collected in the clinic, provide the date of the clinic visit. Date is specified as month, day, year with each component a 2-digit field.

1. Has a doctor ever told you that you have or had the following?

Show the participant CARD A and read off each condition.

Clarification:

"Ever" refers to one or more times any time in the past, regardless of recency.

"Doctor" is a licensed M.D. or O.D.

The distinction here is whether a doctor has ever told them. The respondent's own personal opinion is not to be coded in this question.

Coding:

Permissible codes: 0, 1, 8

Each of the four items have the same set of permissible codes.

If respondent was told they had the condition by one doctor, but was negated by a second doctor, code as YES (code=1).

2. Have you ever had any of the following procedures?

Show the participant CARD B and read off each procedure.

Clarification:

“Ever” refers to one or more times any time in the past, regardless of recency.

Coding:

Permissible codes: 0, 1, 8

Each of the four items have the same code.

If a participant answers “YES” to “Other heart or cardiac surgery,” ask the participant what kind of surgery it was and record the response. There are 50 spaces allocated for the coding of this response.

3. Has a doctor ever told you that you have the following?

Inquire about each condition listed on the questionnaire.

Clarification:

“Ever” refers to one or more times any time in the past, regardless of recency.

“Doctor” is a licensed M.D. or O.D.

The distinction here is whether a doctor has ever told them. The respondent’s own personal opinion is not to be coded in this question.

Coding:

Permissible codes: 0, 1, 8

Each of the four items have the same set of permissible codes.

If respondent was told they had the condition by one doctor, but was negated by a second doctor, code as YES (code=1).

4. Have you had an attack of asthma at any time in the last 12 months?

Coding:

Permissible codes: 0, 1, 8

5. Do you cough on most days for as much as 3 months of the year?

Clarification:

The 3 months is a summary time period and does not have to be consecutive.

Coding:

Permissible codes: 0, 1, 8

6. Do you bring up phlegm from your chest on most days for as much as 3 months of the year?

Clarification:

The 3 months is a summary time period and does not have to be consecutive.

Coding:

Permissible codes: 0, 1, 8

7. Do you usually have a runny nose or stuffy nose?

Clarification:

This may occur during the day or in the evening or both.

Coding:

Permissible codes: 0, 1, 8

8. Do you usually have sinus trouble?

Clarification:

Sinus trouble is pain/swelling in the region of the upper face.

Coding:

Permissible codes: 0, 1, 8

SMOKING QUESTIONS

In the box provided indicate whether the data are being collected today at the home visit or were collected in the clinic within 3 months of the home visit date.

If data were collected in the clinic, provide the date of the clinic visit. Date is specified as month, day, year with each component a 2-digit field.

9. Have you ever smoked cigarettes? By “ever” we mean at least 20 packs in your lifetime.

This is a lead-in question to the smoking question section.

If the answer is YES, continue with question 10.

If the answer is NO, SKIP to question 11.

If the respondent smokes cigars or a pipe, code as NO and SKIP to question 11.

Coding:

Permissible codes: 0 or 1.

If respondent says “YES” (code=1), then question 10 should have an answer.

If respondent says “NO” (code=0), then question 10 should be SKIPPED. However, if question 10 has a valid response check with study coordinator to identify interviewer who may not be following the SKIP pattern.

10. Do you now smoke cigarettes?

Coding:

Permissible codes: 0, 1

If “YES” (code=1), then how many cigarettes per day do you now smoke?

Number per day is a 2-digit field.

Permissible range: 01 - 80.

If “NO” (code=0), when did you stop?

Code Month as a 2-digit code. Range 1-12.

Code Year as a 4-digit code. Range 00-99, 8888, 9999

CAFFEINE QUESTIONS

In the box provided indicate whether the data are being collected today at the home visit or were collected in the clinic within 3 months of the home visit date.

If data were collected in the clinic, provide the date of the clinic visit. Date is specified as month, day, year with each component a 2-digit field.

11. On a typical day,

How many cups of coffee (with caffeine, “regular”) do you drink?

Clarification:

This is caffeinated coffee. This includes drip and instant. One shot of espresso in a drink counts as 1 cup.

Coding:

Number of cups is a 2-digit field.

Permissible codes: 00-80

If respondent does not drink coffee, code as 00.

How many cups of tea (with caffeine, “regular”) do you drink?

Clarification:

Herbal tea does not contain caffeine. If participant is not sure whether the tea he/she drinks contains caffeine, have him/her check the container.

Some types of Snapple contain caffeine, some do not. If participant mentions drinking Snapple, clarify whether it is caffeinated or ask to see the container.

Coding:

Number of cups is a 2-digit field.

Permissible codes: 00-80

If respondent does not drink tea, code as 00.

How many glasses or cans of cola or other soda with caffeine do you drink?

Clarification:

Sodas containing caffeine are: Coke, Pepsi, RC Cola, Jolt, Mountain Dew, Dr. Pepper, Diet Coke, Diet Pepsi, etc.

Sodas that do not contain caffeine are: All “caffeine free” varieties, 7-up, Squirt, Sprite, Root beer, etc.

Coding:

Number of glasses/cans is a 2-digit field.
Permissible codes: 00-80

If respondent does not drink sodas, code as 00.

12. During the last two weeks, did you take any aspirin or aspirin-containing medicines such as Bufferin, Anacin, or Ascriptin?

Clarification:

Tylenol, Advil, Motrin, and Alleve do not contain aspirin.

Coding:

Permissible codes: 0, 1, 8

If "YES," then how many days during the last two weeks did you take this medicine?

Number of days is a 2-digit field.
Permissible range: 00-14, 99

If "NO," code number of days as 00.

If "UNSURE," code number of days as missing (99).

13. Do you take sleeping pills one or more times a week?

Clarification:

Include both prescription and over-the-counter sleeping pills?

Coding:

Permissible codes: 0, 1, 8

14. Did a doctor prescribe nitroglycerin for you in the last year?

Coding:

Permissible codes: 0, 1, 8

15. What time did you go to sleep last night?

Coding:

Hours and minutes are each 2-digit fields.
AM or PM designation needs to be indicated.
Hours permissible range: 1 to 12
Minutes permissible range: 0 to 59

Data for Questions 15 and 16 should be visually compared for consistency of times and AM/PM designations. Inconsistencies must be rectified at the time of the interview. It is possible that someone may actually sleep during the day so care must be taken when checking the consistency to get AM/PM designations correct.

NOTE: Midnight is 12:00 AM by definition. A major point where inconsistencies will occur is when the respondent misspecifies 12 midnight as PM instead of AM.

16. What time did you wake up today?

Coding:

Hours and minutes are each 2-digit fields.

AM or PM designation needs to be indicated.

Hours permissible range: 1 to 12

Minutes permissible range: 0 to 59

Again, data for Questions 15 and 16 should be visually compared for consistency of times and AM/PM designations. Inconsistencies must be rectified at the time of the interview. It is possible that someone may actually sleep during the day so care must be taken when checking the consistency to get AM/PM designations correct.

17. How long did you sleep last night?

Coding:

Code hours and minutes each as a 2-digit field.

Hours permissible range: 0-24.

Minutes permissible range: 00-59

If fraction of an hour is written in, convert to minutes.

If a range of hours is given, take the midpoint.

Minutes must be coded, even if only 00.

Example: range of 8 to 9 hours is coded as 8 hours and 30 minutes

range of 6 to 8 hours is coded as 7 hours and 00 minutes

18. How well did you sleep last night? Check one response.

Show respondent CARD D.

Coding:

Permissible codes: 1, 2, 3, 4, 5

If participant is unsure, ask him/her to estimate the closest response.

If he/she still does not answer, code as missing (9).

19. If you took any naps today, for how long did you sleep during the naps?

Coding:

Code hours and minutes each a 2-digit field.

Hours permissible range: 0-24.

Minutes permissible range: 00-59

If person did not take any naps, code both hours and minutes as 00.

If fraction of an hour is written in, convert to minutes.

If a range of hours is given, take the midpoint.

Minutes must be coded, even if only 00.

Example: range of 1 to 2 hours is coded as 1 hours and 30 minutes

Half an hour to an hour converts to 00 hours and 45 minutes

20. How stressful was your day today?

Read off the three choices but only check one response.

Coding:

Permissible codes: 1, 2, 3

Post-questionnaire data

Record in what language the questionnaire was administered. Permissible codes are: 1, 2, 3, 4, 5, 6.

Record interviewer ID number in the box at the bottom of the last page and the date of the interview. Date is coded as month, day, year with each component a 2-digit number.

*Health Interview – ARIC, CHS, Tucson/Strong Heart form (4/5/96)
Three pages inserted after this page.*



SLEEP HEART HEALTH STUDY

HEALTH INTERVIEW
ARIC, CHS, Tucson/Strong Heart

ID#:

Field Center: _____

Before we get started, I have a few questions to ask you. These are questions mostly about your health history.

**PREVALENT DISEASE QUESTIONS (1,2):
(3 MONTHS)**

1 Data collected today at home visit

2 Data collected in clinic:
Date: _____
 month day year

1 Has a doctor ever told you that you have or had the following? (Show Card A)

	YES	NO	UNSURE
angina	<input type="checkbox"/> 1	<input type="checkbox"/> 0	<input type="checkbox"/> 8
heart attack (myocardial infarct)	<input type="checkbox"/> 1	<input type="checkbox"/> 0	<input type="checkbox"/> 8
stroke	<input type="checkbox"/> 1	<input type="checkbox"/> 0	<input type="checkbox"/> 8
heart failure	<input type="checkbox"/> 1	<input type="checkbox"/> 0	<input type="checkbox"/> 8

2 Have you ever had any of the following procedures? (Show Card B)

	YES	NO	UNSURE
coronary bypass surgery ("CABBAGE")	<input type="checkbox"/> 1	<input type="checkbox"/> 0	<input type="checkbox"/> 8
coronary angioplasty (balloon angioplasty)	<input type="checkbox"/> 1	<input type="checkbox"/> 0	<input type="checkbox"/> 8
insertion of a pacemaker (defibrillator)	<input type="checkbox"/> 1	<input type="checkbox"/> 0	<input type="checkbox"/> 8
other heart or cardiac surgery	<input type="checkbox"/> 1	<input type="checkbox"/> 0	<input type="checkbox"/> 8

If "YES" to "other heart or cardiac surgery," please specify:

3 Has a doctor ever told you that you have the following? (Show Card C)

	YES	NO	UNSURE
sleep apnea	<input type="checkbox"/> 1	<input type="checkbox"/> 0	<input type="checkbox"/> 8
emphysema	<input type="checkbox"/> 1	<input type="checkbox"/> 0	<input type="checkbox"/> 8
chronic bronchitis	<input type="checkbox"/> 1	<input type="checkbox"/> 0	<input type="checkbox"/> 8
COPD (chronic obstructive pulmonary disease)	<input type="checkbox"/> 1	<input type="checkbox"/> 0	<input type="checkbox"/> 8
asthma	<input type="checkbox"/> 1	<input type="checkbox"/> 0	<input type="checkbox"/> 8

4 Have you had an attack of asthma at any time in the last 12 months?

YES	NO	UNSURE
<input type="checkbox"/> 1	<input type="checkbox"/> 0	<input type="checkbox"/> 8

5 Do you cough on most days for as much as three months of the year?

YES	NO	UNSURE
<input type="checkbox"/> 1	<input type="checkbox"/> 0	<input type="checkbox"/> 8

6 Do you bring up phlegm from your chest on most days for as much as three months of the year?

YES	NO	UNSURE
<input type="checkbox"/> 1	<input type="checkbox"/> 0	<input type="checkbox"/> 8

7 Do you usually have a runny nose or stuffy nose?

YES	NO	UNSURE
<input type="checkbox"/> 1	<input type="checkbox"/> 0	<input type="checkbox"/> 8

8 Do you usually have sinus trouble?

YES NO UNSURE
 1 0 8

The next few questions are about cigarette smoking.

SMOKING QUESTIONS (9, 10): (3 MONTHS)

1 Data collected today at home visit
 2 Data collected in clinic:
Date: ____ ____ ____
 month day year

9 Have you ever smoked cigarettes? By "ever," we mean at least 20 packs in your lifetime.

YES NO
 1 0 → *Skip to Question 11.*

10 Do you now smoke cigarettes?

YES NO
 1 0

If "Yes," how many cigarettes per day do you now smoke?

(number per day)

If "No," when did you stop?

____ month ____ year

CAFFEINE QUESTIONS (11): (3 MONTHS)

1 Data collected today at home visit
 2 Data collected in clinic:
Date: ____ ____ ____
 month day year

11 On a typical day, how many cups of regular coffee (with caffeine) do you drink?

____ ____ cups

How many cups of regular tea (with caffeine) do you drink?

____ ____ cups

How many glasses or cans of cola or other soda with caffeine do you drink?

____ ____ glasses or cans

12 During the last two weeks, did you take any aspirin or aspirin-containing medicines such as Bufferin, Anacin, or Ascriptin?

YES NO
 1 0

If "Yes," on how many days during the last two weeks did you take this medicine?

____ ____ (number of days)

13 Do you take sleeping pills one or more times a week?

YES NO UNSURE
 1 0 8

14 Did a doctor prescribe nitroglycerin for you in the last year?

YES NO UNSURE
 1 0 8

The next few questions I have are about your sleep last night.

15 What time did you go to sleep last night?

_____ : _____ 1 A.M.
(Midnight is 12:00 A.M.)
 2 P.M.

16 What time did you wake up today?

_____ : _____ 1 A.M.
(Midnight is 12:00 A.M.)
 2 P.M.

17 How long did you sleep last night?

_____ hours _____ minutes

18 How well did you sleep last night?

(Show Card D, then check one.)

- 1 Much worse than usual
- 2 Somewhat worse than usual
- 3 As well as usual
- 4 A little better than usual
- 5 Much better than usual

19 If you took any naps today, for how long did you sleep during the naps? (Use "0" for no naps.)

_____ hours _____ minutes

**20 How stressful was your day today?
Was it: (Check one.)**

- 1 A typical day?
- 2 Less stressful than usual?
- 3 More stressful than usual?

Field Center Use Only

Interviewer administered, in:

- 1 English
- 2 Spanish
- 3 Lakota
- 4 Pima
- 5 Other, specify: _____
- 6 Unknown

Interviewer or Reviewer _____

Date: _____
month day year

SHHS Form HI, Card A

angina
heart attack (myocardial infarct)
stroke
heart failure

SHHS Form HI, Card C

sleep apnea
emphysema
chronic bronchitis
COPD (chronic obstructive pulmonary disease)
asthma

SHHS Form HI, Card B

coronary bypass surgery ("CABBAGE")
coronary angioplasty (balloon angioplasty)
Insertion of a pacemaker (defibrillator)
Other heart or cardiac surgery

SHHS Form HI, Card D

- 1 Much worse than usual
- 2 Somewhat worse than usual
- 3 As well as usual
- 4 A little better than usual
- 5 Much better than usual

6.5.3 Interview and Coding Instructions for Framingham

The instructions that follow outline the permissible clarifications and coding instructions on a question by question basis. This protocol should be consistently adhered to. Any deviations from protocol should be referred to the study coordinator. Any proposed changes in protocol should be referred to the Operations Subcommittee.

6.5.3.1 Review for Completeness

Questionnaires that are interviewer administered should be checked for completeness and accuracy as the questionnaire is administered. If questions arise that are not covered here, make note on survey and review with the study coordinator.

6.5.3.2 General Instructions

General rules for coding and editing

1. Indicate responses clearly and neatly.
2. Complete paper form with black pen.
3. Using a red pen or pencil, make corrections on interview, "X-ing" out the discrepancy and writing next to it the corrected response. Stray marks on the forms should be scratched out using red as well.
4. Leading zeros are not required to fill in all fields of a variable.
5. Missing data
 - a) By type of Administration
 - i) On self-administered forms, data not completed by the participant will be left as blanks.
 - ii) On interviewer-administered forms, all questions should be marked with a response except those that are SKIPPED as a result of a SKIP pattern. Items SKIPPED by a SKIP pattern should be left blank on the form.
 - b) Coding Specifications

The following guidelines specify how to deal with coding "don't know" and "blank" data. However, there may be exceptions to these rules, so please consult the question-specific details provided for each form.

- i) If a participant explicitly responds “don’t know” to a question, the interviewer should fill the field with 8’s. For example: If someone can’t remember what year they stopped smoking, code the month as 88 and year as 8888.

Thus, 8’s imply that data are missing because the participant explicitly responded “Don’t Know” or “Unsure.”

- ii) If a participant refuses to answer or does not give a valid response, the interviewer should fill the field with 9’s.
6. If a range of values is given, take the midpoint. If data are collected only as integer values, then find the midpoint and round up to nearest integer. For example, 6-8 cups a day is 7 cups. The midpoint of the range 6-7 cups a day is 6.5 and should be rounded up to 7 cups as the final answer.
 7. The year in a date is to be entered as a 2-digit number without the “19” prefix. Exception to this rule is when the response is “don’t know” or question is left blank by the respondent and is not part of a SKIP pattern. Since 1988 and 1999 may be valid responses in this study, year will have to be filled with a 4-digit number, 8888 or 9999, respectively.
 8. For questions where “hours” and “minutes” are to be specified, convert fractional hours to minutes. Both hours and minutes fields must be completed, even if the response is 0. For example, if a respondent indicates 3/4 of an hour, then neatly “X-out” in red the 3/4 and recode data to 0 “hours” and 45 “minutes.”
 9. By definition, midnight is 12:00 A.M.
 10. Record your ID number at the appropriate spot on the interview form.

6.5.3.3 Question by Question Specifications

Pre-questionnaire Data

Affix a participant label at the top right of page 1 before going to the home. Write your 2-digit Field Center ID number in the indicated space.

PREVALENT DISEASE QUESTIONS

In the box provided indicate whether the data for questions 1 and 2 are being collected today at the home visit or were collected in the clinic within 3 months of the home visit date.

If data were collected in the clinic, provide the date of the clinic visit. Date is specified as month, day, year with each component a 2-digit field.

1. Has a doctor ever told you that you have or had the following?

Show the participant CARD A and read off each condition.

Clarification:

“Ever” refers to one or more times any time in the past, regardless of recency.

“Doctor” is a licensed M.D. or O.D.

The distinction here is whether a doctor has ever told them. The respondent’s own personal opinion is not to be coded in this question.

Coding:

Permissible codes: 0, 1, 8

Each of the four items have the same set of permissible codes.

If respondent was told they had the condition by one doctor, but was negated by a second doctor, code as YES (code=1).

2. Have you ever had any of the following procedures?

Show the participant CARD B and read off each procedure.

Clarification:

“Ever” refers to one or more times any time in the past, regardless of recency.

Coding:

Permissible codes: 0, 1, 8

Each of the four items have the same code.

If a participant answers “YES” to “Other heart or cardiac surgery,” ask the participant what kind of surgery it was and record the response. There are 50 spaces allocated for the coding of this response.

3. Has a doctor ever told you that you have the following?

Inquire about each condition listed on the questionnaire.

Clarification:

“Ever” refers to one or more times any time in the past, regardless of recency.

“Doctor” is a licensed M.D. or O.D.

The distinction here is whether a doctor has ever told them. The respondent’s own personal opinion is not to be coded in this question.

Coding:

Permissible codes: 0, 1, 8

Each of the four items have the same set of permissible codes.

If respondent was told they had the condition by one doctor, but was negated by a second doctor, code as YES (code=1).

4. Have you had an attack of asthma at any time in the last 12 months?

Coding:

Permissible codes: 0, 1, 8

5. Do you cough on most days for as much as 3 months of the year?

Clarification:

The 3 months is a summary time period and does not have to be consecutive.

Coding:

Permissible codes: 0, 1, 8

6. Do you bring up phlegm from your chest on most days for as much as 3 months of the year?

Clarification:

The 3 months is a summary time period and does not have to be consecutive.

Coding:

Permissible codes: 0, 1, 8

7. Do you usually have a runny nose or stuffy nose?

Clarification:

This may occur during the day or in the evening or both.

Coding:

Permissible codes: 0, 1, 8

8. Do you usually have sinus trouble?

Clarification:

Sinus trouble is pain/swelling in the region of the upper face.

Coding:

Permissible codes: 0, 1, 8

SMOKING QUESTIONS

In the box provided indicate whether the data are being collected today at the home visit or were collected in the clinic within 3 months of the home visit date.

If data were collected in the clinic, provide the date of the clinic visit. Date is specified as month, day, year with each component a 2-digit field.

9. Have you ever smoked cigarettes? By “ever” we mean at least 20 packs in your lifetime.

This is a lead-in question to the smoking question section.

If the answer is YES, continue with question 10.

If the answer is NO, SKIP to question 11.

If the respondent smokes cigars or a pipe, code as NO and SKIP to question 11.

Coding:

Permissible codes: 0 or 1.

If respondent says “YES” (code=1), then question 10 should have an answer.

If respondent says “NO” (code=0), then question 10 should be SKIPPED. However, if question 10 has a valid response check with study coordinator to identify interviewer who may not be following the SKIP pattern.

10. Do you now smoke cigarettes?

Coding:

Permissible codes: 0, 1

If “YES” (code=1), then how many cigarettes per day do you now smoke?

Number per day is a 2-digit field.

Permissible range: 01 - 80.

If “NO” (code=0), when did you stop?

Code Month as a 2-digit code. Range 1-12.

Code Year as a 4-digit code. Range 00-99, 8888, 9999

CAFFEINE QUESTIONS

In the box provided indicate whether the data are being collected today at the home visit or were collected in the clinic within 3 months of the home visit date.

If data were collected in the clinic, provide the date of the clinic visit. Date is specified as month, day, year with each component a 2-digit field.

11. On a typical day,

How many cups of coffee (with caffeine, "regular") do you drink?

Clarification:

This is caffeinated coffee. This includes drip and instant. One shot of espresso in a drink counts as 1 cup.

Coding:

Number of cups is a 2-digit field.

Permissible codes: 00-80

If respondent does not drink coffee, code as 00.

How many cups of tea (with caffeine, "regular") do you drink?

Clarification:

Herbal tea does not contain caffeine. If participant is not sure whether the tea he/she drinks contains caffeine, have him/her check the container.

Some types of Snapple contain caffeine, some do not. If participant mentions drinking Snapple, clarify whether it is caffeinated or ask to see the container.

Coding:

Number of cups is a 2-digit field.

Permissible codes: 00-80

If respondent does not drink tea, code as 00.

How many glasses or cans of cola or other soda with caffeine do you drink?

Clarification:

Sodas containing caffeine are: Coke, Pepsi, RC Cola, Jolt, Mountain Dew, Dr. Pepper, Diet Coke, Diet Pepsi, etc.

Sodas that do not contain caffeine are: All "caffeine free" varieties, 7-up, Squirt Sprite, Root beer, etc.

Coding:

Number of glasses/cans is a 2-digit field.
Permissible codes: 00-80

If respondent does not drink sodas, code as 00.

12. During the last two weeks, did you take any aspirin or aspirin-containing medicines such as Bufferin, Anacin, or Ascriptin?

Clarification:

Tylenol, Advil, Motrin, and Alleve do not contain aspirin.

Coding:

Permissible codes: 0, 1, 8

If "YES," then how many days during the last two weeks did you take this medicine?
Number of days is a 2-digit field.
Permissible range: 00-14, 99

If "NO," code number of days as 00.

If "UNSURE," code number of days as missing (99).

13. Do you take sleeping pills one or more times a week?

Clarification:

Include both prescription and over-the-counter sleeping pills should be coded.

Coding:

Permissible codes: 0, 1, 8

14. Did a doctor prescribe nitroglycerin for you in the last year?

Coding:

Permissible codes: 0, 1, 8

15. What is the highest grade or year of school you have ever completed, including trade or vocational school, college and graduate or professional?

Clarification:

Only one level of education will be indicated.

If respondent did not go beyond high school, code the number of grades completed in the 2-digit space provided.

If respondent took the GED exam to obtain high school diploma check the GED box. Code as 13.

If respondent went to vocational school, check the appropriate box for number of years. Code as 13+the number of years indicated.

Example: 2 years vocational becomes 13+2=15.

If respondent went to college, check the appropriate box for number of years. Codes as 16+number of years indicated.

Example: 4 years of college becomes 16+4=20.

If respondent went to graduate or professional school, check the appropriate box. Code as 21.

Coding:

Permissible codes: 0-21, 99

16. What time did you go to sleep last night?

Coding:

Hours and minutes are each 2-digit fields.

AM or PM designation needs to be indicated.

Hours permissible range: 1 to 12

Minutes permissible range: 0 to 59

Data for Questions 16 and 17 should be visually compared for consistency of times and AM/PM designations. Inconsistencies must be rectified at the time of the interview. It is possible that someone may actually sleep during the day so care must be taken when checking the consistency to get AM/PM designations correct.

NOTE: Midnight is 12:00 AM by definition. A major point where inconsistencies will occur is when the respondent misspecifies 12 midnight as PM instead of AM.

17. What time did you wake up today?

Coding:

Hours and minutes are each 2-digit fields.
AM or PM designation needs to be indicated.
Hours permissible range: 1 to 12
Minutes permissible range: 0 to 59

Data for Questions 18 and 19 should be visually compared for consistency of times and AM/PM designations. Inconsistencies must be rectified at the time of the interview. It is possible that someone may actually sleep during the day so care must be taken when checking the consistency to get AM/PM designations correct.

18. How long did you sleep last night?

Coding:

Code hours and minutes each as a 2-digit field.
Hours permissible range: 0-24.
Minutes permissible range: 00-59

If fraction of an hour is written in, convert to minutes.

If a range of hours is given, take the midpoint.

Minutes must be coded, even if only 00.

Example: range of 8 to 9 hours is coded as 8 hours and 30 minutes
range of 6 to 8 hours is coded as 7 hours and 00 minutes

19. How well did you sleep last night? Check one response.

Show respondent CARD D.

Coding:

Permissible codes: 1, 2, 3, 4, 5

If participant is unsure, ask him/her to estimate the closest response.

If he/she still does not answer, code as missing (9).

20. If you took any naps today, for how long did you sleep during the naps?

Coding:

Code hours and minutes each a 2-digit field.
Hours permissible range: 0-24.
Minutes permissible range: 00-59

If person did not take any naps, code both hours and minutes as 00.

If fraction of an hour is written in, convert to minutes.

If a range of hours is given, take the midpoint.

Minutes must be coded, even if only 00.

Example: range of 1 to 2 hours is coded as 1 hours and 30 minutes

Half an hour to an hour converts to 00 hours and 45 minutes

21. How stressful was your day today?

Read off the three choices but only check one response.

Coding:

Permissible codes: 1, 2, 3

Post-questionnaire data

Record in what language the questionnaire was administered. Permissible codes are: 1, 2, 3, 4, 5, 6.

Record interviewer ID number in the box at the bottom of the last page and the date of the interview. Date is coded as month, day, year with each component a 2-digit number.

Health Interview – Framingham form (4/5/96)

Three pages inserted after this page.



SLEEP HEART HEALTH STUDY

HEALTH INTERVIEW Framingham

ID#:

Field Center: _____

Before we get started, I have a few questions to ask you. These are questions mostly about your health history.

PREVALENT DISEASE QUESTIONS: (3 MONTHS)

1 Data collected today at home visit

2 Data collected in clinic: Date: _____ month day year

1 Has a doctor ever told you that you have or had the following? (SHOW CARD A)

Table with 4 columns: Condition, YES, NO, UNSURE. Rows include angina, heart attack (myocardial infarct), stroke, heart failure.

2 Have you ever had any of the following procedures? (SHOW CARD B)

Table with 4 columns: Procedure, YES, NO, UNSURE. Rows include coronary bypass surgery ("CABBAGE"), coronary angioplasty (balloon angioplasty), insertion of a pacemaker (defibrillator), other heart or cardiac surgery.

If "YES" to "other heart or cardiac surgery," please specify: _____

3 Has a doctor ever told you that you have the following? (Show Card C)

Table with 4 columns: Condition, YES, NO, UNSURE. Rows include sleep apnea, emphysema, chronic bronchitis, COPD (chronic obstructive pulmonary disease), asthma.

4 Have you had an attack of asthma at any time in the last 12 months?

Table with 4 columns: YES, NO, UNSURE.

5 Do you cough on most days for as much as three months of the year?

Table with 4 columns: YES, NO, UNSURE.

6 Do you bring up phlegm from your chest on most days for as much as three months of the year?

Table with 4 columns: YES, NO, UNSURE.

7 Do you usually have a runny nose or stuffy nose?

Table with 4 columns: YES, NO, UNSURE.

8 Do you usually have sinus trouble?

YES NO UNSURE
 1 0 8

The next few questions are about cigarette smoking.

SMOKING QUESTIONS (9, 10): (3 MONTHS)

1 Data collected today at home visit

2 Data collected in clinic:
Date: ____ ____ ____
 month day year

9 Have you ever smoked cigarettes? By "ever," we mean at least 20 packs in your lifetime.

YES NO
 1 0 → *Skip to Question 11.*

10 Do you now smoke cigarettes?

YES
 1

NO
 0

If "Yes," how many cigarettes per day do you now smoke?

____ ____
(number per day)

If "No," when did you stop?

____ ____
month year

CAFFEINE QUESTIONS (11): (3 MONTHS)

1 Data collected today at home visit

2 Data collected in clinic:
Date: ____ ____ ____
 month day year

11 On a typical day, how many cups of regular coffee (with caffeine) do you drink?

____ ____ cups

How many cups of regular tea (with caffeine) do you drink?

____ ____ cups

How many glasses or cans of cola or other soda with caffeine do you drink?

____ ____ glasses or cans

12 During the last two weeks, did you take any aspirin or aspirin-containing medicines such as Bufferin, Anacin, or Ascriptin?

YES NO
 1 0

If "Yes," on how many days during the last two weeks did you take this medicine?

____ ____ (number of days)

13 Do you take sleeping pills one or more times a week?

YES NO UNSURE
 1 0 8

14 Did a doctor prescribe nitroglycerin for you in the last year?

YES NO UNSURE
 1 0 8

15 What is the highest grade or year of school you have ever completed, including trade or vocational school, college, and graduate or professional school? (Do not read responses.)

Grades 1 - 12 (record number; use "0" for none.)

GED: 13

Vocational School:
1 year 14
2 years 15
3 years 16

College:
1 year 17
2 years 18
3 years 19
4 years 20

Graduate or professional: 21

Refused to answer: 99

19 How well did you sleep last night?
(Show card D, then check one.)

- 1 Much worse than usual
- 2 Somewhat worse than usual
- 3 As well as usual
- 4 A little better than usual
- 5 Much better than usual

20 If you took any naps today, for how long did you sleep during the naps? (Use "0" for no naps.)

_____ hours _____ minutes

21 How stressful was your day today?
Was it: (Check one.)

- 1 A typical day?
- 2 Less stressful than usual?
- 3 More stressful than usual?

The next few questions I have are about your sleep last night.

16 What time did you go to sleep last night?

1 A.M.
(Midnight is 12:00 A.M.)
____ : ____ 2 P.M.

17 What time did you wake up today?

1 A.M.
(Midnight is 12:00 A.M.)
____ : ____ 2 P.M.

18 How long did you sleep last night?

_____ hours _____ minutes

Field Center Use Only

Interviewer administered, in:

- 1 English
- 2 Spanish
- 3 Lakota
- 4 Pima
- 5 Other, specify: _____
- 6 Unknown

Interviewer or Reviewer _____

Date: _____
month day year

SHHS Form HI, Card A

angina
heart attack (myocardial infarct)
stroke
heart failure

SHHS Form HI, Card C

sleep apnea
emphysema
chronic bronchitis
COPD (chronic obstructive pulmonary disease)
asthma

SHHS Form HI, Card B

coronary bypass surgery ("CABBAGE")
coronary angioplasty (balloon angioplasty)
Insertion of a pacemaker (defibrillator)
Other heart or cardiac surgery

SHHS Form HI, Card D

- 1 Much worse than usual
- 2 Somewhat worse than usual
- 3 As well as usual
- 4 A little better than usual
- 5 Much better than usual

6.5.4 Interview and Coding Instructions for New York

The instructions that follow outline the permissible clarifications and coding instructions on a question by question basis. This protocol should be consistently adhered to. Any deviations from protocol should be referred to the study coordinator. Any proposed changes in protocol should be referred to the Operations Subcommittee.

6.5.4.1 Review for Completeness

Questionnaires that are interviewer administered should be checked for completeness and accuracy as the questionnaire is administered. If questions arise that are not covered here, make note on survey and review with the study coordinator.

6.5.4.2 General Instructions

1. Indicate responses clearly and neatly.
2. Complete paper form with black pen.
3. Using a red pen or pencil, make corrections on interview, "X-ing" out the discrepancy and writing next to it the corrected response. Stray marks on the forms should be scratched out using red as well.
4. Leading zeros are not required to fill in all fields of a variable.
5. Missing data
 - a) By type of Administration
 - i) On self-administered forms, data not completed by the participant will be left as blanks.
 - ii) On interviewer-administered forms, all questions should be marked with a response except those that are SKIPPED as a result of a SKIP pattern. Items SKIPPED by a SKIP pattern should be left blank on the form.

b) Coding Specifications

The following guidelines specify how to deal with coding "don't know" and "blank" data. However, there may be exceptions to these rules, so please consult the question-specific details provided for each form.

- i) If a participant explicitly responds “don’t know” to a question, the interviewer should fill the field with 8’s.

For example: If someone can’t remember what year they stopped smoking, code the month as 88 and year as 8888.

Thus, 8’s simply that data are missing because the participant explicitly responded “Don’t Know” or “Unsure.”

- ii) If a participant refuses to answer or does not give a valid response, the interviewer should fill the field with 9’s.

For example: If someone refuses to answer the questions regarding “alcohol” consumption, then code the data as 99.

If on a self-administered form the participant responds by writing in an involved response, this should be coded as 9’s. Some questions on self-administered forms purposely do not include a “Don’t Know” option. If the participant writes in “Don’t Know,” code as 9.

Thus, 9’s indicate that data are missing because of some kind of error in the data or a refusal.

6. If a range of values is given, take the midpoint. If data are collected only as integer values, then find the midpoint and round up to nearest integer. For example, 6-8 cups a day is 7 cups. The midpoint of the range 6-7 cups a day is 6.5 and should be rounded up to 7 cups as the final answer.
7. The year in a date is to be entered as a 2-digit number without the “19” prefix. Exception to this rule is when the response is “don’t know” or question is left blank by the respondent and is not part of a SKIP pattern. Since 1988 and 1999 may be valid responses in this study, year will have to be filled with a 4-digit number, 8888 or 9999, respectively.
8. For questions where “hours” and “minutes” are to be specified, convert fractional hours to minutes. Both hours and minutes fields must be completed, even if the response is 0. For example, if a respondent indicates 3/4 of an hour, then neatly “X-out” in red the 3/4 and recode data to 0 “hours” and 45 “minutes.”
9. By definition, midnight is 12:00 A.M.
10. Record your ID number at the appropriate spot on the interview form.

6.5.4.3 Question by Question Specifications

Pre-questionnaire Data

Affix a participant label at the top right of page 1 before going to the home. Write your 2-digit Field Center ID number in the indicated space.

PREVALENT DISEASE QUESTIONS

In the box provided indicate whether the data for question 1 are being collected today at the home visit or were collected in the clinic within 3 months of the home visit date.

If data were collected in the clinic, provide the date of the clinic visit. Date is specified as month, day, year with each component a 2-digit field.

1. Have you ever had any of the following procedures?

Show the participant CARD B and read off each procedure.

Clarification:

“Ever” refers to one or more times any time in the past, regardless of recency.

Coding:

Permissible codes: 0, 1, 8

Each of the four items have the same code.

If a participant answers “YES” to “Other heart or cardiac surgery,” ask the participant what kind of surgery it was and record the response. There are 50 spaces allocated for the coding of this response.

2. Has a doctor ever told you that you have the following?

Inquire about each condition listed on the questionnaire.

Clarification:

“Ever” refers to one or more times any time in the past, regardless of recency.

“Doctor” is a licensed M.D. or O.D.

The distinction here is whether a doctor has ever told them. The respondent’s own personal opinion is not to be coded in this question.

Coding:

Permissible codes: 0, 1, 8

Each of the four items have the same set of permissible codes.

If respondent was told they had the condition by one doctor, but was negated by a second doctor, code as YES (code=1).

3. Have you had an attack of asthma at any time in the last 12 months?

Coding:

Permissible codes: 0, 1, 8

4. Do you cough on most days for as much as 3 months of the year?

Clarification:

The 3 months is a summary time period and does not have to be consecutive.

Coding:

Permissible codes: 0, 1, 8

5. Do you bring up phlegm from your chest on most days for as much as 3 months of the year?

Clarification:

The 3 months is a summary time period and does not have to be consecutive.

Coding:

Permissible codes: 0, 1, 8

6. Do you usually have a runny nose or stuffy nose?

Clarification:

This may occur during the day or in the evening or both.

Coding:

Permissible codes: 0, 1, 8

7. Do you usually have sinus trouble?

Clarification:

Sinus trouble is pain/swelling in the region of the upper face.

Coding:

Permissible codes: 0, 1, 8

SMOKING QUESTIONS

In the box provided indicate whether the data are being collected today at the home visit or were collected in the clinic within 3 months of the home visit date.

If data were collected in the clinic, provide the date of the clinic visit. Date is specified as month, day, year with each component a 2-digit field.

8. Have you ever smoked cigarettes? By “ever” we mean at least 20 packs in your lifetime.

This is a lead-in question to the smoking question section.

If the answer is YES, continue with questions 9 through 12.

If the answer is NO, SKIP to question 13.

If the respondent smokes cigars or a pipe, code as NO and SKIP to question 13.

Coding:

Permissible codes: 0 or 1.

If respondent says “YES” (code=1), then questions 9 through 12 should have answers.

If respondent says “NO” (code=0), then questions 9 through 12 should be SKIPPED. However, if questions 9 through 12 contain valid responses, check with study coordinator to identify interviewer who may not be following the SKIP pattern.

9. How old were you when you first started regularly smoking cigarettes.

Clarification:

If participant does not remember, ask them to estimate.

Coding:

Number of years is a 2-digit field.

Permissible range: 00 to 80

If participant cannot or will not answer, code as 99.

Skipped data are to be left blank. However, if a response is given, enter data as given.

If they give a range, code the midpoint rounding up to the nearest year. If they provide a descriptive response, code as best as possible.

Example: “In my teens” can be coded as 15 years.

10. Since you began smoking, was there ever a period of one year or more that you did not smoke?

Coding:

Permissible codes: 0, 1

If "YES" (code=1), then for how many years did you NOT smoke?
Years is a 2-digit field.

Permissible range: 00 - 80

If "NO" (code=0), then leave blank.

11. Do you now smoke cigarettes?

Coding:

Permissible codes: 0, 1

If "YES" (code=1), then how many cigarettes per day do you now smoke?
Number per day is a 2-digit field.
Permissible range: 01 - 80.

If "NO" (code=0), when did you stop?
Code Month as a 2-digit code. Range 1-12.
Code Year as a 4-digit code. Range 00-99, 8888, 9999

12. On average, of the entire time you smoked, how many cigarettes did you usually smoke?

This question should be answered by both current and former smokers.

Coding:

Number of cigarettes is a 2-digit field.
Permissible range: 01-80.

CAFFEINE QUESTIONS

In the box provided indicate whether the data are being collected today at the home visit or were collected in the clinic within 3 months of the home visit date.

If data were collected in the clinic, provide the date of the clinic visit. Date is specified as month, day, year with each component a 2-digit field.

13. On a typical day,

How many cups of coffee (with caffeine, “regular”) do you drink?

Clarification:

This is caffeinated coffee. This includes drip and instant. One shot of espresso in a drink counts as 1 cup.

Coding:

Number of cups is a 2-digit field.

Permissible codes: 00-80

If respondent does not drink coffee, code as 00.

How many cups of tea (with caffeine, “regular”) do you drink?

Clarification:

Herbal tea does not contain caffeine. If participant is not sure whether the tea he/she drinks contains caffeine, have him/her check the container.

Some types of Snapple contain caffeine, some do not. If participant mentions drinking Snapple, clarify whether it is caffeinated or ask to see the container.

Coding:

Number of cups is a 2-digit field.

Permissible codes: 00-80

If respondent does not drink tea, code as 00.

How many glasses or cans of cola or other soda with caffeine do you drink?

Clarification:

Sodas containing caffeine are: Coke, Pepsi, RC Cola, Jolt, Mountain Dew, Dr. Pepper, etc.

Sodas that do not contain caffeine are: All “caffeine free” varieties, 7-up, Squirt, Sprite, Root beer, etc.

Coding:

Number of glasses/cans is a 2-digit field.
Permissible codes: 00-80

If respondent does not drink sodas, code as 00.

ALCOHOL QUESTIONS

In the box provided indicate whether the data are being collected today at the home visit or were collected in the clinic within 3 years of the home visit date.

If data were collected in the clinic, provide the date of the clinic visit. Date is specified as month, day, year with each component a 2-digit field.

14. Within the last 6 months did you drink any alcoholic beverages?

Coding:

Permissible codes: 0, 1, 9

If "NO" (code=0), then code the three questions that follow as 00.

If "YES" (code=1), then ask the following three questions:

If the participant refuses to answer, code as 9.

How many glasses (4 oz) of wine do you usually have per week?

How many bottles or cans of beer (12 oz) do you usually have per week?

How many drinks with hard liquor (1 shot) do you usually have per week?

Number is a 2-digit field.

Permissible range: 00-80, 99.

If participant refuses to answer these questions, code as 99.

15. During the last two weeks, did you take any aspirin or aspirin-containing medicines such as Bufferin, Anacin, or Ascriptin?

Clarification:

Tylenol, Advil, Motrin, and Alleve do not contain aspirin.

Coding:

Permissible codes: 0, 1, 8

If "YES," then how many days during the last two weeks did you take this medicine?

Number of days is a 2-digit field.

Permissible range: 00-14, 99

If "NO," code number of days as 00.

If "UNSURE," code number of days as missing (99).

16. Do you take sleeping pills one or more times a week?

Clarification:

Include both prescription and over-the-counter sleeping pills?

Coding:

Permissible codes: 0, 1, 8

17. Did a doctor prescribe nitroglycerin for you in the last year?

Coding:

Permissible codes: 0, 1, 8

18. What time did you go to sleep last night?

Coding:

Hours and minutes are each 2-digit fields.

AM or PM designation needs to be indicated.

Hours permissible range: 1 to 12

Minutes permissible range: 0 to 59

Data for Questions 18 and 19 should be visually compared for consistency of times and AM/PM designations. Inconsistencies must be rectified at the time of the interview. It is possible that someone may actually sleep during the day so care must be taken when checking the consistency to get AM/PM designations correct.

NOTE: Midnight is 12:00 AM by definition. A major point where inconsistencies will occur is when the respondent misspecifies 12 midnight as PM instead of AM.

19. What time did you wake up today?

Coding:

Hours and minutes are each 2-digit fields.

AM or PM designation needs to be indicated.

Hours permissible range: 1 to 12

Minutes permissible range: 0 to 59

Again, data for Questions 18 and 19 should be visually compared for consistency of times and AM/PM designations. Inconsistencies must be rectified at the time of the interview. It is possible that someone may actually sleep during the day so care must be taken when checking the consistency to get AM/PM designations correct.

20. How long did you sleep last night?

Coding:

Code hours and minutes each as a 2-digit field.

Hours permissible range: 0-24.

Minutes permissible range: 00-59

If fraction of an hour is written in, convert to minutes.

If a range of hours is given, take the midpoint.

Minutes must be coded, even if only 00.

Example: range of 8 to 9 hours is coded as 8 hours and 30 minutes

range of 6 to 8 hours is coded as 7 hours and 00 minutes

21. How well did you sleep last night? Check one response.

Show respondent CARD D.

Coding:

Permissible codes: 1, 2, 3, 4, 5

If participant is unsure, ask him/her to estimate the closest response.

If he/she still does not answer, code as missing (9).

22. If you took any naps today, for how long did you sleep during the naps?

Coding:

Code hours and minutes each a 2-digit field.

Hours permissible range: 0-24.

Minutes permissible range: 00-59

If person did not take any naps, code both hours and minutes as 00.

If fraction of an hour is written in, convert to minutes.

If a range of hours is given, take the midpoint.

Minutes must be coded, even if only 00.

Example: range of 1 to 2 hours is coded as 1 hours and 30 minutes

Half an hour to an hour converts to 00 hours and 45 minutes

23. How stressful was your day today?

Read off the three choices but only check one response.

Coding:

Permissible codes: 1, 2, 3

Post-questionnaire data

Record in what language the questionnaire was administered. Permissible codes are: 1, 2, 3, 4, 5, 6.

Record interviewer ID number in the box at the bottom of the last page and the date of the interview. Date is coded as month, day, year with each component a 2-digit number.

Health Interview – New York form (4/5/96)
Three pages inserted after this page.

See the SHHS Form HI, Cards A through D on page 199 of this chapter.



SLEEP HEART HEALTH STUDY

**HEALTH INTERVIEW
New York**

ID#:

Field Center: _____

Before we get started, I have a few questions to ask you. These are questions mostly about your health history.

1 Have you ever had any of the following procedures? (SHOW CARD B)

	YES	NO	UNSURE
coronary bypass surgery ("CABBAGE")	<input type="checkbox"/> 1	<input type="checkbox"/> 0	<input type="checkbox"/> 8
coronary angioplasty (balloon angioplasty)	<input type="checkbox"/> 1	<input type="checkbox"/> 0	<input type="checkbox"/> 8
insertion of a pacemaker (defibrillator)	<input type="checkbox"/> 1	<input type="checkbox"/> 0	<input type="checkbox"/> 8
other heart or cardiac surgery	<input type="checkbox"/> 1	<input type="checkbox"/> 0	<input type="checkbox"/> 8

If "YES" to "other heart or cardiac surgery," please specify:

2 Has a doctor ever told you that you have the following? (Show Card C)

	YES	NO	UNSURE
sleep apnea	<input type="checkbox"/> 1	<input type="checkbox"/> 0	<input type="checkbox"/> 8
emphysema	<input type="checkbox"/> 1	<input type="checkbox"/> 0	<input type="checkbox"/> 8
chronic bronchitis	<input type="checkbox"/> 1	<input type="checkbox"/> 0	<input type="checkbox"/> 8
COPD (chronic obstructive pulmonary disease)	<input type="checkbox"/> 1	<input type="checkbox"/> 0	<input type="checkbox"/> 8
asthma	<input type="checkbox"/> 1	<input type="checkbox"/> 0	<input type="checkbox"/> 8

3 Have you had an attack of asthma at any time in the last 12 months?

YES	NO	UNSURE
<input type="checkbox"/> 1	<input type="checkbox"/> 0	<input type="checkbox"/> 8

4 Do you cough on most days for as much as three months of the year?

YES	NO	UNSURE
<input type="checkbox"/> 1	<input type="checkbox"/> 0	<input type="checkbox"/> 8

5 Do you bring up phlegm from your chest on most days for as much as three months of the year?

YES	NO	UNSURE
<input type="checkbox"/> 1	<input type="checkbox"/> 0	<input type="checkbox"/> 8

6 Do you usually have a runny nose or stuffy nose?

YES	NO	UNSURE
<input type="checkbox"/> 1	<input type="checkbox"/> 0	<input type="checkbox"/> 8

7 Do you usually have sinus trouble?

YES	NO	UNSURE
<input type="checkbox"/> 1	<input type="checkbox"/> 0	<input type="checkbox"/> 8

The next few questions are about cigarette smoking.

SMOKING QUESTIONS (8-12): (3 MONTHS)

1 Data collected today at home visit

2 Data collected in clinic:

Date: _____
month day year

8 Have you ever smoked cigarettes? By "ever," we mean at least 20 packs in your lifetime.

YES NO
 1 0 → *Skip to Question 13.*

9 How old were you when you first started regularly smoking cigarettes?

_____ years old

10 Since you began smoking, was there ever a period of one year or more that you did not smoke?

YES NO
 1 0
↓

If "YES," for how many years did you NOT smoke?

_____ years

11 Do you now smoke cigarettes?

YES NO

↓ ↓

If "Yes," how many cigarettes per day do you now smoke?

_____ (number per day)

If "No," when did you stop?

_____ month _____ year

12 On average, during the entire time you smoked, how many cigarettes did you usually smoke per day?

_____ (number of cigarettes)

CAFFEINE QUESTIONS (13): (3 MONTHS)

1 Data collected today at home visit

2 Data collected in clinic:

Date: _____
 month day year

13 On a typical day, how many cups of regular coffee (with caffeine) do you drink?

_____ cups

How many cups of regular tea (with caffeine) do you drink?

_____ cups

How many glasses or cans of cola or other soda with caffeine do you drink?

_____ glasses or cans

ALCOHOL QUESTIONS (14): (3 MONTHS)

1 Data collected today at home visit

2 Data collected in clinic:

Date: _____
 month day year

14 How many glasses (4 oz.) of wine do you usually have per week?

_____ glasses

How many bottles or cans of beer (12 oz.) do you usually have per week?

_____ cans/bottles

How many drinks with hard liquor (1 shot) do you usually have per week?

_____ drinks

15 During the last two weeks, did you take any aspirin or aspirin-containing medicines such as Bufferin, Anacin, or Ascriptin?

YES 1 NO 0

If "Yes," on how many days during the last two weeks did you take this medicine?

_____ (number of days)

16 Do you take sleeping pills one or more times a week?

YES 1 NO 0 UNSURE 8

17 Did a doctor prescribe nitroglycerin for you in the last year?

YES 1 NO 0 UNSURE 8

21 How well did you sleep last night?
(Show card D, then check one.)

- 1 Much worse than usual
- 2 Somewhat worse than usual
- 3 As well as usual
- 4 A little better than usual
- 5 Much better than usual

22 If you took any naps today, for how long did you sleep during the naps? (Use "0" for no naps.)

_____ hours _____ minutes

23 How stressful was your day today?
Was it: (Check one.)

- 1 A typical day?
- 2 Less stressful than usual?
- 3 More stressful than usual?

The next few questions I have are about your sleep last night.

18 What time did you go to sleep last night?

_____ 1 A.M.
(Midnight is 12:00 A.M.)
_____ : _____ 2 P.M.

19 What time did you wake up today?

_____ 1 A.M.
(Midnight is 12:00 A.M.)
_____ : _____ 2 P.M.

20 How long did you sleep last night?

_____ hours _____ minutes

Field Center Use Only

Interviewer administered, in:

- 1 English
- 2 Spanish
- 3 Lakota
- 4 Pima
- 5 Other, specify: _____
- 6 Unknown

Interviewer or Reviewer _____

Date: _____
month day year

6.6 Medications

6.6.1 Background and Rationale

The SHHS medication inventory is designed to assess current medication use. It is adapted from the protocols used for CHS, ARIC and Strong Heart Study. Because the methods used across all SHHS field Centers were either widely variable in time or not comparable in method, the comparability committee recommended assessing current use with the same method at the time of polysomnography for all centers.

At the baseline home polysomnography visit, the participant provides the technician with all prescription medications used during the two weeks prior to the visit, as well as certain selected over-the-counter medications and supplements. The technician transcribes information from the container onto the data collection form. After the information is transcribed, the interviewer queries the participant about each medication and asks several additional questions regarding the use of medications for sleep, caffeine, and other selected over-the-counter medications.

The medication form has several important purposes.

1. Medication use will be used to better define those reporting prevalent heart disease, hypertension, diabetes and other conditions. For example, a person taking nitroglycerin will generally have coronary heart disease. Diabetes may be insulin-requiring or not.
2. Medications may be prescribed for sleep or may have side effects of sedation.
3. Medication use may be an essential covariate in the analysis of the primary effects of sleep apnea on cardiovascular disease.

6.6.2 Definitions

6.6.2.1 Time Frame

All prescription medications, and selected over-the-counter medications taken within the two week period prior to the home visit are included.

6.6.2.2 Prescription Medication

SHHS Definition: A medication for which a prescription was written by a physician, dispensed by a pharmacist or physician, and taken by the participant during the two weeks prior to the interview. This includes prescription:

- Eye drops
- Pills, tablets, or capsules
- Solutions
- Creams, salves, or ointments

- Dermal patches
- Injectables (such as insulin)
- Inhalants

6.6.2.3 Non-Prescription Medications

Medications that may be purchased without a physician prescription.

Note: Physicians sometimes write prescriptions for medications which can be purchased without a prescription (over-the-counter medicines). For example, the participant may take one aspirin a day. When the physician wrote a prescription for the aspirin, it is considered a prescription medication. When the physician recommended that the participant take aspirin, but did not write a prescription for it, the aspirin is not considered a prescription medication.

6.6.3 Methods

Below are the instructions for gathering and transcribing medication data, and the conducting of the medications interview.

A Medications Form must be completed for every participant. If a participant has not taken any medications, then only Section A of the form needs to be completed and processed by data entry.

6.6.3.1 Home Visit

- Gathering Medicine Containers
 - The participant is asked to gather all prescription medications taken in the previous two weeks; this request is made during the pre-visit confirmation call.
 - Reception of Medications (Section A of Medication Form)
 - During the Home Visit, the interviewer inquires whether all prescription medications taken during the last two weeks are available. The responses are recorded in Section A.
 - Script:

As you know, the Sleep Heart Health Study will be describing prescription and non-prescription medications its participants are using. We are particularly interested in medications your doctor prescribed for you and were filled by a pharmacist. These include pills, solutions, dermal patches, eye drops, creams, salves, injections, and inhalants. Are these all the medications that you took in the last two weeks?

- An alternative ending sentence for the script is:

Please gather all the medications that you have taken in the last two weeks.
- When the medications have not been gathered prior to the visit, or all are not available, the interviewer requests that the participant proceed with gathering them.
- When the participant has not taken any prescription medications during the previous two weeks, check “Took no medicines” on the Medications Form and proceed to Section C.
- Only medications which were actually taken during the previous two week period are recorded. Medications prescribed by a physician, but not taken will not be recorded. This includes instances where a physician wrote a prescription but it was not filled, or even if filled, no medications were taken during the previous two weeks.
- When the participant refuses, the interviewer attempts conversion; when the participant still refuses, record the reason for refusal on the form and proceed to Section C of the Medications Form.

6.6.3.2 Transcription Process (Section B-1)

6.6.3.2.1 Medication Name

- Print complete names using block capital letters, one letter per box.
- Record all identifying characters and numbers referring to strength.
- Include as much identifying information as possible. When the drug is longer than the 20 spaces available on the form, include a note in the margin (“See Comments”) and record the complete name in the Comments Section on page 2.
- Combination Drugs:

Combination medicines contain two or more drugs in a single pill or tablet. Some combination medicines such as Dyazide come in only one fixed combination (hydrochlorothiazide 25 mg and triamterene 50 mg); these combination medicines do not generally list a strength. Record DYAZIDE in the space name of medicine and leave the strength column blank.

Other combination medicines such as Inderide are available in more than one fixed dose combination (propranolol 40 mg and hydrochlorothiazide 25 mg; or propranolol 80 mg and hydrochlorothiazide 25 mg); these combination medicines generally list the strength as in “Inderide 40/25” or “Inderide 80/25.” For these medicines, record INDERIDE, in the space for name, and “40/25” or “80/25” in the space provided for strength.

EXAMPLES:

- Drugs containing two or more medications:

Example: Dyazide (hydrochlorothiazide and triamterene) is recorded as:

Name: “DYAZIDE”

Strength: blank

- Variable Dosage:

Examples:

Inderide 40/25 (40 mg Inderal, 25 mg hydrochlorothiazide) is recorded as:

Name: “INDERIDE”

Strength: “40/25”

Inderide 80/25 (80 mg Inderal, 25 mg hydrochlorothiazide) is recorded as:

Name: “INDERIDE”

Strength: “80/25”

- Do not record flavors of products and whether the preparations are sugar-free or sodium free.
- When it is not possible to transcribe the drug name, code “*” and explain in the comment section.
- If participant is part of another study and is on a “study drug” and does not know what the drug is, then code the medication name as “STUDY DRUG.” See Section 6.6.5 - Study Drugs - for complete instructions.

6.6.3.2.2 Strength (mg)

- Record the strength in milligrams of each medication; left justify the strength.
- When the strength is recorded as milligrams (mg) DO NOT record the abbreviation “mg.”
- When strength is not recorded as milligrams (mg) record all numbers digits and characters used to denote strength; this includes:
 - - decimal point,
 - ml – milliliter
 - /ml - per milliliter
 - mEq – milliequivalent

- hr - hour,
- /hr - per hour and
- % - percent Note: When the abbreviation, “PC” (percent) is used, record percent symbol, “%.”

SPECIFICS:

- Record strength of combination drugs where strength is separated by a “/” in this section.
- When the strength is given in grains (gr), convert to milligrams by multiplying by 65 milligrams per grain.
 - 1 grain = 65 milligrams;
 - 2 grains = 130 milligrams;
 - 5 grains = 325 milligrams.
- Liquid medicines strength is often written in mg/ml (milligrams per milliliter). For example, Ampicillin 125 mg / 5 ml, is recorded as:

Name: Ampicillin

Strength: “125/5ML.”

NOTE: Omit “mg” for milligrams.

- Strength for some medicines may be written as a percentage. For example: Alupent 0.6%, is recorded as:

Name: ALUPENT

Strength: 0.6%

- Strength for insulin is generally “U100” or “100 units per milliliter.” This is often written as “100/ml” or “100U/ml.” Record Insulin strength as “U100” unless another strength is listed on the label. NOTE: The other available strengths include U40, U500, and U1000; but they are rarely used.
- When it is not possible to transcribe the strength, code “*” and explain in the comment section. This includes instances where strength is not recorded on the label.

NOTE: Do not record the quantity or number of pills/tablets dispensed as strength.

- If participant is part of another study and is on a “study drug” and does not know what the drug is, then code the strength = 9999. See Section 6.6.5 - Study Drugs - for complete instructions.

6.6.3.2.3 Number Prescribed

- Record the total number of pills/times prescribed for the time period.
- Circle the appropriate letter to indicate whether the prescribed administration is per “D - day,” “W – week” or “M - month.”
- When the instructions include a range, record the lowest number of pills/times administered recommended. Examples.
 - “Take 1-2 pills 3-4 times a day,” code “3.”
 - “Take 1-2 pills every 4 hours while awake,” code “5.” (24 hours - 8 hours sleep/4 = 4 plus 1 for those taken at start of day)
 - “Take 2-4 pills every 4 hours,” code “12.”
- When it is not possible to transcribe the number prescribed per day, code “*” and explain in the Comment section.

SPECIFICS:

- When instructions indicate “Take as directed,” record “1” in the number of pills prescribed per day.
 - **COMPLEX INSTRUCTIONS:** record the average: for instance, code “take 1 pill every other day, alternating with 2 pills every other day” as “1.5” pills per day.
 - **PILLS, CAPSULES, or TABLETS:** record the total number prescribed per day, week or month.
 - **SOLUTIONS:** record the total number of milliliters taken per day, week or month.
- NOTE:**

1 teaspoon = 5 ml

1 tablespoon = 15 ml

1 ounce = 30 ml

- **EYE DROPS:** record the total numbers of drops prescribed per day, week or month.
Examples:

Two drops in right eye, three times a day = 6
One drop in each eye, twice a day = 4
- **INHALERS:** record the total number of sprays or puffs prescribed per day, week or month.
- **INSULIN,** record the total number of units injected per day, week or month.

- CREAMS, LOTIONS, and OINTMENTS: record the total number of applications prescribed per day, week, or month.
- PATCHES: record the total number to be applied to the skin per day, week, or month.
- NITROGLYCERIN OINTMENT: record the total number of inches to be applied to the skin per day, week, or month.

6.6.3.2.4 PRN Medicine

- Indicate whether the medication is prescribed to be taken on an “as needed” basis.
- Circle “Y” only when the prescription instructions indicates “as needed,” “when needed,” “if needed,” or a synonym.
 - The words, “as directed,” do not mean the same as “as needed.”
 - PRN is generally used for allergy, pain or sleep medications, or some form of sublingual nitroglycerin.
- Circle “N” when the prescription instruction do not use the words “as needed,” “when needed,” “if needed,” or a synonym.

6.6.3.3 Medication Use Interview (Section B-2)

- Prior to beginning the interview, place all medications in front of the participant.
- When asking about a medication, show the bottle to the participant keeping other medications in view. Following the inquiry for a medication, place the bottle off to the side.
- Conclude the interview with a probe regarding completeness of the prescription medications taken during the previous two weeks.
- Shared prescriptions should be noted in the comments.
- When, following probes for completeness, the participant recalls additional prescription medications taken during the previous two weeks, ask the participant to retrieve the medication container. If for some reason the container is not available, record the name, strength and dose with as much detail as possible and explain in the Comment section.
- When doubt exists regarding recall accuracy, make arrangements to telephone the participant to verify the prescription label information.

6.6.3.3.1 Number Taken per Day

- Script: On the average during the last two weeks, how many of these pills did you take a (day, week, month).
- Record the total number of pills taken on average each day/week/month during the last two weeks.
- Circle the appropriate letter to indicate whether the prescribed administration was taken per “D - day,” “W – week” or “M - month.”
- When the number taken cannot be determined, code “***” and explain in the Comment section.

6.6.3.3.2 Number Unable to Transcribe

- Record the number of medications where complete transcription was not possible. This includes:
 - Medications with non-readable, missing labels
 - Medications whose containers were not available for transcription

6.6.4 Selected Over-the-Counter Medications and Supplements (Section C of Medication Form)

This section may repeat some information gathered in Section B, however it is important to record the information in both sections. For example when a participant takes aspirin as a prescription medicine (using the SHHS definition), record the details of the prescription in Section B. If they take other aspirin containing medications without a prescription, record these in Section C.

6.6.5 Study Drugs

Sometimes participants are involved in other studies and may be taking some medications as part of that study. The medication and strength may be unknown to the participant. Code this data in Section B as follows:

Medication name: STUDY DRUG
Strength: 9999

The data regarding number prescribed, PRN, and amount actually taken should still be available. Under COMMENTS, record the name of the study in which the participant is involved.

Medications – Prescription and Over-the-Counter form (3/17/96)

Two pages inserted after this page



SLEEP HEART HEALTH STUDY

*MEDICATIONS - PRESCRIPTION
AND OVER-THE-COUNTER*

ID#:

Field Center: ____ ____

Section A Medication Reception

As you know, the Sleep Heart Health Study will be describing all medications its participants are using, both prescription and over-the-counter. These include pills, dermal patches, eye drops, creams, salves, and injections, as well as vitamins, cold or allergy remedies, aspirin, and Tylenol. Are these all the medications that you took in the last two weeks?

yes 1 **May I see them?**
 no 0 *Make arrangements to obtain*
 took no medicines 2 **Go to Section C**
 refused 9
 ↓

Reasons for refusal: _____

Go to Section C

Section B Prescription Medications

1 Copy the name of the medicine, the strength in milligrams (mg) and the total number of doses prescribed per day week or month. (Include pills, dermal patches, eye drops, creams, salves, and injections.)

2 On the average during the last two weeks, how many of these pills did you take a day (or week/month)?

	Medication Name <i>Print the first 20 letters only--please print clearly.</i>	Strength (mg) <i>Write the decimal as one of the digits.</i>	Number Prescribed <i>Circle: day, week, or month</i>	PRN Medicine?	
1	<input type="text"/>	<input type="text"/>	<input type="text"/> D W M	Y N	<input type="text"/> D W M
2	<input type="text"/>	<input type="text"/>	<input type="text"/> D W M	Y N	<input type="text"/> D W M
3	<input type="text"/>	<input type="text"/>	<input type="text"/> D W M	Y N	<input type="text"/> D W M
4	<input type="text"/>	<input type="text"/>	<input type="text"/> D W M	Y N	<input type="text"/> D W M
5	<input type="text"/>	<input type="text"/>	<input type="text"/> D W M	Y N	<input type="text"/> D W M
6	<input type="text"/>	<input type="text"/>	<input type="text"/> D W M	Y N	<input type="text"/> D W M
7	<input type="text"/>	<input type="text"/>	<input type="text"/> D W M	Y N	<input type="text"/> D W M
8	<input type="text"/>	<input type="text"/>	<input type="text"/> D W M	Y N	<input type="text"/> D W M
9	<input type="text"/>	<input type="text"/>	<input type="text"/> D W M	Y N	<input type="text"/> D W M
10	<input type="text"/>	<input type="text"/>	<input type="text"/> D W M	Y N	<input type="text"/> D W M
11	<input type="text"/>	<input type="text"/>	<input type="text"/> D W M	Y N	<input type="text"/> D W M
12	<input type="text"/>	<input type="text"/>	<input type="text"/> D W M	Y N	<input type="text"/> D W M
13	<input type="text"/>	<input type="text"/>	<input type="text"/> D W M	Y N	<input type="text"/> D W M
14	<input type="text"/>	<input type="text"/>	<input type="text"/> D W M	Y N	<input type="text"/> D W M
15	<input type="text"/>	<input type="text"/>	<input type="text"/> D W M	Y N	<input type="text"/> D W M

Number unable to transcribe: _____

ID#:

Field Center: ____ ____

Section C Over-the-Counter Medications

3 Copy the name of the medicine, the strength in milligrams (mg) and the total number of doses taken per day, week or month. (Include pills, dermal patches, eye drops, creams, salves, vitamins, cold or allergy remedies, aspirin, and injections.)

4 On the average during the last two weeks, how many of these pills did you take a day (or week/month)?

Medication Name

Print the first 20 letters only--please print clearly.

Strength (mg)

Write the decimal as one of the digits.

Circle: day, week, or month

1	<input type="text"/>	<input type="text"/>	<input type="text"/> D W M
2	<input type="text"/>	<input type="text"/>	<input type="text"/> D W M
3	<input type="text"/>	<input type="text"/>	<input type="text"/> D W M
4	<input type="text"/>	<input type="text"/>	<input type="text"/> D W M
5	<input type="text"/>	<input type="text"/>	<input type="text"/> D W M
6	<input type="text"/>	<input type="text"/>	<input type="text"/> D W M
7	<input type="text"/>	<input type="text"/>	<input type="text"/> D W M
8	<input type="text"/>	<input type="text"/>	<input type="text"/> D W M
9	<input type="text"/>	<input type="text"/>	<input type="text"/> D W M
10	<input type="text"/>	<input type="text"/>	<input type="text"/> D W M
11	<input type="text"/>	<input type="text"/>	<input type="text"/> D W M
12	<input type="text"/>	<input type="text"/>	<input type="text"/> D W M
13	<input type="text"/>	<input type="text"/>	<input type="text"/> D W M
14	<input type="text"/>	<input type="text"/>	<input type="text"/> D W M
15	<input type="text"/>	<input type="text"/>	<input type="text"/> D W M

Number unable to transcribe:

Comments:

Interview				First Edit		Second Edit			
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
Interviewer	month	day	year	hour	: min	month	day	hour	: min

6.7 Morning Survey

6.7.1 Purpose

The purposes of the Morning Survey are: 1) to collect data on the perceived quality of sleep during the PSG to help interpret the data, 2) to record drugs used in the day and during the night of the PSG, and 3) to record alcohol, tobacco, and caffeine use in the 4 hour period before bed. A question on the discomfort of the monitor will be included for the first 200 participants at each field site in order to correct any problems.

6.7.2 Interview and Coding Instructions

6.7.2.1 Introduction

The Morning Survey is a self-administered form that will be completed by the participant after getting up on the morning after the home visit. The technician will collect the Morning Survey and review responses for completeness and validity when he/she comes to pick up the PSG equipment. Any discrepancies the technician sees should be clarified with the participant before leaving the home if possible. If the participant's schedule does not allow this, the technician should call the participant later that day or in the evening to clarify any discrepancies.

If the participant has not completed the survey when the technician arrives to pick up the PSG equipment, the technician should ask the participant to complete the survey. The technician should not turn the survey into an interview, unless the person is unable to complete the survey on his/her own. If the participant does not have time to complete the survey right then, leave stamped envelope addressed to clinic.

The instructions that follow outline the permissible clarifications and coding instructions on a question by question basis. This protocol should be consistently adhered to. Any deviations from protocol should be referred to the study coordinator. Any proposed changes in protocol should be referred to the Operations Subcommittee.

6.7.2.2 Review for Completeness

Questionnaires should be examined for completeness and accuracy prior to data entry. See question by question specification of codes to clarify or correct data on the questionnaire. Any questions regarding how data are coded that are not covered below should be reviewed by the study coordinator.

6.7.2.3 General Instructions

1. Indicate responses clearly and neatly.
2. Complete paper form with black pen, if possible.

3. Using a red pen or pencil, make corrections on interview, “X-ing” out the discrepancy and writing next to it the corrected response. Stray marks on the forms should be scratched out using red as well.
4. Leading zeros are not required to fill in all fields of a variable.
5. Missing data

- a) By type of Administration

- i) On self-administered forms, data not completed by the participant will be left as blanks.
- ii) On interviewer-administered forms, all questions should be marked with a response except those that are skipped as a result of a SKIP pattern. Items skipped by a SKIP pattern should be left blank on the form

If a participant explicitly responds “don’t know” to a question, the interviewer should fill the field with 8’s.

- b) Coding Specifications

The following guidelines specify how to deal with coding “don’t know” and “blank” data. However, there may be exceptions to these rules, so please consult the question-specific details provided for each form.

- i) If a participant explicitly responds “don’t know” to a question, the interviewer should fill the field with 8’s. For example: If someone can’t remember what year they stopped smoking, code the month as 88 and year as 8888.

Thus, 8’s imply that data are missing because the participant explicitly responded “Don’t Know” or “Unsure.”

- ii) If a participant refuses to answer or does not give a valid response, the interviewer should fill the field with 9’s. For example: If someone refuses to answer the questions regarding “alcohol” consumption, then code the data as 99.

If on a self-administered form the participant responds by writing in an involved response, this should be coded as 9’s. Some questions on self-administered forms purposely do not include a “Don’t Know” option. If the participant writes in “Don’t Know,” code as 9.

Thus, 9’s indicate that data are missing because of some kind of error in the response or a refusal.

6. If a range of values is given, take the midpoint. If data are collected only as integer values, then find the midpoint and round up to nearest integer. For example, 6-8 cups a day is 7 cups. The midpoint of the range 6-7 cups a day is 6.5 and should be rounded up to 7 cups as the final answer.
7. The year in a date is to be entered as a 2-digit number without the "19" prefix. Exception to this rule is when the response is "don't know" or question is left blank by the respondent and is not part of a skip pattern. Since 1988 and 1999 may be valid responses in this study, year will have to be filled with a 4-digit number, 8888 or 9999, respectively.
8. For questions where "hours" and "minutes" are to be specified, convert fractional hours to minutes. Both hours and minutes fields must be completed, even if the response is 0. For example, if a respondent indicates 3/4 of an hour, then neatly "X-out" in red the 3/4 and recode data to 0 "hours" and 45 "minutes."
9. By definition, midnight is 12:00 A.M.
10. Record your ID number at the appropriate spot on the interview form.

6.7.2.4 Question by Question Specifications

Pre-questionnaire Data

Affix a participant label at the top right of page 1 before going to the home. Write your 2-digit Field Center ID number in the indicated space.

What is today's date? This is the date the form is completed. It should either be completed by the participant or completed by the technician the night before (with the next day's date).

1. What time did you go to sleep last night?

Clarification:

Go to sleep refers to the time they turned out the lights and attempted to go to sleep. E.g., if the person got into bed at 10 PM, read until 11 PM, and then turned out the light and had a conversation with their bed partner for 10 minutes, the response would be 11:10 PM.

Coding:

Hours and minutes are each 2-digit fields.
AM or PM designation needs to be checked.
Hours permissible range: 1 to 12
Minutes permissible range: 0 to 59

If no AM/PM designation is checked, look at question 2 for the wake up time to determine, if possible, if the missing data are AM or PM.

If the participant wore the sleep monitor during the day (e.g., a shift worker whose main sleep period is during the day), special care must be taken in verifying the consistency of the time the person went to sleep and the time he/she woke up.

NOTE: Midnight is 12:00 AM by definition. A major point where inconsistencies will occur is when the respondent misspecifies 12 midnight as PM instead of AM.

If a range of time is given, take the midpoint.

2. What time did you wake up today?

Clarification:

Wake-up time is the time the person finally woke up and stayed awake, whether they actually got out of bed or not.

Coding:

Hours and minutes are each 2-digit fields.
AM or PM designation needs to be checked.
Hours permissible range: 1 to 12
Minutes permissible range: 0 to 59

If no AM/PM designation is checked, look at question 1 for the wake up time to determine, if possible, if the missing data are AM or PM. Data for Questions 1 and 2 should be visually compared for consistency. Inconsistencies must be rectified.

If the participant wore the sleep monitor during the day (e.g., a shift worker whose main sleep period is during the day), special care must be taken in verifying the consistency of the time the person went to sleep and the time he/she woke up.

If a range is given, take the midpoint.

3. How long did you sleep last night?

Clarification:

Participant should try to estimate actual sleep time, discounting significant wake time after the first sleep onset.

Example: If the person slept from 11pm to 2am, was awake until 3 am, then slept until 7am, sleep time would be 7 hours.

Coding:

Code hours and minutes each as a 2-digit field.
Hours permissible range: 0-24.
Minutes permissible range: 00-59
If fraction of an hour is written in, convert to minutes.
If a range of hours is given, take the midpoint.
Minutes must be coded, even if only 00.

Example: range of 8 to 9 hours is coded as 8 hours and 30 minutes
range of 6 to 8 hours is coded as 7 hours and 00 minutes

4. Please rate the quality of your sleep last night by circling a number from 1 to 5 for each scale.

Clarification:

The participant should rate the actual sleep quality, not how it compares with the usual sleep quality.

Coding:

Permissible codes: 1, 2, 3, 4, 5 for all 3 parts (A., B., C.)

If two responses have been circled and it is not clear which is the intended single response, code the value which is closest to 5.

If the response is in between two values, code the value which is closest to the value 5.

5. Compared to your usual night's sleep, how well did you sleep last night? (check one).

Coding:

Permissible codes: 1, 2, 3, 4, 5

If two boxes have been marked or a mark was made between two boxes, and it is not clear which is the intended single response, code the value which is closest to value 3.

6. Did you have difficulty falling asleep last night? Check one.

Clarification:

Difficulty is subjective, but may refer to taking longer to get to sleep, having a hard time getting in a comfortable position, not being able to "drift off" to sleep as usual (e.g., just starting to fall asleep and then suddenly being wide-awake again.)

Coding:

Permissible codes: 0, 1

7. How many minutes did it take for you to fall asleep at bedtime last night?

Clarification:

If participant cannot estimate or give best guess as to sleep latency, code as missing (999).

Coding:

A 3-digit field is allowed for specification of minutes.
Permissible range: 00 to 480, 999.

Any hour specification must be converted to minutes.

If a range is given, take the midpoint. If midpoint is a fraction of a minute, the midpoint should be rounded up to nearest minute.

Example: 10-20 minutes should be coded as 15 minutes.
10-15 minutes should be coded as 13 minutes.

8. Please list all prescription, over-the-counter or other drugs and medications that you took yesterday and last night. Include anything you took during the night, too.

Clarification:

Participants should list drugs used for the entire previous day (from wake up to bedtime with PSG), as well as drugs taken during the night or early AM while the PSG was still hooked up and recording.

Coding:

Unlike Medications Survey, the Morning Survey only records medication name and strength, and none of the other data that the SHHS Meds program requires. Thus, when using the program, code # prescribed as "1" and the # taken as "1." Code PRN="N."

See Section 6.6 for coding of medications.

9. How much beer, wine, or liquor (if any) did you have during the 4 hours before you sent to sleep last night? Please write "0" for each if you did not drink any of that beverage.

Clarification:

If participant notes that they did have alcohol, but are not sure if it was 4 hours before bed or a little more, or that they were not sure when, but it was in the evening, or that it was sometime between 4-6 hours before bed code as if it were 4 hours.

Coding:

How much of a particular alcoholic beverage is a 2-digit field.
Permissible range: 00-50, 99.

If a range is given, take the midpoint. If midpoint is a fraction of a unit, the midpoint should be rounded up to the nearest unit.

Example: 2 or 3 glasses of wine should be coded as 3 glasses.

10. How much of the following drinks with caffeine (if any) did you have during the 4 hours before you went to sleep last night? Please write "0" for each if you did not drink any of that beverage.

Clarification:

If participant notes that they did have caffeine, but are not sure if it was 4 hours before bed or a little more, or that they were not sure when, but it was in the evening, or that it was sometime between 4-6 hours before bed, code as if it were 4 hours.

Caffeinated coffee includes drip and instant. One shot of espresso in a drink counts as 1 cup.

Coding:

Number of cups or glasses/cans is a 2-digit field.

Permissible codes: 00-50, 99

If respondent does not drink a particular beverage code as 00.

If a range is given, take the midpoint. If midpoint is a fraction of a unit, the midpoint should be rounded up to the nearest unit.

Example: 2 or 3 cups of coffee should be coded as 3 cups.

11. How much did you smoke (if at all) during the 4 hours before you went to sleep last night?

Clarification:

If participant notes that they did smoke, but are not sure if it was 4 hours before bed or a little more, or that they were not sure when, but it was in the evening, or that it was sometime between 4-6 hours before bed code as if it were 4 hours.

Coding:

Number of each item is a 2-digit field.

Permissible codes: 00-50, 99

If respondent does not smoke at all code as 00.

If a range is given, take the midpoint. If midpoint is a fraction of a unit, the midpoint should be rounded up to the nearest unit.

Example: 4 or 5 cigarettes should be coded as 5 cigarettes.

12. How much discomfort, if any, did the following parts of the monitor cause for you?

Clarification:

The term discomfort may mean "hurt, bothered, annoyed, worried" you or kept you awake.

Coding:

There are six parts to this question and each uses the same coding system.

Permissible codes: 1, 2, 3, 4

If two boxes have been checked and it is not clear which is the intended single response, code the value that is closest to 1.

13. At what time did you finish filling out this survey?

Coding:

Hours and minutes are each 2-digit fields.

AM or PM designation needs to be checked.

Hours permissible range: 1 to 12

Minutes permissible range: 0 to 59

If a range is given, take the midpoint.

Post-question Data -- Field Center Use Only questions.

Indicate whether the questionnaire was self-administered (code=0) or if it was administered by an interviewer. If interviewer administered, indicate in which language the interview was administered.

If the form was interviewer administered, enter the interviewer ID and the interview date. Date should be coded in the MM/DD/YY format, 2-digits for each component of the date. For example, December 7, 1995 should be coded as 120795.

If the form was self-administered, enter the ID of the person who reviewed the form and the date of the review.

*Morning Survey form (1/8/97) inserted here
Three pages inserted after this page.*



SLEEP HEART HEALTH STUDY

MORNING SURVEY

ID#:

Field Center: _____

Today's date: _____ month _____ day _____ year

After you get up, please fill out this form as completely as you can. If you have any questions, the technician will be happy to help you when your monitor is collected.

1 What time did you go to sleep last night?

_____ : _____ 1 A.M. (Midnight is 12:00 A.M.) 2 P.M.

2 What time did you wake up today?

_____ : _____ 1 A.M. 2 P.M.

3 How long did you sleep last night?

_____ HOURS _____ MINUTES

4 Please rate the quality of your sleep last night by circling a number from 1 to 5 on each of the scales below.

My sleep last night was:

A. Light					Deep
	1	2	3	4	5

B. Short					Long
	1	2	3	4	5

C. Restless					Restful
	1	2	3	4	5

5 Compared to your usual night's sleep, how well did you sleep last night? (Check one)

- 1 Much worse than usual
- 2 Somewhat worse than usual
- 3 As well as usual
- 4 A little better than usual
- 5 Much better than usual

6 Did you have difficulty falling asleep last night? (Check one)

- YES NO
- 1 0

7 How many minutes did it take for you to fall asleep at bedtime last night?

_____ MINUTES

8 Did you take any medications last night that you didn't tell us about yesterday? (Check one)

- 1 YES (Please list them below.) 0 NO → Skip to Question 9 on page 3.
- 2 UNSURE (If you are unsure that you told us about a medication, please list it below.)

Medication Name

Strength (mg)

Print the first 20 letters only--please print clearly.

1	<input type="text"/>	<input type="text"/>
2	<input type="text"/>	<input type="text"/>
3	<input type="text"/>	<input type="text"/>
4	<input type="text"/>	<input type="text"/>
5	<input type="text"/>	<input type="text"/>

(Please continue on the back of this survey if you need additional space.)

6.8 Quality of Life Survey -- The SF-36 Health Survey

6.8.1 Purpose

The SF-36 Health Survey measures health status from a participant's point of view. The survey has been validated in diverse patient groups for self-completion or administration by a trained interviewer in person or over the telephone. The 36 items in the survey are derived from a 245-item questionnaire used in the Medical Outcomes Study and measure eight health concepts each on a multi-item scale: 1) physical functioning; 2) role limitations because of physical health problems; 3) bodily pain; 4) social functioning; 5) general mental health (psychological distress and psychological well-being); 6) role limitations because of emotional problems; 7) vitality (energy/fatigue); and 8) general health perceptions.

6.8.2 Procedures and Methods for Data Collection

6.8.2.1 Method of Data Collection

The Quality of Life survey is designed to be self-administered. Depending on the Field Center, participants may complete this form by mail, at a clinic exam, or during a personal visit from one of the parent study personal recruitment visits.

6.8.2.2 Completion of Surveys

- a) Participants' queries about how to answer the items.

Participants will vary in their access to help in filling out the survey. This may introduce a bias in the completeness and validity of the survey data by site. Participants who receive the survey by mail will need to call the study office for help, while those who are given the survey during a study visit will have ample opportunity to ask for clarification and get other kinds of help. As a counter measure, participants should not be encouraged to ask for help in the in-person settings, and staff in all settings should adhere to the permitted clarifications below. Fortunately, most items are self-explanatory and are unlikely to raise questions. However, if clarification is needed, see clarification instructions in coding and editing instructions (Section 6.8.3).

- b) Participants with problems: illiterate, poor eyesight, other handicaps that preclude reading and writing. Another person is permitted to read the items and mark the answers if necessary. For the mailed-survey setting, it is most likely that participants will find someone else to help them. For the in-person setting, a staff member should be identified who will assist such participants if they do not already have someone to help them.

6.8.3 Interview and Coding Instructions

6.8.3.1 Introduction

If the survey is returned by mail, respondents will not be called for missing or incorrect information. If the survey is completed in the presence of SHHS study personnel, the survey can be checked for completeness/accuracy by the study personnel and any missing data or discrepancies can be double-checked with the study participant.

The instructions that follow outline the permissible clarifications and coding instructions on a question by question basis. This protocol should be consistently adhered to. Any deviations from protocol should be referred to the study coordinator. Any proposed changes in protocol should be referred to the Operations Subcommittee.

6.8.3.2 Review for Completeness

Surveys should be examined for completeness and accuracy prior to data entry. See question by question specification of codes to clarify or correct data on survey. Any questions regarding how data are coded that are not covered in this document should be reviewed with the study coordinator.

6.8.3.3 General Instructions

1. Indicate responses clearly and neatly.
2. Complete paper form with black pen.
3. Using a red pen or pencil, make corrections on interview, “X-ing” out the discrepancy and writing next to it the corrected response. Stray marks on the forms should be scratched out using red as well.
4. Leading zeros are not required to fill in all fields of a variable.
5. Missing data
 - a) By type of Administration
 - i) On self-administered forms, data not completed by the participant will be left as blanks.
 - ii) On interviewer-administered forms, all questions should be marked with a response.
 - b) Coding Specifications

The following guidelines specify how to deal with coding “don’t know” and “blank” data. However, there may be exceptions to these rules, so please consult the question-specific details provided for each form.

- i) The Quality of Life survey specifically does not allow for “Don’t Know” or “Not Applicable” responses. Thus, such responses should be coded as missing (9). If the form has been self-administered, then leave such responses as blanks.
- ii) When completed by interview, if a participant refuses to answer or does not give a valid response, the interviewer should fill the field with 9’s.

Thus, 9's indicate that data are missing because of some kind of error in the response or a refusal.

6. The year in a date is to be entered as a 2-digit number without the "19" prefix. Exception to this rule is when the response is "don't know" or question is left blank by the respondent and is not part of a SKIP pattern. Since 1988 and 1999 may be valid responses in this study, year will have to be filled with a 4-digit number, 8888 or 9999, respectively.
7. Record your ID number at the appropriate spot on the interview form.
8. If 2 responses are given, code value closest to the "normal" response. See particular question for definition and coding instructions.

6.8.3.4 Question by Question Specifications

Prequestion data

The participant information and Field Center ID at the top right of page 1 should be complete before the form is given or sent to the participant.

The date should be coded in the MM/DD/YY format, two-digits for each component of the date. For example, December 7, 1995 should be coded as 120795. If the participant codes the date in some other way (e.g., writing "Dec" instead of 12 for the month), the person reviewing the form should convert the date to the proper format before giving the form to the data entry staff.

1. In general, would you say your health is:

Coding:

Permissible codes: 1, 2, 3, 4, 5

If two responses are given, code the value closest to 1 (Excellent).

2. Compared to a year ago, how would you rate your health in general now?

Coding:

Permissible codes: 1, 2, 3, 4, 5

If two responses are given, code the value closest to 3 (About the same).

3. The following questions are about activities you might do during a typical day. Does your health now limit you in these activities? If so, how much?

Clarification:

Is the participant's health limited by any of the 10 activities listed?

Read off the 10 questions one at a time and record the response.

If the participant does not do a particular activity on a typical day or never does that particular activity, have them indicate what their limitations might be if they did that activity.

Coding:

All ten questions in this section follow the same coding scheme.

Permissible codes: 1, 2, 3

4. During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health?

Clarification:

Read off the four activities one at a time. Indicate YES or NO.

The time frame is the past 4 weeks.

Coding:

All four parts to this question follow the same coding scheme.

Permissible codes: 1, 2

5. During the past 4 weeks have you had any of the following problems with your work or other regular daily activities as a result of any emotional problems (such as feeling depressed or anxious)?

Clarification:

Read off the three activities one at a time. Indicate YES or NO.

The time frame is the past 4 weeks.

Coding:

All three parts to this question follow the same coding scheme.

Permissible codes: 1, 2

6. During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?

Coding:

Permissible codes: 1, 2, 3, 4, 5

If two responses are given, code the value closest to 1 (Not at all).

7. How much bodily pain have you had during the past 4 weeks?

Coding:

Permissible codes: 1, 2, 3, 4, 5, 6

If two responses are given, code the value closest to 1 (None).

8. During the past 4 weeks how much did pain interfere with your normal work (including both work outside the home and housework)?

Coding:

Permissible codes: 1, 2, 3, 4, 5

If two responses are given, code the value closest to 1 (Not at all).

9. These questions are about how you feel and how things have been with you during the past 4 weeks. For each question, please indicate the one answer that comes closest to the way you have been feeling.

How much of the time during the past 4 weeks...

Clarification:

Read off the nine questions one at a time. Circle the appropriate response.

The time frame is the past 4 weeks.

Coding:

All nine parts to this question follow the same coding scheme.

Permissible codes: 1, 2, 3, 4, 5, 6

If two responses are given, code the value closest to the "normal" value for each part of this question. "Normal" values for each part are: a. - 1; b. - 6; c. - 6; d. - 1; e. - 1; f. - 6; g. - 6; h. - 1; i. - 6.

10. Has your health limited your social activities (like visiting with friends or close relatives)?

Coding:

Permissible codes: 1, 2, 3, 4, 5

If two responses are given, code the value closest to 5 (None of the time).

11. Please choose the answer that best describes how true or false each of the following statements is for you.

Clarification:

Read off the four statements one at a time. Circle the appropriate response.

Coding:

All four statements in this section follow the same coding scheme.

Permissible codes: 1, 2, 3, 4, 5

If two responses are given, code the value closest to the “normal” value for each part of this question. “Normal” values for each part are: a. - 5; b. - 1; c. - 5; d. - 1.

Post-question Data -- Field Center Use Only questions

Indicate whether the survey was self-administered (code=0) or if it was administered by an interviewer (code=1). Enter the ID of the interviewer or reviewer and the date of the interview or review.

6.8.4 Scoring

The domain scales are scored using the Likert method of summated ratings which assumes that the score for a particular item is linearly related to the underlying health concept being measured. Before summing the item responses for each domain, two of the items are recalibrated, and the scoring of nine items is reversed so that a higher score always indicates a better health state. If more than half of the components of a domain are missing, the scale score is assigned as missing. If one-half or fewer of the components are missing, the mean of the non-missing items is substituted for each missing component. The SHHS will follow the algorithms in the SF-36 Manual for scoring the individual items and scales. Scoring will be done at the Coordinating Center. The range of scores and their interpretation is given in Table 6.8.4.1 below.

Table 6.8.4.1 Scores and Interpretation

Concepts	No. of Items	No. of Levels	Meaning of Scores	
			Low	High
Physical functioning	10	21	Limited a good deal in performing all physical activities including bathing or dressing	Performs all types of physical activities including the most vigorous without limitations due to health
Role limitations due to physical problems	4	5	Problems with work or other daily activities as a result of physical health	No problems with work or other daily activities as a result of physical health, past 4 weeks
Social functioning	2	9	Extreme and frequent interference with normal social activities due to physical and emotional problems	Performs normal social activities without interference due to physical or emotional problems, past 4 weeks
Bodily pain	2	11	Very severe and extremely limiting pain	No pain or limitations due to pain, past 4 weeks
General mental health	5	26	Feeling of nervousness and depression all of the time	Feels peaceful, happy, and calm all of the time, past 4 weeks
Role limitations due to emotional problems	3	4	Problems with work or other daily activities as a result of emotional problems	No problems with work or other daily activities as a result of emotional problems, past 4 weeks
Vitality	4	21	Feels tired and worn out all of the time	Feels full of pep and energy all of the time, past 4 weeks
General health perceptions	5	21	Believes personal health is poor and likely to get worse	Believes personal health is excellent

*Quality of Life Survey (SF 36) form (12/4/95) inserted here.
Three pages inserted after this page.*



SLEEP HEART HEALTH STUDY

Quality of Life Survey (SF 36)

ID#:

Field Center: _____

Today's date: _____
month day year

This survey asks you for your views about your health. Answer every question by checking the appropriate response. If you are unsure about how to answer a question, please give the best answer you can and make a comment in the left margin.

1 In general, would you say your health is: (Check one box.)

- | | | | |
|-----------|----------------------------|------|----------------------------|
| Excellent | <input type="checkbox"/> 1 | Fair | <input type="checkbox"/> 4 |
| Very good | <input type="checkbox"/> 2 | Poor | <input type="checkbox"/> 5 |
| Good | <input type="checkbox"/> 3 | | |

2 Compared to one year ago, how would you rate your health in general now? (Check one box.)

- | | | | |
|---------------------|----------------------------|--------------------|----------------------------|
| Much better now | <input type="checkbox"/> 1 | Somewhat worse now | <input type="checkbox"/> 4 |
| Somewhat better now | <input type="checkbox"/> 2 | Much worse now | <input type="checkbox"/> 5 |
| About the same | <input type="checkbox"/> 3 | | |

3 The following questions are about activities you might do during a typical day. Does your health now limit you in these activities? If so, how much? (Check one box for each question.)

	Yes, limited a lot	Yes, limited a little	No, not limited at all
a. Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports.	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3
b. Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf.	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3
c. Lifting or carrying groceries.	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3
d. Climbing several flights of stairs.	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3
e. Climbing one flight of stairs.	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3
f. Bending, kneeling, or stooping.	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3
g. Walking more than a mile.	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3
h. Walking several blocks.	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3
i. Walking one block.	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3
j. Bathing and dressing yourself.	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3

4 During the past four weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? (Please check either YES or NO for each question.)

	Yes	No
a. Cut down on the amount or time you spent on work or other activities.	<input type="checkbox"/> ₁	<input type="checkbox"/> ₀
b. Accomplished less than you would like.	<input type="checkbox"/> ₁	<input type="checkbox"/> ₀
c. Were limited in the kind of work or other activities you were able to do.	<input type="checkbox"/> ₁	<input type="checkbox"/> ₀
d. Had difficulty performing the work or other activities. (For example, it took extra effort.)	<input type="checkbox"/> ₁	<input type="checkbox"/> ₀

5 During the past four weeks, have you had any of the following problems with your work or other regular daily activities as a result of emotional problems (such as feeling depressed or anxious)? (Please check either YES or NO for each question.)

	Yes	No
a. Cut down on the amount or time you spent on work or other activities.	<input type="checkbox"/> ₁	<input type="checkbox"/> ₀
b. Accomplished less than you would like.	<input type="checkbox"/> ₁	<input type="checkbox"/> ₀
c. Didn't do work or other activities as carefully as usual.	<input type="checkbox"/> ₁	<input type="checkbox"/> ₀

6 During the past four weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups? (Check one box.)

Not at all	<input type="checkbox"/> ₁	Quite a bit	<input type="checkbox"/> ₄
Slightly	<input type="checkbox"/> ₂	Extremely	<input type="checkbox"/> ₅
Moderately	<input type="checkbox"/> ₃		

7 How much bodily pain have you had during the past four weeks? (Check one box.)

None	<input type="checkbox"/> ₁	Moderate	<input type="checkbox"/> ₄
Very mild	<input type="checkbox"/> ₂	Severe	<input type="checkbox"/> ₅
Mild	<input type="checkbox"/> ₃	Very severe	<input type="checkbox"/> ₆

8 During the past four weeks, how much did pain interfere with your normal work (including both work outside the home and housework? (Check one box.)

Not at all	<input type="checkbox"/> ₁	Quite a bit	<input type="checkbox"/> ₄
Slightly	<input type="checkbox"/> ₂	Extremely	<input type="checkbox"/> ₅
Moderately	<input type="checkbox"/> ₃		

9 These questions are about how you feel and how things have been with you during the past 4 weeks. For each question, check the box for the one answer that comes closest to the way you have been feeling.

During the past 4 weeks, how much of the time...

	All of the time	Most of the time	A good bit of the time	Some of the time	A little of the time	None of the time
a. Did you feel full of pep?	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5	<input type="checkbox"/> 6
b. Have you been a very nervous person?	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5	<input type="checkbox"/> 6
c. Have you felt so down in the dumps that nothing could cheer you up?	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5	<input type="checkbox"/> 6
d. Have you felt calm and peaceful?	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5	<input type="checkbox"/> 6
e. Did you have a lot of energy?	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5	<input type="checkbox"/> 6
f. Have you felt downhearted and blue?	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5	<input type="checkbox"/> 6
g. Did you feel worn out?	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5	<input type="checkbox"/> 6
h. Have you been a happy person?	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5	<input type="checkbox"/> 6
i. Did you feel tired?	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5	<input type="checkbox"/> 6

10 During the past 4 weeks, how much of the time has your health limited your social activities (like visiting with friends or close relatives)? (Check one box.)

All of the time	Most of the time	Some of the time	A little of the time	None of the time
<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5

11 Please choose the answer that best describes how true or false each of the following statements is for you. (Check one box for each statement.)

	Definitely true	Mostly true	Not sure	Mostly false	Definitely false
a. I seem to get sick a little easier than other people.	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
b. I am as healthy as anybody I know.	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
c. I expect my health to get worse.	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
d. My health is excellent.	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5

Field Center Use Only	<input type="checkbox"/> 0 Self administered	<input type="checkbox"/> 1 Interviewer administered
Interviewer or Reviewer _____	Date: _____	
	month	day year

6.9 PSG Study

6.9.1 Overview

6.9.1.1 Definition of Sleep Apnea

Sleep Apnea (also referred to as obstructive sleep apnea syndrome, sleep apnea hypopnea, sleep disordered breathing) is a condition characterized by loud disruptive snoring, snorting/gasping (during sleep), and daytime sleepiness. These symptoms result from abnormal breathing during sleep occurring as a result of intermittent and repetitive (>5 hour) apneas or hypopneas. Risk factors for sleep apnea include obesity, mandibular retrognathia, tonsillar hypertrophy, macroglossia, male gender, older age, and family history of sleep apnea. Prevalence is estimated at 4-9% in middle-aged subjects, and >25% in older (>65 yrs) subjects. The consequences of sleep apnea are related to: snoring, sleep disruption, and irregular breathing. These, in turn, are thought to cause sleepiness, fatigue, and neuropsychological deficits. Hypoxia and sympathetic activation that occur in association with breathing irregularities are also thought to contribute to the pathogenesis of hypertension, and cardio- and cerebrovascular diseases. However, there remains great controversy whether these associations are causally related, or rather have occurred as a result of confounding.

6.9.1.2 Polysomnography

Evaluation of sleep apnea in clinical settings usually requires **polysomnography**, a procedure in which an individual is monitored, usually for an entire night in a sleep laboratory, with a **polygraph**. There are three types of signals that are collected:

1. Bioelectrical Potentials. These are produced by the body's own tissues.

Examples:

- electroencephalogram (EEG) (brain waves)
- electrooculogram (EOG) (Eye movements)
- electromyogram (EMG) (muscle activity)
- electrocardiogram (ECG) (heart rate)

2. Received from Transducers. These are devices that translate non-electrical physiological activity (e.g., temperature, movement) into electrical signals.

Examples:

- thermistors/thermocouples (measure airflow in response to temperature changes)
- inductance respiratory bands (measures chest/abdomen effort in response to movement position sensors)

3. From Auxiliary Devices. These are specialized devices that are used with the polygraph to translate other signals into physiologic data.

Example:

oximetry (measures hemoglobin oxygen saturation)

The respiratory irregularities which are the focus of the SHHS are **apneas** and **hypopneas**.

An apnea is a complete or almost complete cessation of airflow, lasting ≥ 10 seconds, and usually associated with desaturation or an arousal.

A hypopnea is a reduction in airflow ($< 70\%$ of a “baseline” level), associated with desaturation or arousal.

Events (apneas or hypopneas) are also classified on the basis of the extent of the associated respiratory effort. “**Obstructive**” events (the most common form in sleep apnea) are associated with chest and/or abdominal respiratory effort (occurring in face of an obstructed throat (upper airway)). “**Central**” events are associated with insufficient or highly irregular breathing efforts; an obstructed upper airway may or may not be a feature. This breathing pattern may be seen in heart failure and after strokes.

With disorders such as sleep apnea, **sleep architecture** (the progression and distribution of sleep stages) may be disrupted. The stresses associated with breathing through a blocked or partially blocked throat cause abrupt changes in brain activity (arousals), sometimes waking up the person, and other times, moving him/her to a lighter sleep stage (e.g., Stage I). This often results in shorter total sleep time and reduced slow wave (III/IV) and REM sleep. Often, this *sleep deprivation and fragmentation* results in daytime sleepiness and poor daytime functioning.

Thus, accurate recording of these events requires measurement of airflow, oxygen saturation, respiratory effort, and EEG, EOG, and EMG, as summarized:

EEG, EOG, EMG. Provides the information necessary to determine whether the breathing irregularity occurred in wakefulness or sleep. EEG (and ECG) provide information for identifying **arousals** (which may be the physiological response that identifies the event as abnormal).

Airflow. Qualitative assessment of breathing amplitude. Often measured with changes in temperature that occur with breathing as measured by a thermistors or thermocouples placed in the pathway of airflow (nose and mouth).

Respiratory Effort. Qualitative assessment of effort associated with breathing (allows distinction of central from obstructive events). May be recorded with bands that measure changes in distention/movement with breathing (inductance bands, piezoelectric).

Oximetry. Measures oxygen saturation levels in the blood by passing light through the finger and measuring absorption patterns (made by the oxygen carrying pigment -- hemoglobin -- in the blood).

Other important information that is measured:

Body Position. To distinguish supine, upright, and side positions. This permits identification of the extent to which sleep apnea is **positional**.

Heart Rate. Allows assessment of heart rate responses to breathing-related stresses, and arrhythmia detection.

In the SHHS, we will use very advanced technology (Compumedics SleepWatch PS) that permits recording this information in an unattended setting (the participant's home) with portable equipment.

6.9.1.3 System Overview

The Compumedics Portable Sleep Unit is composed of:

1. A Main Unit. This is the unit that is brought to the participant's home. It receives all of the signals traveling from the sensors (attached to the participant), and stores them in a tiny computer (a PCMCIA flash card). It also contains a power supply (a 15 hour rechargeable battery), a LED display for visualizing signals (after hook-up), and an impedance meter for checking the adequacy of the electrical contacts for recording EEG, ECG, EOG, and EMG.
2. A Participant Interface Box (sometimes referred to as a "headbox"). This device is embedded in a pocket in a special vest that also is brought to the participant's home. It is the device that contains amplifiers and filters for proper processing of the physiological signals. All electrodes and probes, other than the oximeter, are connected to this device. The processed signals from this box are sent to the Main Unit by an Analogue cable.
3. A special vest and sensors. The vest is a specially designed garment that is worn during sleep monitoring and holds the headbox, secures the chest and abdomen belts, and secures electrode wires and cables. It is designed to improve the comfort of overnight monitoring, minimize the number of visible wires, and improve mobility.
4. A computer and software for preparing the PCMCIA card, and for reviewing and transferring data. This computer is based in the area in your office, clinic or hospital where you prepare and process the sleep records. It is not brought to the home.
5. A battery charger (for the clinic).
6. A calibration unit (for the clinic).

6.9.2 Methods

6.9.2.1 The Setting

Ask to see the sleeping quarters to identify any problems (e.g. where will the recording device sit?). This will also help you to determine on which hand the oximeter should be placed (e.g., closest to a bed table, or the non-dominant hand).

Set up can be done in any comfortable chair. Many people will be comfortable with having the hook-up performed in the kitchen. Clear a flat surface area to set up supplies (kitchen table, dining room, etc.). Set all materials on a tray and position it for easy access. Have the participant sit close to your supply tray during hookup. Place a cover (e.g., a towel) over the back of any finished or upholstered furniture to avoid stains from the various electrode creams. Make sure you have easy access to participant's head, chest, etc.

If the participant has not taken a shower (24 hrs) prior to your arrival, ask him/her to wash his/her face and chest with soap and water before applying electrodes. Explain that the electrodes will adhere better and a better study will be produced if the skin is cleansed in this manner.

6.9.2.2 Sensor Placement

Proper sensor placement is very important for effectively recording sleep patterns. Because you will be connecting the sensors to the patient, you should become familiar with each sensor and learn how to correctly place and connect them. All sensors should be labeled to simplify their identification and connections.

[Note: When connecting the sensors, be sure to hold the sensors by the ends, **not** by the wires. For cleanliness, also use latex gloves when applying electrodes.]

Below are general rules for good sensor placement:

1. Have subject shampooed, shaved, showered and in bedclothes
2. Prep only areas of skin that electrodes cover
3. Clean thoroughly, but don't inflict pain!
4. Use only small pieces of tape
5. Provide for "stress" in wire/cables
6. Secure loose cables/wire with tape
7. For elements that require participant's hook-up, have subject demonstrate ability to place/replace/remove sensors (use a mirror if necessary)
8. Use non-dominant hand for oximeter placement

You will use 12 electrodes (2 ground [PG1 and PG2], C3 , C4 , A1, A2, left EOG, right EOG, 2 chin EMG, and 2 ECG (snaps).

You also will be using a vest, abdomen and chest belts, an oximeter and a thermocouple.

Suggested order of placement:

1. Put sleep vest on participant with thoracic and abdominal belts in place. (Secure headbox in anterior or posterior pocket of vest.)
2. PG2 (driven) Ground Cz (central scalp) *
3. C4 (connected to EEG1) Central Right EEG
4. C3 (connected to EEG2) Central Left EEG
5. A2 (mastoid) (EEG2) Right Reference for C3
6. A1 (mastoid) (EEG1) Left Reference for C4
7. Ground (forehead) PG1 Ground (for EOG)
8. Right EOG Below right outer canthus
9. Left EOG Below left outer canthus
10. Chin EMG (2) Submental EMG
11. EKG (2) Below right and left clavicles
12. Oximeter & Thermocouple Should be placed last on the subject, or subject should be shown how to place these, if needed

* Alternative site: behind, below A1 (left mastoid) (if sleeps on right side) or behind below A2 (right mastoid) (if sleeps on left side)

[NOTE: Bioelectric signals are based on differences in potentials between 2 points (positive and negative). Thus, each measurement (EEG, EMG) requires the use of 2 electrodes referenced to each other. EEG1 should link C4 and A1; EEG2 should link C3 and A2). Electrodes that are “positive” are marked in red; and “negative” in black.]

STEP 1: PLACE RESPIRATORY BANDS

Respiratory bands (Yellow lead is connected to the chest band, and blue lead to the abdomen band.)

Place the chest band (enclosed within a nylon sheath) (with the **yellow** lead wire facing up) under the armpits, above any pendulous breast tissue. The stretchy material should extend minimally from the mid back to the mid front (around the left). Adjust the black extender belt so the belt is secure, but not tight. The abdominal band should be around the umbilicus (belly button), (or, if this position is not possible, **below** the lower edge of the rib cage), so that the **blue lead wire faces upward**. Ensure the respiratory bands are attached firmly around the participant but the bands do not restrict the participant’s comfort or breathing. Incorrect application of respiratory bands can cause very poor signals.

STEP 2: POSITION VEST (BIB DESIGN)

Ask the participant what position he usually sleeps in (front, back, sides, etc.) to ascertain whether the headbox should be on the front or back of the vest. If the participant routinely sleeps primarily on his sides or back, place the headbox in front rather than in back (it is much easier to hook up while the participant is sitting); if he sleeps predominantly on his front, use the back pocket. After positioning the abdominal and thoracic bands, undo the velcro straps on the side of

the sleep vest and have the participant put the vest on over his head (placing the pouch on either the front or back, according to participant's sleeping position). Before securing the side velcro straps, pull the wires to the abdominal and thoracic bands through the back buttonhole on the vest pouch and place them inside the pouch. Use a rubber band or twisty wire to bind the wires together in the pouch, or they can get tangled in the rest of the equipment.

Secure the side velcro straps, using the extenders if necessary for large girth. Adjust the velcro shoulder straps so that the pouch of the vest is breastbone level (in front), or bottom of the shoulder blade (in back). If a participant has an extremely long torso, the extender straps can be used at the shoulders also.

Make sure that the side velcro straps are as tight as comfortably possible, because the weight of the headbox has a tendency to pull the vest pouch down, bringing the opposite side uncomfortably close to your neck. If the bottom straps are secure, this does not happen as easily.

Put the foam rubber in the vest pouch and then the PIB inside of the foam rubber (folded side at the bottom of the pouch). Secure the velcro of the pouch halfway up and then attach the PIB cable, bands, and LDR/Mic to the headbox. The LDR/Mic should be pulled through the button hole on the front of the pouch. Be sure that the light sensor is exposed. Position the PIB so that the wires point up toward the participant's head. Unwrap the lead wires and lay them over the left shoulder and then close the velcro on the pouch completely (except for a small space where the wires come through!).

Overview of electrode and sensor placement:

First attach the leads to the head, mastoids, forehead and eyes as described below, bringing all wires into a ponytail (temporarily secured with a posey wrap) at the back of the head. Attach the EMG leads to the bottom of the chin, loop the wires up and over the ears and secure in the ponytail. Attach the right ECG lead to the chest, run the wire up over the shoulder and secure into the bottom of the ponytail. Attach the left ECG lead to the chest and run the wire over the left shoulder and into the bottom of the ponytail. (*Tip: This works better than running the ECGs down to the pouch from the chest because it uses up some of the excessively long ECG wires and keeps them from getting tangled and feeling bulky in the vest pouch.*) Attach the oximeter as usual. Then attach the thermocouple which is secured with tape on the cheeks, looped over the ears and secured into the posey wrap at the back of the head.

When all leads and the thermocouple are secured into the ponytail, remove the posey wrap, smooth out the wires and wrap a small piece of transpore tape around them in a spiral motion, securing them about every 4 inches. This creates a "rope" of wires which should be easy to manipulate and secure. Open the shoulder pocket on the left side and lay the "rope" inside, closing the velcro firmly.

If the pouch is in the back, bring the wires up from the headbox, attach the wires as above, secure in a "rope," and run through either shoulder pocket. (Running the wires through the pockets uses up some of the length of the wires and minimizes overfill of the pouch, which can be bulky and heavy.) Pull enough "rope" out of the shoulder pocket to allow plenty of slack at the base of the neck. Before feeding the remainder of the wires (not in the cable) into the pouch, perform the

position and light sensor calibrations (see below). Now feed the remaining wires into the pouch around the headbox as neatly as possible and secure the velcro for the last time.

STEP 3: APPLY ELECTRODES

Application of Electrodes

General comments about electrode placement: Good electrical connections are required. This requires the skin or scalp to be as clean as possible and free of oils, etc., that interfere with electrical conductivity. Conducting gel or cream is also required to form an interface between the subject and electrode. The snap electrodes have a gel pre-embedded on their surface. The cup electrodes require application of a conductant cream (Elefix). The adequacy of the electrical connections can be tested with an **impedance meter**, which tests the electrical resistance through the given circuit. All electrodes also need to be placed in correct position and secured well.

Preparation of skin or scalp

First, identify the point of attachment. For the scalp, use hair pins to separate hair to reveal underlying scalp, as needed. Using an Alcohol Prep Pad or Electrode Prep Pad, clean spot by rubbing back and forth for several seconds. (If sites other than near the eyes are very oily, use an Acetone-Alcohol Prep Pad.) Apply a small amount of OmniPrep or NuPrep on the tips of two cotton tipped applicators held together. Holding the applicators at a 45 degree angle, now clean the electrode site by rubbing lightly using a small circular motion (NO bigger than the size of the electrode). Next wipe off OmniPrep with a dry gauze pad using a few brisk quick motions.

[NOTE: Pay attention to participant's skin sensitivity. You do not want to overscrub, causing subject severe discomfort or injury to the skin. If the subject reports sensitivity, skip the Omniprep step, and only use soap and water.]

Attachment of Electrodes (Cup Method)

Hairy areas (scalp, bearded chin): Scoop a small amount of Elefix cream into the cup of each electrode (fill but not overflow; no "holes"). Place the electrode against the skin. Place a small quantity of EC2 cream on a pre-cut gauze (1"x1"). Cover the electrode with the gauze square. Press firmly around rim of electrode cup to insure a good seal, pressing towards the cup. (Do not press down on electrode; this may hurt and cause seepage of cream.) Hold in place until it begins to dry (feels secure).

Skin (near eyes, mastoids, forehead, non-bearded chin): Scoop a small amount of Elefix into the cup and apply to area, as above. Cover the electrode with a pre-cut (1x1□) gauze adhesive (Hypafix, Medipore, or Cover All). Press around electrode with wire pointing upward toward the top of the head.

Identifying EEG Placement Sites

The attachment process for placing sensors on an adult patient will follow the 10-20 electrode placement system. The 10-20 electrode placement standards were developed to provide consistent application of EEG sensors for collection of brain wave data. This system is based on measurements from 4 standard points on the ear, the nasion, inion, and left and right preauricular points (see Glossary in PSG Training Manual for definitions).

C3 and C4 are symmetrically placed on either side of the center of the top of the head. To find the exact points follow this procedure: Measure from the bridge of the nose (nasion) to the small bump on the back of the head just at the base of the skull (inion). If you have trouble finding this bump, ask the participant to tilt his head backward. Halfway (by tape measure) between these points, mark point with a wax pencil. [NOTE: If using a red pencil, warn participant that the red is a washable marker, not blood!] Next measure distance just in front of the ear (pre-auricular point: the bony prominence just in front of each ear canal) that passes through the previously measured point. (The pre-auricular point can be identified by having the participant open and close his mouth, feeling for the ridge that moves.) Mark half of this distance with wax pencil, perpendicularly to tape. **Cz** is the place where the two marks cross. Next, take 20% of the total distance between the ear points and measure down to the left and right of Cz. These point are marked as C3 (left) and C4 (right).

If a SHHS tape measure is available, you may do the following:

Identify and mark Cz as described above. Select the C3/C4 tape that corresponds to the pre-auricular-pre-auricular distance. Run this tape just in front of the middle of the ear, through Cz, to the corresponding point on the other side of the ear. Mark C3 (left side) and C4 (right side) accordingly through pre-punched holes. Mark spot with a wax pencil.

[Note: When marking Cz, C3 and C4, use very large X's (2-3 cm long), so that these marks will remain even after cleaning center during electrode skin prep procedure.]

[Note: When measuring, always round up to the nearest one cm (e.g., 33.25, 33.5, and 33.75 would all be 34)].

Ground 1 (driven ground) (preferred site): is placed on **Cz**. If scalp is sensitive, or scalp impedance high, may use **alternative site**. This is directly behind and below the mastoid on the side of the neck the participant reports he spends the least amount of the time sleeping against.

C4 (right central EEG) and C3 (left central EEG) (scalp) electrodes: Placed on either side of Cz as described above.

A1 (left) and A2 (right) are placed over the bony prominences just behind each ear.

[NOTE: Be sure that the lead used for C4 is paired with the one for A1 (EEG1), and that C3 is paired to A2 (EEG2).]

Ground 1 (eye reference) is placed on the center of the forehead, above the bridge of the nose (nasion).

Right EOG is placed so that the electrode center is one cm out and one cm down from the outer corner (canthus) of the right eye, on the bony ridge.

Left EOG is placed so that the electrode center is one cm out and one cm down from the outer corner of the left eye, on the bony ridge.

Chin EMG electrodes (2) are placed on the lower chin, separated by about 1- 2 cm, in areas that are relatively hair free. Choose a site on the lower chin (above or below jaw line) that appears most stable: relatively hair free, near a bony ledge. The *preferred site (if stable)* is directly under the edge of the lower jaw, 1 cm to the right and left of the midline (chin tip).

Alternative sites (if bearded): On chin surface, halfway down from the lips, in area supported by a bony ledge, or over the masseter muscle. This muscle is near the angle of the jaw, where you feel the muscle tense when the subject clenches his jaw.

[Note: Make sure the lead wires from all electrodes point upward and backward (toward top of head); this will relieve tension on wires.]

STEP 4: ECG PLACEMENT

Attachment of the ECG Electrodes

Remove electrode from sealed package (e.g., Medtronic Medclear ECG electrodes). Snap electrode to lead wire **before** applying to subject's skin. Position each electrode 3-5 cm below the middle of the right and left collarbones, in spaces between rib bones. The red electrode should be placed under the left collarbone, and the black under the right collarbone. Place gel electrode on cleansed sites, with gel side down. Form a small "stress" loop with the wire immediately feeding the electrode, taping it with a small amount of tape.

*Illustration **Electrodes Placement** inserted after this page.*

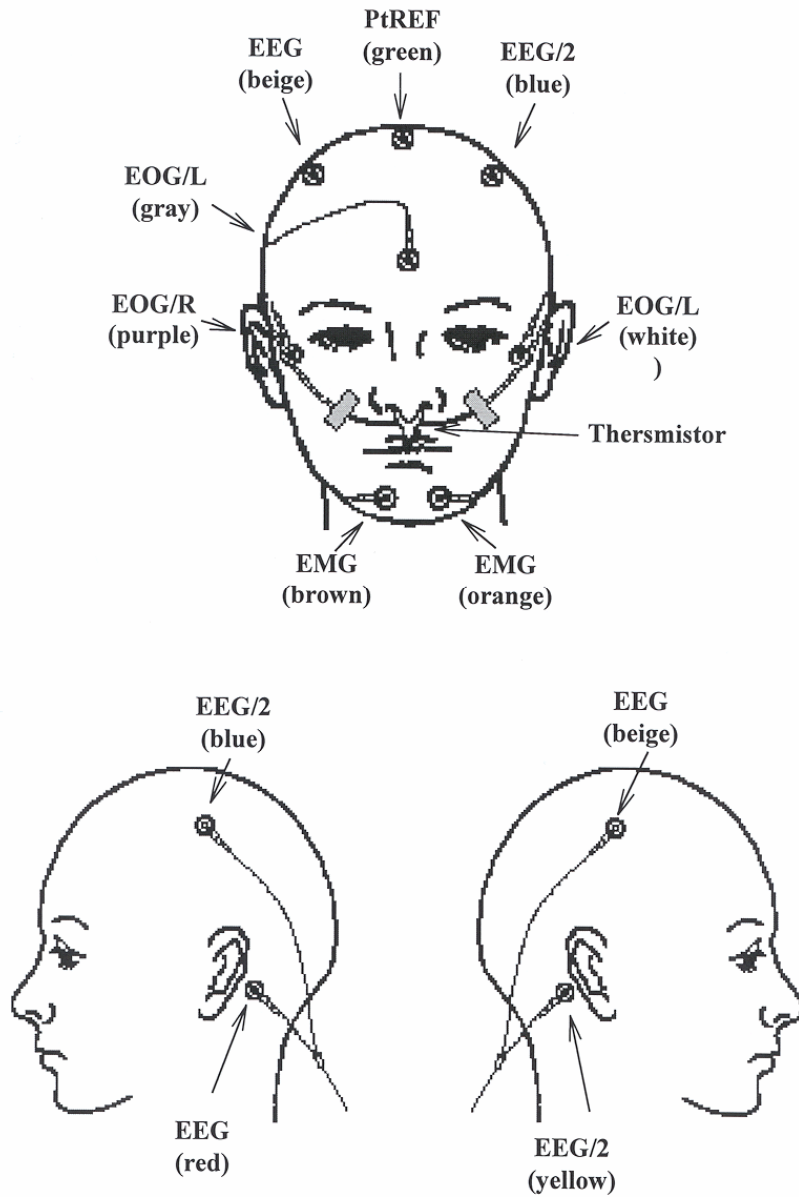


Diagram of Electrode Placements

STEP 5: OXIMETER

The finger oximeter records pulse and oxygen saturation using a small light shined through the finger. Oximeter should be placed on the ring finger of the non-dominant hand. (If large rings are worn, may use the middle or index fingers.) Nail polish must be removed from this finger.

Directions for disposable probe: Grip the tab on the sensor's bottom adhesive cover and peel the adhesive cover off. Place the finger into the sensor nail-side up with the tip of the finger against the center line mark in the curved area. Wrap the tape firmly around the finger. The fingernail should not be covered with tape during this step. Fold the sensor's top over the top of the finger and make sure the sensors are vertically aligned. Do not stretch the tape while applying the sensor. This may cause inaccurate readings or skin blister. Be sure that the emitting and receiving diodes directly "face" each other.

Directions for non-disposable probe: Place probe, white side against adhesive, on the surface of a piece of gauze tape cut so that its width extends approximately .5 cm on either side of the probe (placed in the middle of the tape), and its length is approximately 1 cm longer than each top and bottom edge of the probe. Place the probe (covered with this tape) over the top of the finger with light sensor nail side up. Be sure that the receiving circle directly "faces" the light emitting circle. Place a second piece of gauze tape around the probe (perpendicular to the first tape), spiraling the tape so the beginning and end are displaced about .5-1 cm. This prevents perfusion problems to the finger. To further secure, place posey wrap around sensor/finger, so that sensor is securely in place but not tight.

After securing oximeter sensor, ask the participant if any throbbing is felt. If so, reapply, loosening tape.

Pass the oximeter cable over the surface of the hand, creating a circular "stress" loop, also securing with tape. Use several additional pieces of tape along the hand and lower arm, securing loose areas of cable (to prevent the cable from getting tugged.) Check that the participant can move/bend his hand in all directions; if not, reapply, with more "slack" in the cabling.

STEP 6: THERMOCOUPLE

These are made of temperature sensitive wires which are positioned directly in the flow of air.

Directions for the EPMS (green disposable thermistor): Choose the medium or large size -- the tabs should sit directly under each nostril, in the path of air, but not jut into the nose. Connect the disposable probe to the wire from the headbox by gently sliding the square end into the thermistor receptacle. (The black lines should face away from the participant.) Position the two prongs in front of the nares and a second prong in front of the mouth, as close to the lips as possible, but not touching either the lips or inner surface of the nares.) Secure in place by looping wire around ear and taping ends over cheek and across sensor.

Directions for use of the disposable Pro-Tec thermistor: Place cardboard surface above the upper lip, with the two wires facing upward, and one prong downward. Gently bend the upper wires so they point to the nose (directly into the path of airflow) but do not jut into the nose. Bend lower prong so that it points over the mouth, but does not touch the lip. *Tip: Ask the*

participant to blow out while you hold your two fingers in front of his nose. Reposition the wires so that they point directly at the points of maximal airflow. Secure wires over each ear, using a small piece of tape to secure in place.

Note: The thermocouple is sensitive to displacement or moisture. Before leaving the house, show the participant (in a mirror) and/or a family member how the thermocouple should be positioned. Show the participant how to readjust this, if needed. Warn him to try and keep his upper lip dry.

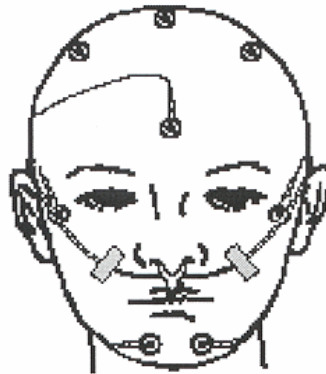


Illustration Air Flow

STEP 7: BODY POSITION

A mercury gauge, sensitive to changes in position, is embedded in the headbox. No special attachment is needed.

6.9.2.3 Checking the Signals

After hook-up, you will test the quality of each signal from each electrode or sensor. You will check the impedance of each EEG, EOG, ECG, and EMG sensor. You will also be able to check the quality/accuracy of the tracings or values of the signals. You will record the results of your impedance and signal checks on a **Signal Verification form (below)**.

Impedance Checks:

For EEG, EOG, and EMG, you want to achieve impedances of < 10 kohms, and a difference between the two paired electrodes (e.g., C4 and A1, C3 and A2) is < 5 kohms. (< 5 kohms, however, is optimal.) Impedances of < 40 kohms are acceptable for ECG. When recording a high impedance, first check that the system (all cables) are connected and electrodes are secured in place.

1. If any electrode (other than ECG) is > 10 kohm, or the difference between any pair of electrodes is > 5 , remove the electrode and re-prepare the electrode site.

2. If on a second placement, impedance is still high, there are two possible problems: a) the area of the skin identified for sensor placement has an unusually high impedance; or b) the lead wire or sensor is damaged. Therefore, attempt to address both potential problems by choosing an alternative electrode site (e.g., immediately adjacent to previous site, or use of one of the alternative sites indicated above), and change lead wires.
3. If impedance is still high on a third attempt do not attempt to re-prepare area. Document your activities on the **Signal Verification** form.

Procedures for Checking Card Initialization, Signal Viewing, Impedance Checks, and Calibration:

1. FIRST, check to see that the memory card is properly inserted into the Main Unit.
2. Then check Participant Data and Battery Charge:
 - a. Connect cable from headbox to middle right side of recorder.
 - b. Turn the power switch on located at bottom left side of recorder. The unit will go into a self-test mode. You should see a series of (3) "OKs." (Note: *If 2 beeps sound, an error occurred. Turn unit on and off again and re-try. If still a problem, study may need to be aborted unless a spare unit is available.*)
 - c. Wait 2 minutes for pulse oximeter to initialize.
 - d. At the MAIN menu, select PATIENT. Ascertain that the following information is correct:
 - i. That the participant ID displayed on the LED screen matches the Participant ID on all paper forms and is correct. If the ID on the monitor and the ID on the front of the signal verification form differ, the technician must immediately determine which is correct. If the flashcard is correct, all the forms from the home visit must be changed; if the paper forms are correct, note the error on the Signal Verification Form and tape a note to the monitor, so the error can be corrected in the morning. You will need to correct this information during in-clinic data *retrieval (described under procedure for correcting ID during data retrieval process)*.
 - ii. The Tech ID is correct (your ID).
 - iii. The monitor ID corresponds to the monitor ID affixed to the PIB and monitor, and is the correct ID written on the Signal Verification Form.

- e. Check Battery Charge: Select Options (Main Menu). Press OK. Check that the voltage recorded in upper right hand corner of screen reads $> 7V$. If less than this, use spare battery. If a reading of $0.3V$ is obtained, your unit may be faulty and may need to be returned to Compumedics for repair.
3. Adjust the offset for each channel:
 - a. From the Main Menu select OPTIONS \square ADJUST OFFSET
 - b. Use [Next] to select each channel and [Offset] to adjust

4. Check impedances and signal quality:

You will now use the function keys on the Main Unit to select each channel, one at a time, and check the impedance and tracing quality.

At the Main Menu, use the UP and DOWN buttons to move the cursor to CHANNEL. Select OK.

Hit NEXT to advance to Channel 3 (EEG).

- a. Use UP and DOWN button to move the cursor to Impedance. Select OK.
- b. Check that Impedance is < 10 kohms (or 40 for ECG). If impedance is high, re-prep/re-apply applicable sensors (as described above), select BACK and then select Impedance again. Continue until impedance is < 5 kohms. Then select "OK."
- c. Once Impedance is acceptable, hit NEXT button to advance to next channel (or directly proceed to VIEW signal - see 6).
- d. Repeat Impedance checks for all applicable channels.
- e. Press NEXT to return to Channel 3.
- f. Use UP and DOWN to position cursor arrow to VIEW CHANNEL - Select OK.
- g. View tracing quality.
*Each View Channel window is 2 screens wide. Use --> and <--- to page forward and back. Screen one allows for gain change (middle button) and screen 2 allows for speed change. Note that changing gain and speed does not change the data signals that are captured, only the present view.
- h. Select NEXT to continue viewing all channels. The NEXT selection is on the right screen.

5. Viewing Signals:

This is to further check that sensors have been applied correctly and are functioning.

Note: if you encounter difficulty viewing signals (i.e., not centered or signal appears to be off the screen) you can use Offset Adjustment (if the channel has an offset) to center the trace so you can view it more clearly. See Instructions on using Offset Adjustment located in the Reference Section of the PSG Training Manual.

- a. EOG (right and left):
Ask the subject to move eyes up and down and back and forth and make sure eye movements are clearly displayed (as sharp up and down deflections).
Check for the absence of a thick fuzzy line (>3mm high).
- b. EEG (C3/A1, C4/A2):
Check for the absence of a thick fuzzy line (>3mm high).
- c. ECG:
Check for the absence of a thick fuzzy line (>3mm high).

[NOTE: If "Noise" is seen on the electrode (EEG, EOG, EMG channels, first check the integrity of the wire lead. If OK, then first reapply the ground electrode. If still a problem, recheck impedances, reapplying any electrodes with impedances > 5 kohms (trying to improve signal quality). If still present, exclude electromagnetic interference by having the subject turn in different directions, viewing change in signal quality.]

- d. Airflow:
Ask the subject to take a few deep breaths; check that deflections are seen with each breath. If not, reposition sensor. If still a problem, replace sensor with new sensor.
- e. Respiratory Bands (chest and abdomen):
Ask the subject to take a few deep breaths; check that deflections are seen with each breath. If not, reposition bands.
- f. The oximeter (and heart rate):
*NOTE: these channels only display a value -- channel 1 is oxygen saturation; channel 2 is pulse.

These are the channels that also provide information that will be used to identify Immediate or Urgent Referrals (see Section 6.10, Medical Alerts).

The adequacy of the oximeter reading will be assessed by:

- Checking that oxygen saturation reads “GOOD.” A reading of “POOR” or “MARGINAL” indicates that the pulse reading is poor, probably due to poor placement or an overly tight probe. Sometimes, a poor or marginal reading will occur during movement. If so, wait 10 seconds and recheck. If still poor, replace sensor.
- Checking that the reading appears reasonable (>88%). If <88%, reposition, wait 2 minutes, and re-record. If abnormal on a second try, apply to your own finger. If signals correct (>88% sat and correct heart rate), try again on a different finger and/or switch probes. If still abnormal, see Medical Alerts (below).
- Checking that the pulse from the oximeter agrees with a pulse that you will manually check. Take subject's pulse at his/her wrist (count the beats per 30 seconds, multiplying by 2 to get the minute pulse). Compare this with the display. If the displayed HR differs by > 5 beats per minute from the pulse recorded at the wrist, reposition sensor. If HR >120 or <30, record for 2 minutes. If HR over 2 minutes >150, see Medical Alerts.

6. Performing Calibrations:

*The signals from two sensors -- **position and light** are not only checked, but are calibrated.* To do this move the -- UP -- TO CALIBRATION MENU

Position Sensor:

AT CALIBRATION, Select POSITION by advancing to Position and hitting OK.

- a. Move the cursor to FRONT.
- b. Manipulate the headbox to be in the position that would represent the patient lying on his/her stomach.
- c. Hit OK...note the number in the upper right corner.
- d. Wait 10 seconds and hit OK again. Compare the number in the upper right corner to the previous number.
- e. Repeat until the numbers are consistent.
- f. Hit CAL.

- g. Repeat for all other positions.

Note: As the last position is calibrated, you will be returned to the Calibration Menu.

Calibrating the Light Sensor:

You will need to do this in the room that the participant plans on sleeping in (ambient light conditions may differ from room to room). At this point, explain that you need the monitor to sense the light of the room he/she will be sleeping in. After entering the room, ask the participant to adjust the lights to reflect the brightness of the room before he/she actually turns off the lights for bed.

AT CALIBRATION, press LIGHT.

Use the down button to move the pointer to LIGHTS ON.

Click OK.

Then ask the participant to shut off any lights that will be turned off at bedtime (e.g., night lights that are left on should be left on at this time).

Now click OK for Lights OFF.

Click DONE.

NOTE: If possible, it is during this bedroom check that re-checking for any displacement of the chest or abdominal bands is recommended. Ask the participant to lie on the bed. Check that the respiratory bands still feel secure (have not loosened) while the participant is recumbent. If they have loosened, tighten.

7. Begin Recording

After all signals are checked:

Select the BACK option once or twice to return to the main menu.

- a. Use UP and DOWN buttons to move cursor to "Patient." Select OK.
- b. Check to be sure participant information is correct.
- c. Select "BACK" to Main Menu.
- d. Use "UP" and "DOWN" buttons to move cursor to "Recording." Select "OK."
- e. Select "START RECORDING."
- f. Enter start time. This should be one half hour earlier than participant reports his usual bedtime to be (or his planned bedtime this evening). Select "OK."
- g. Enter END time. This should be two hours later than participant's usual wake time (or his planned wake time for the following morning).

IMPORTANT: The first generation software requires that the portable must be manually returned to the Main Menu for the AutoRecord to work. While the portable automatically reverts back to the Main Menu screen after 5 minutes of being idle, the autorecord function and date/time are not activated. The autorecord times are not displayed on the screen and the date/time does not update.

When autorecord is being used, the technicians must manually exit from the set start and end time screens, and ensure the autorecord times are displayed on the screen before they leave.

- h. Select "YES" to begin recording.

6.9.2.4 Documenting Hook-up Procedures

A log of key events related to the in-home procedures will be kept by the technician. Data from this document will be used to monitor the technical aspects of the study (time requirements, adequacy of hook-ups, etc), will be used to identify and document Immediate and Urgent Referrals, and will provide information that may be useful for "trouble-shooting" bad studies (e.g., impedance checks).

This form includes the following:

1. Time of arrival (to home)
2. Time of departure (from home)
3. Notation for presence of living conditions that might influence sleep quality (usual sleeping quarters; number of people in sleeping quarters, presence of unusual noise, extreme temperatures, etc.)
4. The values of oximetry and heart rate noted during hook-up
5. The values of the impedances for each channel.
6. Confirmation of calibration of light and position sensors
7. Notes on any problems during hook-up and whether hook-up was completed.

6.9.2.5 Final Sensor Equipment Check

Now that you have ascertained that all sensors have been properly applied, you will need to check that everything is secured -- both to guarantee that leads won't be lost during the night as well as to maximize the participant's comfort and mobility.

1. Make sure that all lead wires on the face and scalp point up and back towards the top of the head.
2. Secure all face and scalp lead wires and cables through the loops and pockets in the vest. Note the wires from the face and scalp should be pulled away from the face, draped to back of subject's head, with enough lag to prevent them from being pulled out but not so much as to restrict head movement. (Check by having subject move head back and forth and ascertaining that sufficient freedom of movement exists.) Gather all leads into a "pony tail" on top of the head. Secure with several pieces of tape (with a small edge folded down to facilitate removal) that encircle wire pony tail (at the origin of the pony tail, and mid-way along its length).
3. Use "stress" loops as needed. These are small loops made near the sensor that act to buffer any pull on the sensor. Use on the dorsum of the hand (for the oximeter), and on the upper chest for the ECG. They may be used elsewhere (especially in people who report fitful sleep), but be careful to use minimum tape on the face.
4. Check the following:

Re-check the oximetry signal: is the probe still giving the same reading as during initial hook-up?

Check that the respiratory bands and thermocouple are still secure and in place.

Re-check the battery charge: be sure that it reads $> 7 V$.

6.9.2.6 Leaving The Home

If it is early in the evening, or the subject wishes to remove the thermistor before bed, instruct him carefully on its reapplication at bedtime, providing him with a written reminder to reposition it at bedtime. (Try to discourage this, offering him a straw to use for drinking.)

Carefully check that the subject understands all aspects of the study, knows how to move about with the recording unit and/or connect/disconnect it for bathroom trips. Review written materials (containing these instructions). Walk around the participant's living area. Be sure that he/she feels comfortable moving about with the equipment.

Discuss any potential problems with any interested family members who can be enlisted to help with any sensor adjustments that may be needed.

Provide the subject with the telephone number of an on-call technician who could answer any questions should they arise

Confirm the time of the morning pick-up. **Ascertain the participant's preference for removal of electrodes and sensors: self-removal or by a study technician. If the former is chosen, be sure to clearly instruct the participant on all aspects of sensor removal. Stress that all sensors should be held by their ends and not their wires. Ask the participant not to discard anything, but to pack all equipment and accessories in the carrying case.**

Clean up, leaving the area as neat as it was before your visit. Take any rubbish with you.

If you will not be picking up equipment in the morning, provide the participant with the name(s) and description(s) of the personnel assigned to this task.

Tip: If a male participant reports the need to make frequent trips to the bathroom, consider providing a hand held urinal for bedside use.

6.9.2.7 Morning Pick-Up

Be prompt! Many participants have a busy morning schedule and will be quite distressed if you are delayed.

Inquire about any problems or questions that might have arisen. If the participant expresses concern that a sensor fell off, reassure him/her that there is still a good likelihood that the study will be interpretable.

To remove electrodes, use a wet gauze pad and soap, lightly rubbing until the electrode is released. Work quickly. Do not use the participant's time to disconnect electrodes or sensors from their wires or cables -- that is better done in the clinic.

Check to see that all equipment and accessories (the Main Unit, vest with headbox, cable, and sensors) are all present and packed.

Check that the morning questionnaire has been completed.

Provide the participant with a "feed-back" postcard.

Provide the participant with a letter that will detail when results should be sent out.

6.9.2.8 Signal Verification Form

6.9.2.8.1 Overview

The Signal Verification Form is completed during the PSG hook-up to provide a guide through the required technical aspects of the procedure. It documents the impedance of the sensors to confirm the study protocol has been adhered to, the quality and accuracy of the signals, confirmation of calibration of light and position sensors, oximeter placement, pulse of participant, and battery check. It documents the arrival and departure times of the technician, whether hook-up was completed, and if not, why not, and any pertinent environmental conditions which may have an impact on the hook-up or sleep monitoring. Sleep monitoring start and end times are noted. It is used to document the identification of any Medical Alerts or Adverse Events.

6.9.2.8.2 Question by Question Coding Specifications

Pre-questionnaire Data

The upper right grey box should be completed with the following data:

Participant ID Number
Field Center ID Number: a 2-digit field
Technician ID Number: a 3-digit field
Monitor ID/Headbox ID: each a 2-digit field
Date of Study (use month, day, year format; each a 2-digit field)
Time of Arrival: specified in hours (00-12), minutes (00-59), and AM (1) or PM (2)
Time of Departure: specified in hours (00-12) and minutes (00-59), and AM (1) or PM (2)

NOTE: Each box must be completed. Empty boxes will be interpreted as indicating the check was not performed.

Section-specific instructions

1. Impedances

All EEG, ECG, EOG, and EMG sensors will have their impedances checked. The first impedance value is recorded (in kohms). If the impedance does not meet study protocol and the sensor is re-applied, the new value is noted in the second column (labeled Final Check).

If the first check is OK, then record that value in the second column, the FINAL check, as well. All impedance values are to be recorded as integers.

In the third column, record the number of times the electrode was replaced. For # times electrodes replaced, code = 0 if the original placement was accurate.

2. View Signals

This section requires the checking of the sensors' signals, airflow, and respiratory bands.

- a) Check for good deflection. (This is not done for the EEG sensors.)

Coding:

Permissible codes: 0 (= NO), 1 (=YES)

- b) Check for the presence or absence of a fuzzy line for each sensor, airflow, and respiratory bands.

Coding:

Permissible codes: 0 (= NO), 1 (=YES)

c) Value of Signal

This data is recorded for oximeter, pulse checks, and battery check. The spaces left for abdomen and thermistor are left blank.

All data are recorded in integer values.

Oxygen saturation is interpreted as a percent and pulse is recorded in beats per minutes. Battery check is recorded in volts. A fully charged battery will have a voltage of >7 Volts.

3. Calibration Check

The body positions (back, front, L side, R side) are programmed so the headbox knows what position the participant is lying in. The light sensor is also calibrated so it knows when lights are on or off.

Coding:

Permissible codes: 0 (check not performed), 1 (check performed)

4. Environmental Conditions

Question 1: Was hook-up completed?

Coding:

Permissible codes: 0 (= NO), 1 (=YES)

If NO, indicate why hook-up was not completed.

Coding:

Permissible codes: 1 - 7

Complete "other" line when code 7 used.

Was study rescheduled?

Coding:

Permissible codes: 0 (= NO), 1 (=YES)

If YES, indicate date in month/day/year numeric format.

Question 2: Were any environmental conditions present which could cause problems with sleep monitoring?

Coding:

Permissible codes: 0 (= NO), 1 (=YES)

Space is provided for written comments.

Question 3: Does participant have a beard?

Coding:

Permissible codes: 0 (=NO), 1 (=YES)

If YES, were alternative placement sites needed?

Coding:

Permissible codes: 0 (=NO), 1 (=YES)

Write in which ones and where placed, and any problems with hook-up or sensor checks.

Question 4: Were any Medical Alerts or Adverse Events noted?

Coding:

Permissible codes: 0 (=NO), 1 (=YES)

If YES, complete the ADVERSE EVENTS form.

Participant Data (from Recorder):

Participant ID Number

Field Center ID Number: a 2-digit field

Technician ID Number: a 3-digit field

Monitor ID/Headbox ID: each a 2-digit field

Start test (time): specified in hours (00-12), minutes (00-59), and AM (1) or PM (2)

End test (time) : specified in hours (00-12), minutes (00-59), and AM (1) or PM (2)

*Signal Verifications form (8/12/96) inserted here.
Two pages inserted after this page.*



SLEEP HEART HEALTH STUDY

SIGNAL VERIFICATIONS

ID#: _____

Field Center: _____

Technician ID: _____

Monitor ID/Headbox ID: _____/_____

Date of Study: _____

Time of Arrival: _____:_____

Time of Departure: _____:_____

Fill in each box. Empty boxes will be interpreted as indicating check not performed.

Impedances (Record Value in kohms)			
	First Check § (Both)	Final Check (use 1st check if orig. placement was accurate)	# Times Electrodes Replaced ("0" if original = final)
EEG 2 (C3/A2)			
ECG			
EMG			
EOG - L			
EOG - R			
EEG 1 (C4/A1)			

§ Indicate first impedance value; if > 10 (except ECG-40) check each individual channel to identify the problem channel. Replace the higher sensor and recheck both.

CALIBRATION CHECKS (Mark each box after performing specific calibration.)

Data entry: Enter 1 if check performed, 0 if check not performed.

Position: Back Front

 L Side R Side

Light: On Off

	Good Deflection		Fuzzy Line		Value
	Yes	No	Yes	No	
EEG 2			1	0	
ECG	1	0	1	0	
EMG Chin	1	0	1	0	
EOG - L	1	0	1	0	
EOG - R	1	0	1	0	
EEG 1			1	0	
Chest	1	0	1	0	
Abdomen	1	0	1	0	
Thermistor	1	0	1	0	
Oximeter *					
Pulse **					
Manual Pulse **					
Battery Check					

* (If <88% re-position, check sensor, consult Med Alerts)

** (If > 120 or < 30, check for 2 minutes; consult Med Alerts for HR > 150)

ECG placement: (check one)

₁ subclavicular ₂ modified CL5

Montage used for ECG: (check one)

₁ SHHS (standard) ₂ SHHS_2 (250 Hz)

Environmental Conditions:

1. Was hookup completed?

₁ YES

₀ NO →

Why not?

₁ Participant not home

₂ Participant sick/indisposed

₃ Participant refused entry in home

₄ Participant refused Informed Consent

₅ Participant refused hookup

₆ Participant could not tolerate hookup

₇ Other: _____

Was study rescheduled? ₀ NO ₁ YES _____ (date)

2. Were any environmental conditions present which could cause problems with sleep monitoring?

₁ YES

₀ NO

Comments: _____

(Check "Yes" if ≥ 3 people sleeping in room; extremely cold or hot; or frequent noises in home or outside home, etc.)

3. Does participant have a beard?

₁ YES

₀ NO

If yes, were alternative placement sites needed?

₁ YES

₀ NO

If yes, which ones and where placed: _____

Describe any problems with hook-up or sensor checks: _____

4. Were any Medical Alerts or Adverse Events noted?

₁ YES

₀ NO

If yes, complete the Adverse Events form.

Participant Data (from Recorder):

ID#: _____

Field Center: _____

Technician ID: _____

Monitor /Headbox ID: _____ / _____

Start Test: _____

am/pm

End Test: _____

am/pm

6.10 Medical Alerts and Adverse Events

6.10.1 Background and Rationale

Certain findings made at the time of the home visit or during analysis of the sleep study may require medical intervention. Although the sleep study performed as part of the SHHS is not considered a diagnostic study, the SHHS investigators have an obligation to refer special cases to their local source of medical care. Therefore, a referral system has been established that is based on the urgency of the finding. To document medical alerts identified at the home visit, a SHHS Adverse Events Form (see Section 6.10.4.3) is to be completed.

The criteria used to determine that a medical alert condition exists were based on :

1. The distinct situation related to performing tests in a research setting as contrast to a clinical setting; and
2. The lack of data that suggest that apneic activity can be used as a sole criteria from which to make clinical recommendations.

Research setting. The participants in the SHHS studies consist of community-based volunteers, in whom participation in sleep studies resulted from investigator-initiated contact. The research studies are not intended to, and, we believe, should not be used to, yield information for clinical decision making. The research studies are performed and interpreted by research staff who are not responsible for the medical care of the participants. Data are thus generated independently of information regarding clinical history and physical examination -- the latter which may be critical in interpreting the results of any given sleep study. We deemed it inappropriate to use the results of these research studies, in the absence of clinical data, to make recommendations regarding treatment, in other than cases of frank, severe sleep apnea (i.e., medical alert conditions, see below).

Inability to use apneic activity as the sole criteria for judging severity and making treatment recommendations. In two recent ATS consensus conferences (“Sleep, Sleepiness, and Driving Risk,” AJRCCM, 150: 1463-1473, 1994 and “The Second ATS Consensus Conference on Adult Sleep Apnea,” in preparation, personal communication, Kingman Strohl), no consensus was achieved that specific levels of apneic activity could be used to either predict functional impairment or could be used as criteria for initiating treatment. Further, the wide age range of the participants in SHHS, and the known marked variation of AHI with age in asymptomatic subjects (AJRCCM, 151:104, 1995), further limits the ability to use strict threshold values as criteria for “abnormality.”

We, therefore, recommend that the content of participant feedback information be shaped accordingly, with the following objectives:

1. To provide “interesting” information to the participant about the quality of his/her sleep, including information on the frequency of breathing pauses as compared to levels found in other people, and

2. To provide information that alerts the participant that data had been collected suggesting the possibility of a serious medical condition (frank, severe sleep apnea) that should be investigated further.

We favor an approach that minimizes the use of specific threshold levels of apneic activity (e.g., AHI > 15%) to judge “severity” or that triggers a recommendation for physician follow-up. We also recommend avoiding the words “abnormal” or “normal” in these community volunteers. (We emphasize that, other than at the high extreme, we do not believe that a given AHI by itself should be used to grade abnormality.) Rather, participants should be told that, if symptomatic, they should consider further medical evaluation (regardless of level of apnea).

We do recognize that there are levels of apneic activity/hypoxemia so high that the likelihood of health risks/functional impairment may be substantial. Although limited by an inadequate literature in which to choose a specific threshold, we elected an AHI level of ≥ 50 and level of hypoxemic stress, defined as the time in desaturation (< 75% sat.) for > 10% sleep time, as levels that merited individual physician/investigator review (within 10 days of the sleep study), with tailoring of specific feedback to participants, and to the physicians caring for these participants. We also recognize that very low heart rates (<30 BPM for > 2 minutes) or very high heart rates (150 BPM > 2 minutes) should trigger a review of the participant’s record, with consideration of notifying the participant that a finding was noted that may require medical intervention.

6.10.2 Immediate Referrals

Immediate referrals are potential medical emergencies which may require immediate notification of both the participant and his/her primary physician or other available health care provider. These are findings made at the time of the sleep study setup in the participant’s home. Because the technicians performing the setup are in general neither trained nor licensed to perform clinical diagnostic assessments, all findings requiring immediate referral will be referred by the technician to a physician-investigator of the SHHS. This physician, based on information obtained from the technician and/or the participant, will determine whether immediate referral is indicated. Participants receiving immediate referrals are those who would be advised to go directly from home to their physician or to a hospital.

Notification of the participant should be performed by the SHHS physician-investigator and should occur prior to the technician’s departure from the home (See below). Notification of the participant’s physician, or other available health care provider (such as a hospital Emergency Department physician), will occur as deemed necessary by the SHHS physician-investigator. A follow-up letter documenting the information discussed by telephone may also be sent to the participant’s physician.

Findings requiring immediate referral at the time of sleep study setup are as follows, unless the parent cohort specifies different criteria (see “local” manuals for definitions):

- awake blood pressure:
 - systolic blood pressure > 200 mm Hg
 - diastolic blood pressure > 120

awake oximetry:

oxygen saturation < 80% for longer than 2 minutes while at rest

awake heart rate:

> 150 beats/minute for longer than 2 minutes at rest

< 30 beats/minute for longer than 2 minutes at rest

Referral type	Parameter	Threshold At setup	Threshold At study review
Immediate	Heart rate	>150 or <30	----
	SaO ₂	<80%	----
	AHI	----	----
	BP	>200(S) or > 120(D)	
Urgent	Heart rate	----	>150 or <30
	SaO ₂	<85% (but>80%)	<75% sat for>10% of TST
	AHI	----	≥ 50
	BP	>170(S) or > 100(D)	

6.10.3 Urgent Referrals

Urgent referrals are made for abnormalities detected at the time of hook-up or on review of the sleep study which require medical attention but not on an emergency basis. Notification of the participant and his/her physician should be sent by mail within 10 days.

Findings requiring urgent notification are as follows, unless the parent cohort specifies different criteria (see “local” manuals for definitions):

awake blood pressure:

systolic blood pressure > 170

diastolic blood pressure > 100

awake oximetry:

baseline awake oxygen saturation <85% (but > 80%)

oximetry (during sleep):

oxygen saturation < 75% for >10% of total sleep time

apnea-hypopnea index (during sleep):

AHI ≥ 50 events/hr

heart rate during sleep:

> 150 beats/minute for longer than 2 minutes

< 30 beats/minute for longer than 2 minutes

6.10.4 Methods

6.10.4.1 Immediate Referrals

The technicians performing these studies need to understand that these studies have been initiated as a result of a research initiative (which the participant consented to, but did not initiate because of specific health concerns). Studies will be performed largely in free living members of their community without acute or unstable medical problems. Thus, the occurrences of true medical emergencies are likely to occur only rarely, if ever. It is of utmost importance that if an abnormality is detected, the technician first ascertain whether the abnormal signal was an artifact from faulty sensor placement or faulty equipment. Only after this is ascertained (see instructions for channel 2, oximetry), is he/she to contact a SHHS investigator. This should be done after he/she calmly informs the participant that a finding was made during hook-up that required him/her to discuss a possible problem with his/her supervisor. Technicians also need to understand that they are not trained or authorized to provide any medical advice; instead they need to encourage participants to speak with their own physicians about any such issues raised.

The SHHS investigator, upon receiving a call regarding a possible immediate referral, may ask to speak with the participant (over the telephone) to assess other medical conditions, place of routine care, etc. that will help in determining the level of acuity and form of specific evaluation (emergency room, doctor's office, etc.). The SHHS investigator should use his/her clinical judgment to determine how to proceed at this point. Possible responses range from advising the participant to go directly to the nearest emergency room; immediately telephoning the participant's physician; advising the participant to contact his/her physician within the next several days to taking no action based on the investigator's judgment that the condition is already known to the participant and his/her physician. The investigator will complete an Emergency Contact Form, documenting the time/date of contact, the problem identified, and the action taken or recommended to the participant. This form should be returned to the clinic (Field Center) within 24 hours.

The Clinic Coordinator will log the completed Emergency Contact Form into a record book. Within 48 hours of the referral, the Clinic Coordinator also will contact the participant by telephone and ascertain what follow-up was taken, documenting this in the Referral Follow-up Form. Copies of all correspondence will be filed in a secure area.

The Emergency Contact Form and Referral Follow-up Form follow this section.

EMERGENCY CONTACT FORM

Participant's Name/ID:

Time _____ pm/am

Date _____

Completed by: _____ (investigator)

Description of emergency:

Recommended action:

Comments:

EMERGENCY REFERRAL FOLLOW-UP FORM

Participant's Name/ID:

Telephone Number:

Date of sleep study/emergency referral:

Date and time of follow-up call:

Call made by: _____ (clinic coordinator)

Description of referral:

Participant's report of follow-up action taken:

6.10.4.2 Urgent Referrals

Urgent Referrals Initiated by the Technician (based on findings during hook-up)

Within 48 hours of the home visit, the Study Coordinator will identify any values noted on the Work Forms that met criteria for Urgent Referral. After confirming these values with the home technician, he/she will complete an Urgent Referral Form. This will be reviewed with a SHHS investigator. Within 10 days of an Urgent Referral, letters (see Doctor's Urgent Referral, Participant's Urgent Referral) will be sent to the participant and his/her physician, if the participant has requested it.

Urgent Referrals Initiated by the Reading Center

Within 10 days after the sleep study, the record will be reviewed at the Reading Center. The RC Chief Polysomnologist (RCCP) will identify any records meeting the heart rate, oximetry or AHI criteria indicated above for Urgent Referrals (Table 6.10.2.1). She/he will review the findings with the Director of the RC (or her designee). The RCCP then will complete an Urgent Referral Form which will be faxed to the Study Coordinator of the respective clinical site, and filed in a RC record book. The Study Coordinator will log the forms, review them with a SHHS investigator, and file them. He/she will prepare and issue the letters to participants and their physicians.

The Urgent Referral Form, Physician's Optional Urgent Referral Letter, and Participant's Optional Urgent Referral Letter follow this section (6.10).

<u>URGENT REFERRAL FORM</u>	
Participant's Name/ID:	
Date of sleep study:	
Flagged for referral by:	(study coordinator)(polysomnologist)
Approved for referral by:	(reading center director/designee)
Reason for referral:	
Comments:	

PHYSICIAN'S OPTIONAL URGENT REFERRAL LETTER

[Date]

[Physician's Name]

[Physician's Address]

Re: [Participant's Name]

Dear Dr. [Physician's Name]:

Your patient, [Participant's Name], is a participant in the Sleep Heart Health Study at [Field Center Name]. Sponsored by the National Heart, Lung and Blood Institute and the National Sleep Center, the purpose of this study is to determine the cardiovascular consequences of sleep apnea. As part of this study, participants undergo an ambulatory polysomnogram (PSG) in their homes. Your patient, [Mr./Mrs./Ms] [Participant's Last Name], had a PSG and a measurement of their blood pressure performed on [Date of PSG]. An analysis of these data has revealed the following finding[s] which may require your further evaluation.

[The following should be deleted or included as required]

[Mr./Mrs./Ms.] [Participant's Name] blood pressure was [Systolic Pressure/Diastolic Pressure].

[Mr./Mrs./Ms.] [Participant's Name] oxygen saturation while awake was [oxygen saturation].

[Mr./Mrs./Ms.] [Participant's Name] oxygen saturation while asleep was <75% for [% total sleep time spent with saturation less than 75%] of the time they were asleep.

[Mr./Mrs./Ms.] [Participant's Name] had more than 50 apneas or hypopneas per hour of sleep.

[Mr./Mrs./Ms.] [Participant's Name] had episodes of tachycardia exceeding 150 beats/minute for longer than 2 minutes.

[Mr./Mrs./Ms.] [Participant's Name] had episodes of bradycardia less than 30 beats/minute for longer than 2 minutes.

[Mr./Mrs./Ms.] [Participant's Name] has been sent a letter notifying [him/her] of these findings. [He/She] may be contacting you to discuss them. However, these results were obtained as part of a research protocol and should be interpreted in the context of your patient's current clinical symptoms and condition. If you require additional information or you wish to discuss these results further, please do not hesitate to call Dr. [Investigator's Name] at [Investigator's Phone Number].

[I/We] appreciate the opportunity to have your patient [Mr./Mrs./Ms] [Participant's Name] participate in the Sleep Heart Health Study.

Sincerely yours,

[Investigator Name/Names]

[Investigator Titles]

PATIENT'S OPTIONAL URGENT REFERRAL LETTER

[Date]

[Participant's Name]

[Participant's Address]

Dear [Participant's Name]:

Thank you for agreeing to participate in the Sleep Heart Health Study and to have had a recording of your sleep at night. We have recently reviewed some of the results of your study and have noted the following finding[s] which we believe you should discuss with your physician in the near future.

[The following should be deleted or included as required]

Your blood pressure was [Systolic Pressure/Diastolic Pressure] which is elevated.

The oxygen level in your blood while awake was [oxygen saturation]. This lower than normal.

The oxygen level in your blood while asleep was <75% for [% total sleep time spent with saturation less than 75%] of the time they were asleep. This is lower than normal.

You had more than 50 breathing pauses per hour of sleep. The number is much greater than normal.

You had episodes where your heart beat was faster than 150 beats/minute for longer than 2 minutes. This does not occur in most people.

You had episodes where your heart beat was slower than 30 beats/minute for longer than 2 minutes. This does not occur in most people.

These findings have been sent to your personal physician if you previously have requested us to forward study results to [him/her]. If you wish your study results sent to your personal physician, but you have changed your personal physician or have not identified one to us, please contact us so we may send these findings to [him/her]. If you have difficulty finding a personal physician, your local medical society may be of assistance.

If you require additional information or you wish to discuss these findings further, please do not hesitate to call Dr. [Investigator's Name] at [Investigator's Phone Number]. Thank you again for your participation in the Sleep Heart Health Study.

Sincerely yours,

[Investigator Name/Names]

[Investigator Titles]

6.10.4.3 Adverse Events Form

6.10.4.3.1 Overview

The Adverse Events Form is to be completed during the home visit when a medical alert is identified. It documents data required for determination of medical alerts based on blood pressure, oxygen saturation levels, heart rate, and other problems that may occur during the home visit. If an alert was noted, then the action taken is documented. If action is taken after the home visit, then that information is documented on the Adverse Events Form as well.

6.10.4.3.2 Question by Question Coding Specifications

Pre-questionnaire Data

The upper right grey box should be completed with the following data:

Participant ID Number
Field Center ID Number (2-digit field)
Technician ID Number (3-digit field)
Date of Study (month, day, year format specified in numbers only)

Question-specific instructions

1. Were any of the following *immediate* medical alerts noted?

Five alerts are listed. Check YES or NO for each alert listed.

Coding:

Permissible codes: 0, 1

If any alerts were noted, was a physician notified? Code YES (1) or NO (0).

If physician notified, indicate method of contact: Code by letter (1) or phone (2).
Indicate physician's name and date of contact.

If physician not contacted, indicate other action taken in comment box.

If an alert is noted and no action is taken the night of the home visit, then the section describing the type of action eventually taken should be completed at the time the action is initiated.

2. Were any of the following urgent medical alerts noted?

Three alerts are listed. Check YES or NO for each alert listed.

Coding:

Permissible codes: 0, 1

If any alerts were noted, was a physician notified? Code YES (1) or NO (0).

If physician notified, indicate method of contact: Code by letter (1) or phone (2).

Indicate physician's name and date of contact in month/day/year numeric format.

If physician not contacted, indicate other action taken in comment box.

If an alert is noted and no action is taken the night of the home visit, then the section describing the type of action eventually taken should be completed at the time the action is initiated.

3. Were any other problems noted?

Coding:

Permissible codes: 0, 1

All other problems should be noted in this section. Check YES or NO for each alert listed. Action taken for these problems should be written in the comment section.

"Other" problems may occur during the night of the sleep study and are to be documented the morning the monitor is picked up.

*Adverse Events form (3/29/96) inserted here
One page inserted after this page.*



SLEEP HEART HEALTH STUDY

ADVERSE EVENTS

ID#:

Field Center: ____ ____

1 Were any of the following *immediate* medical alerts noted:

- | | | |
|----------------------------|----------------------------|---|
| YES | NO | |
| <input type="checkbox"/> 1 | <input type="checkbox"/> 0 | Systolic Blood Pressure > 200
(not on bp meds) |
| <input type="checkbox"/> 1 | <input type="checkbox"/> 0 | Diastolic Blood Pressure > 120
(not on bp meds) |
| <input type="checkbox"/> 1 | <input type="checkbox"/> 0 | Oxygen saturation < 80% for longer than 2 minutes at rest |
| <input type="checkbox"/> 1 | <input type="checkbox"/> 0 | Heart rate > 150 for longer than 2 minutes at rest |
| <input type="checkbox"/> 1 | <input type="checkbox"/> 0 | Heart rate < 30 for longer than 2 minutes at rest |

2 Were any of the following *urgent* medical alerts noted?

- | | | |
|----------------------------|----------------------------|---|
| YES | NO | |
| <input type="checkbox"/> 1 | <input type="checkbox"/> 0 | Systolic Blood Pressure > 170
(not on bp meds) |
| <input type="checkbox"/> 1 | <input type="checkbox"/> 0 | Diastolic Blood Pressure > 100
(not on bp meds) |
| <input type="checkbox"/> 1 | <input type="checkbox"/> 0 | Oxygen saturation between 80% and 85% for longer than 2 minutes at rest |

If any alerts were noted:

YES	NO	
<input type="checkbox"/> 1	<input type="checkbox"/> 0	Was a physician notified?

<input type="checkbox"/> 1	By letter	<input type="checkbox"/> 2	By phone
----------------------------	-----------	----------------------------	----------

MD Name: _____

Date: _____

Other action taken: _____

3 Were any other problems noted?

- | | | |
|----------------------------|----------------------------|-------------------------------|
| YES | NO | |
| <input type="checkbox"/> 1 | <input type="checkbox"/> 0 | Skin reaction |
| <input type="checkbox"/> 1 | <input type="checkbox"/> 0 | Tripping, falling |
| <input type="checkbox"/> 1 | <input type="checkbox"/> 0 | Other problem, specify: _____ |

Action taken: _____

Technician I.D. _____

Date: _____

6.10.5 Reports to the Participants

All participants will receive a Participant Sleep Study Summary. The format of the summary and the cover letters to the participants and their physician will be slightly different for those whose PSG results generated a medical alert ($AHI \geq 50$). These summaries will include total sleep time, time spent dreaming (REM), sleep efficiency, Apnea-Hypopnea Index (AHI), average heart rate, and oxygen profile. Those summaries with $AHI \geq 50$ will include additional heart rate and oxygen profile data.

In the cover letters, the tertiles of the AHI distribution (updated monthly based on all PSG studies analyzed to date) for the SHHS cohort will be provided. This will provide the participant with information they can relate their individual score to.

[NOTE: If computer-generated reports are found to provide AHIs that differ by $> 10\%$ of the values determined by hand scoring, then desaturation criteria alone will be in the Preliminary Report as the basis for determining degree of abnormality of the record.]

The Study Coordinator will log and file all Study Summaries.

The cover letters to participants and physicians and the Participant Sleep Study Summaries all follow this section, using the Framingham site as an example.



Physician Letter

Sleep Heart Health Study

Boston University School of Medicine	Framingham Heart Study
80 East Concord St. (R304)	5 Thurber St.
Boston, MA 02118-2394	Framingham, MA 01701
617 638-4933	508 935-3438
Fax: 617 638-5298	Fax: 508 626-1262

Dear Doctor,

Your patient is a participant in a research project called the Sleep Heart Health Study (SHHS) being conducted at the Framingham Heart Study. SHHS is sponsored by the National Heart, Lung and Blood Institute and the National Sleep Center and is designed to determine the cardiovascular consequences of sleep apnea.

Participants undergo an overnight polysomnogram in their homes which includes monitoring of oxygen saturation, respiratory effort, heart rate and sleep stage. A respiratory disturbance index (RDI), the number of apneas or hypopneas per hour of sleep which are associated with a 3% or greater drop in oxygen saturation, is calculated for each participant. In our study, one third of the participants have an RDI below 9, one third between 10 and 19, and one third greater than 20. An RDI of greater than 50 is markedly elevated; however, in the absence of symptoms attributable to sleep apnea, the clinical significance of an elevated RDI, even of this magnitude, is unknown.

A copy of your patient's Sleep Study Summary is attached. This test was performed for research purposes and does not allow a definitive diagnosis to be made. The results should be interpreted in the context of your patient's clinical condition. Please feel free to call me or my colleague Dr. Daniel Gottlieb, at (617) 638-4933 if you have any questions about this study.

Sincerely,

George T. O'Connor, M.D.
Principal Investigator, Sleep Heart Health Study



Physician Report, RDI < 50
Sleep Heart Health Study

Boston University School of
Medicine
80 East Concord St. (R304)
Boston, MA 02118-2394
617 638-4933
Fax: 617 638-5298

Framingham Heart Study
5 Thurber St.
Framingham, MA 01701
508 935-3438
Fax: 508 626-1262

Sleep Study Summary -- Test performed for Research Purposes

Participant Name: [full name]
Date of Study: [date of study]

Total Sleep Time: [sleep hours] hours and [sleep minutes] minutes
Total Time in REM: [total REM (in minutes)] minutes
Sleep Efficiency: asleep for [sleep efficiency] % of the time in bed

Respiratory Disturbance Index (apneas or hypopneas associated with 3% oxygen desaturation)
[RDI] per hour

Average Heart Rate: [average HR] bpm

% Sleep Time with Oxygen Saturation < 90%: [%oxygen < 90]

*TEMPLATE for a Report to a PARTICIPANT with RDI >= 50.
It will be accompanied by an explanatory letter.*



Physician Report, RDI \geq 50

Sleep Heart Health Study

Boston University School of
Medicine
80 East Concord St. (R304)
Boston, MA 02118-2394
617 638-4933
Fax: 617 638-5298

Framingham Heart Study
5 Thurber St.
Framingham, MA 01701
508 935-3438
Fax: 508 626-1262

Sleep Study Summary -- Test performed for Research Purposes

Participant Name: [full name]
Date of Study: [date of study]

Total Sleep Time: [total sleep period (hr:min)] hours
Total Time in REM: [total REM(in minutes)] minutes
Sleep Efficiency: asleep for [sleep efficiency] % of time in bed

Respiratory Disturbance Index (apneas or hypopneas associated with 3% oxygen desaturation)
[RDI] per hour

Average Heart Rate: [average HR] bpm
Minimum HR: [Minimum HR] bpm
Maximum HR: [Maximum HR] bpm

% Sleep Time with Oxygen Saturation < 90%: [SaO2% < 90]
% Sleep Time with Oxygen Saturation < 75%: [SaO2% < 75]
Minimum SaO2: [minimum SaO2] %

*Template for the report to a physician for a participant with RDI \geq 50.
It will be accompanied by a generic physician letter.*



Participant Letter and Report, RDI < 50

Sleep Heart Health Study

Boston University School of
Medicine
80 East Concord St. (R304)
Boston, MA 02118-2394
617 638-4933
Fax: 617 638-5298

Framingham Heart Study
5 Thurber St.
Framingham, MA 01701
508 935-3438
Fax: 508 626-1262

June 20, 1996

[full name]
[street]
[town, state zip]

Dear [Mr or Mrs Name],

Many thanks for participating in the Sleep Heart Health Study being done in conjunction with the Framingham Heart Study. We appreciate the effort, time, and patience you have contributed to this research.

The results of your sleep study are summarized below, and a copy has been sent to your doctor. It is common for adults to have a few brief oxygen dips as a result of breathing pauses or shallow breaths. In our study, one third of the participants have fewer than 9 of these pauses or shallow breaths per hour, one third between 10 and 19 per hour, and one third greater than 20 per hour. One of the purposes of this research is to determine if a mild or moderate elevation in the number of breathing pauses or shallow breaths has any effect on health.

After you went to bed on [date of study] you slept for a total of [sleep hours] hours and [sleep minutes] minutes. You spent [total REM (in minutes)] minutes in the dream stage of sleep and slept for [sleep efficiency] percent of the time you were in bed. During the night you had [RDI] breathing pauses or episodes of shallow breathing per hour. Your heart rate averaged [average HR] beats per minute.

The test we performed was done for research purposes. Regardless of the results of your sleep study, if you experience unsatisfactory or restless sleep, or are often troubled by daytime sleepiness, you may want to discuss this with your doctor to determine if further evaluation is needed. Please feel free to call me or my colleague Dr. Daniel Gottlieb at (617) 638-4933 if you have any questions about this study.

Thank you again for your participation in the Sleep Heart Health Study and the Framingham Heart Study. The contribution you make to research into the causes of heart disease is enormous.

Sincerely,

George T. O'Connor, MD
Principal Investigator, Sleep Heart Health Study

Template for a feedback letter to a participant with RDI >= 50.



Participant Letter, RDI \geq 50

Sleep Heart Health Study

Boston University School of
Medicine
80 East Concord St. (R304)
Boston, MA 02118-2394
617 638-4933
Fax: 617 638-5298

Framingham Heart Study
5 Thurber St.
Framingham, MA 01701
508 935-3438
Fax: 508 626-1262

June 20, 1996

[full name]
[street]
[town, state zip]

Dear [Mr or Mrs Name],

Many thanks for participating in the Sleep Heart Health Study being done in conjunction with the Framingham Heart Study. We appreciate the effort, time, and patience you have contributed to this research.

The results of your sleep study are attached, and a copy has been sent to your doctor. It is common for adults to have a few brief oxygen dips as a result of breathing pauses or shallow breaths. In our study, one third of the participants have fewer than 9 of these pauses or shallow breaths per hour, one third between 10 and 19 per hour, and one third greater than 20 per hour. Oxygen levels in the blood are normally greater than 90%. Your study shows greater than 50 shallow breaths or breathing pauses per hour, a level which is markedly elevated and may be associated with side effects.

The test we performed was done for research purposes and does not allow a definite diagnosis to be made. We recommend you discuss these results with your doctor, who may wish to obtain further evaluation and to determine if treatment is needed. Please feel free to call me or my colleague, Dr. Daniel Gottlieb, at (617) 638-4933 if you have any questions about this study.

Thank you again for your participation in the Sleep Heart Health Study and the Framingham Heart Study. The contribution you make to research into the causes of heart disease is enormous.

Sincerely,

George T. O'Connor, MD
Principal Investigator, Sleep Heart Health Study

Participant Report, RDI \geq 50



Sleep Heart Health Study

Boston University School of
Medicine
80 East Concord St. (R304)
Boston, MA 02118-2394
617 638-4933
Fax: 617 638-5298

Framingham Heart Study
5 Thurber St.
Framingham, MA 01701
508 935-3438
Fax: 508 626-1262

Sleep Study Report -- Test performed for Research Purposes

Participant Name: [full name]
Date of Study: [date of study]

You slept for [total sleep period (hr:min)] hours during the night of your sleep study, and spent [total REM(in minutes)] minutes in the dream stage of sleep. You slept for [sleep efficiency] percent of the time you were in bed.

Throughout the night you had [RDI] breathing pauses or episodes of shallow breathing per hour. During these some of these episodes your oxygen level fell briefly to a low level with a minimum of [minimum SaO2] percent. The oxygen level in your blood was below 90% for [SaO2% < 90] percent of the time you were asleep and below 75% for [SaO2% < 75] percent of the time.

Your heart rate averaged [average HR] beats per minute and ranged from a high of [Maximum HR] to a low of [Minimum HR] beats per minute.

*Template for a report to a participant with RDI \geq 50.
It will be accompanied by an explanatory letter.*

6.11 Common Questions and Appropriate Responses

1. What if you find that I have sleep apnea?

The results of your sleep study will be known within several weeks of the sleep study. In writing, you will be informed of the number of breathing pauses that were observed during your sleep. If a very high number of pauses are observed, we will contact you sooner and you can discuss the findings with your physician. Choice of proceeding with additional testing or therapy are decisions that should be made by you and your doctor.

2. Will I get electrocuted?

NO! The unit is completely battery operated, using low voltage.

3. Can I go to the bathroom and move around?

YES! You can use the carrying pouch to carry the monitor. Just be careful that all wires and cables are draped away from your feet so you do not trip. You do not need to turn on and off any switches when you are walking around.

4. Are you qualified to diagnose me?

NO, I am a (fill in title) . I am trained to collect good quality data, but not to diagnose medical conditions -- diagnosis should be done by a nurse or doctor who does a physical exam and reviews your history and findings from studies.

5. What are the symptoms of sleep apnea?

The most common symptoms are loud disruptive snoring and daytime sleepiness. However, not everyone with these symptoms has sleep apnea. Also, some people with these symptoms do not have sleep apnea.

6. I don't snore (I'm not tired) -- why should I bother?

Your participation will result in information that will allow the SHHS investigators to understand more about the causes of heart and other diseases. Information from people without symptoms is just as important as information collected on individuals with these symptoms. Besides, frequent participation in these studies by people without such symptoms results in information that proves to be interesting or valuable to them (or useful to their doctor in the care of such people).

7. I have insomnia (or I can't sleep) -- will this help? -- or this won't help.

Many people underestimate how much sleep they actually get, and this study may help identify if that is the case. It is likely that you will sleep enough to enable us to collect enough useful information for SHHS and possibly reveal problems that may help explain problems with your sleep.

8. Won't I lose the wires if I twist and turn?

We have secured the wires with special tape and paste that will make it unlikely that they will be lost. Please try not to worry about this -- sleep in your usual fashion. If something does fall off, just gather the wire so it does not pull (demonstrate). (Airflow and oximetry is the exception -- show how to replace.)

9. What about taking my medicines?

Take everything as usual. You can use a straw (or take off airflow sensor) while swallowing.

10. Will my spouse be able to sleep next to me?

Sure! The machine does not make any noise and should not interfere with his/her sleep. It will only record your brain waves and breathing patterns.

11. Will the paste affect my hair color?

No. It is water soluble.

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SLEEP HEART HEALTH STUDY MANUAL OF OPERATIONS

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CHAPTER 7 - PSG STUDIES PROCESSING AND EQUIPMENT MAINTENANCE

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7.1 Overview

After the home visit is completed, the PSG data needs to be reviewed for adequacy, transferred to magnetic cartridges and sent to the Reading Center at Cleveland for processing according to procedures described in this chapter. In addition, the equipment is to be cleaned and checked according to procedures provided.

7.2 Data Retrieval, Coding, and Transfer

7.2.1 Data Retrieval and Review

Please see Section 9.2.3.4 of the MOP for detailed instructions on use of the magnetic cartridges and data retrieval processes.

On the morning following the study (or as soon as you return to the clinic), the data stored on the memory card should be reviewed at the clinic site to assure the adequacy of the study (and identify early any technical problems before they are propagated). Studies are then transferred to magnetic cartridges for filing and transfer to Cleveland.

Procedures for viewing the study:

1. Turn power off the Main Unit (if necessary).
2. Remove flashcard.
3. Put charger on recorder.
4. Insert flashcard into PCMCIA Slot of the Clinic computer.
5. Start "Portable Manager" (at c:> type "portable").**
6. Press F5 (or click on it) -- Convert Card to Disk.

***NOTE: Instructions for Changing Incorrectly Entered Participant IDs after a PSG Study is on the Flashcard. This error will be picked up in the home, when the technician checks the patient information displayed on the portable monitor.*

- a. *Using the mouse, highlight the participant ID number and enter the correct ID.*
- b. *Proceed with uploading the data to the hard drive or Zip Disk (this process does not change the ID on the flashcard, so if you have to upload the study again, you will need to change the ID a second time).*

-
7. Select Storage Medium and press "Enter."
 8. A box will appear, detailing which epoch is being transferred.

Scan the study: For your initial 10 studies, you will scan epoch (screen) by epoch (screen). After this, you will use the "Jump to" key to jump to every 120 epochs (or every one hour of the study). You will also view an oximetry summary graph to determine the oximetry pattern over the study.

Check the following:

1. Offset should be zero, i.e., traces centered on all AC traces at start, during, and end of overnight study: ECG, EMG, EOG/L, EOG/R, EEG(sec), EEG, AIRFLOW, THOR, ABDO, OXIMETRY.
2. All traces should be free of excessive 60Hz at start, during, and end of recording. If excessive noise cannot be explained by high impedance, discuss this with your local Sleep Resource Person. If the same problem persists on several studies, contact the RC.
3. All traces should be inspected at start, during, and end of overnight recording: ECG: e.g., should look like ECG; EMG; EOG/L; EOG/R; EEG; EEG (sec); SaO₂; AIRFLOW; THOR; ABDO; SOUND; POSITION; LIGHT

Complete the Sleep Data Retrieval Form:

1. Are there signals on each of the channels (i.e., no “flat-lined” signals)?
2. Is each channel mostly clear of artifact (usually appearing as thick fuzzy lines)?
3. Is there at least 6 hours of recorded data?
4. Is there at least 4 hours of oximetry?

Record this information on the Sleep Data Retrieval Form. See Section 7.2.2 for coding instructions.

If the answer to question #4 is **Yes**, follow procedures for transferring the study to 2 magnetic cartridges. Record the study on local tracking log as “transferred” to cartridge. If the answer to question #4 is **No**, record the study on local tracking log as “Inadequate.” If there are no readable data, do not transfer to magnetic cartridge. Notify the Study Coordinator of this (a repeat study will need to be scheduled). If the study appears to have some scorable data, follow the procedures for tracking Inadequate Studies/Repeat Studies. Review this study, and any others with problems (as noted for questions #1-3) with your Sleep Study Resource (see Local QA below) to determine possible problems and their solutions.

7.2.2 Documenting Results of Study Viewing

The results of viewing the study are recorded on the Sleep Data Retrieval Form. This section provides the instructions for completing this form. Record the information as specified below.

 Pre-questionnaire Data

The upper right grey box should be completed with the following data:

- | | |
|--|--|
| Participant ID Number | Monitor ID Number (2-digit field) |
| Field Center ID Number (2-digit field) | Date of Study (month, day, year in numeric format) |
| Technician ID Number (3-digit field) | Date Reviewed (month, day, year in numeric format) |
-

Question-specific instructions

1. Was a data file sent to Cleveland?

Coding:

Permissible codes: 0, 1, 2

If answer is NO (code=0), then indicate reason for not sending the data. Reason:
1= Equipment failure; 2= Hook-up problem; 3= Participant problem.

If there is more than one reason, code the predominant reason and note multiple reasons in the extra white space at the left side of the question box. If final coding is not obvious, consult Sleep Study Resource for determination.

2. Are there signals on each of the channels? (i.e., no “flat-lined” signal)?

Coding:

Permissible codes: 0, 1

If answer is NO (code=0), review study with Sleep Study Resource.

3. Is each channel mostly clear of artifact (thick fuzzy line)?

Coding:

Permissible codes: 0, 1

If answer is NO (code=0), review study with Sleep Study Resource.

4. Is there at least 6 hours of recorded data?

Coding:

Permissible codes: 0, 1

If answer is NO (code=0), review study with Sleep Study Resource.

5. Is there at least 4 hours of oximetry data?

Coding:

Permissible codes: 0, 1

If answer is NO (code=0), review study with Sleep Study Resource. Notify Study Coordinator of need to repeat study.

*Sleep Data Retrieval form (12/27/95) inserted here.
One page after this page.*



SLEEP HEART HEALTH STUDY

SLEEP DATA RETRIEVAL

ID#:

Field Center: _____

Technician ID: _____

Monitor ID: _____

Date of Study: _____

Date Reviewed: _____

1. Was a data file sent to Cleveland? ₁ YES - COMPLETE ₂ YES - PARTIAL
₀ NO → ₁ Equipment failure
₂ Hook-up problem
₃ Participant problem

2. Are there signals on each of the channels? (i.e., no "flat-lined" signal) ₁ YES
₀ NO

3. Is each channel mostly clear of artifact (thick fuzzy lines)? ₁ YES
₀ NO

4. Is there at least 6 hours of recorded data? ₁ YES
₀ NO

5. Is there at least 4 hours of oximetry data? ₁ YES
₀ NO

If answer to any question 2 to 5 is "No," review study with Sleep Study Resource.

If answer to question #5 is "No," record study on Study Log as "Inadequate" and do not transfer to RC. Notify Study Coordinator of need to repeat study.

Comments by Sleep Study Resource: _____

7.2.3 Transfer to Magnetic Cartridges and Reading Center

Each magnetic cartridge can store up to 100 megabytes of data, or data from approximately 4 sleep studies. In order to prevent accidental data loss, all studies will be copied in duplicate to 2 different magnetic cartridges. Each cartridge should be labeled with a number, the date and participant IDs of all studies, and a code indicating whether it is an “active” tape (A) (which will be transferred to the RC), or a “back-up” tape (B) for local filing. Keep a “running” log of each study transferred to tape, the tape number it was copied to, and the date the tape was sent to Cleveland.

The “A” tapes should be sent by overnight mail to Cleveland. Mail these in a padded envelope to: Susan Redline, M.D., M.P.H.; Sleep Heart Health Study; Cleveland VA Medical Center; 10701 East Boulevard 111 J; Cleveland, Ohio 44106-1782. Enclose with each tape a list of the IDs and dates that correspond to each study. Also fax one copy to Cleveland and one to Seattle.

Schedule:

Tapes should only be sent on Tuesdays and Fridays. Each Field Center should advise the Reading Center which day they plan to send on and always mail on that day. If a Field Center is not going to mail on their regularly scheduled day, they will inform the Reading Center and indicate when their next mailing will occur.

7.3 Protocol for Repeat Studies

Not all sleep studies that are scheduled are successfully completed. Failures can occur due to participant problems (e.g., participant unhooks the monitor), equipment problems (e.g., cable failure), or technician problems (e.g., lead falls off due to improper hook-up). When a study fails, we will attempt to repeat the study. Tracking repeat studies requires communication between the Field Center, Reading Center, and Coordinating Center. The protocol for tracking and processing repeat studies is described below.

There are several points in the sleep study process at which the failure can occur or can be identified; these will be described below chronologically.

7.3.1 Study is not initiated

This situation occurs any time the technicians arrive at the participant’s home for a scheduled hook-up but do not leave the participant hooked up to the monitor when they leave the home.

This can occur for several reasons such as: participant is not home, is ill, refuses the visit, or begins the hook-up but for some reason does not complete it.

When this occurs, the reason the hook-up was not completed is noted on the Signal Verification Form, which is data-entered and sent to the Coordinating Center. No other forms are required if the study is not successfully initiated.

The Field Center tracks whether the study was rescheduled. If the study is completed at a later date, this is not considered a repeat study. All forms should be completed just as if this was the first attempt to perform the study.

7.3.2 Study is initiated, data are found to be inadequate at Field Center review

In this situation, the technicians leave the participant hooked up to the monitor when they leave the home. The next morning when they review the data, they note that the data are not minimally adequate (e.g., all channels flat-lined). The problem with the sleep data is noted on the Sleep Data Retrieval form, which is data-entered and sent to the Coordinating Center. All of the home visit forms should be data-entered and sent to the Coordinating Center.

The Field Center tracks whether the study was rescheduled. If another hook-up is completed, it will be considered a repeat study. The Coordinating Center will send a list to the Reading Center once a month, listing all failed studies that month that did not result in a data file being sent to the Reading Center, so that if these studies are repeated, the Reading Center will know that they are repeat studies. The Field Center should also inform the Reading Center directly of repeat studies by identifying them as repeat studies on the zip cartridge and/or sending a memo to the Reading Center with the study identifying the study as a repeat.

If the study is repeated, the following forms/procedures must be repeated: Blood Pressure; Weight/Neck circumference (only if repeat is more than one month after original visit); Medications; Health Interview (only the last six questions -- see below); Morning Survey; Sleep Data Retrieval; Signal Verification. For the Health Interview, only the six questions at the end of the form need to be re-administered. These start with "What time did you go to sleep last night?" and end with "How stressful was your day today?" For CHS, ARIC, and SHS, these are questions 15-20; for Framingham they are questions 16-21; and for New York they are questions 18-23.

Since these forms were data-entered for the first unsuccessful study, you will need to use the "Edit/Browse" feature of the data entry system to re-enter the data. That is, using Edit/Browse you will pull up the data from the form that was entered earlier and you will enter any new values over the old ones.

7.3.3 Study is initiated, data are found to be inadequate at the Reading Center

In this situation, the hook-up is completed, the sleep data are reviewed at the Field Center, and the data are then forwarded to the Reading Center. Upon review, the Reading Center determines that the study is not minimally adequate (e.g., does not contain 4 hours of scorable data).

The Reading Center faxes a Repeat Study Request to the Field Center, with a copy to the Coordinating Center. The Field Center has one week to respond to the request and let the Reading Center and Coordinating Center know whether or not the study will be repeated.

7.3.3.1 Study is not repeated

If the study will not be repeated, the Reading Center does not score the data. However, the raw data are sent to the Coordinating Center and are archived onto CD ROM so that they may be retrieved at a future time, should this be deemed necessary. If possible, some preliminary results are sent to the participant by the Reading Center.

7.3.3.2 Study is repeated

If the study will be repeated, the Field Center schedules and tracks this. The Coordinating Center also tracks anticipated repeat studies, and sends a list to the Field Center of any expected repeat studies that have not been received within one month of the Repeat Study Request form being received at the Coordinating Center.

When the second study is performed, the Field Center handles the sleep data just as it would for a first study. The home visit forms must be repeated as described in Section 7.3.2, above. When the Reading Center receives the sleep data, they are handled just like a first study, except that the Quality Assessment form notes that it is a repeat study. The Field Center must also inform the Reading Center that a study is a repeat by identifying the study as a repeat on the zip cartridge and/or sending a memo to the Reading Center with the study identifying the study as a repeat.

If the second study is successful, the sleep data from the first (failed) study are deleted from the Reading Center computer system. However, the sleep data from the first study are not deleted until the second study has been completed and reviewed at the Reading Center. The raw data from the second study and the scored file are forwarded to the Coordinating Center, where they are handled in the same way as first studies.

If the second study is also a failed study, the raw data from one of the studies (the one with the "best" data in the judgement of the Reading Center) is archived at the Coordinating Center, but no scored file exists. No further attempts are made to complete the study.

All efforts should be made to repeat the sleep study as soon as possible, in order to maintain the best possible relationship with the participant. However, since the Home Visit forms will be repeated, there is not a strict window during which the repeat study must be completed.



Reading Center
Cleveland VA Medical Center
10701 East Boulevard
Cleveland, Ohio 44106
216/791-3800
Susan Redline, M.D., M.P.H. x5175

Susan Surovec, x4771
Kathleen Fisher-Polak, x5798

REPEAT STUDY REQUEST

TO: _____
(SITE COORDINATOR)

DATE: _____

Study ID # _____ was received at the
Reading Center on _____. As the preliminary report attached
indicates, this study has insufficient data for reliable scoring due to _____. ***

Please indicate below whether or not this study can be repeated.

_____ Study will be repeated.

_____ Study cannot be repeated.

(Signature)

(Date)

*****Note:**

The Steering Committee have changed the criteria for minimally acceptable data. A study is now required to have four hours of continuous EEG, oximetry, and either the thorax or abdomen.

Please fax your reply to the Reading Center and Coordinating Center within one week of receipt. Fax #216/231-3420.

cc: Coordinating Center

SHHSQA5:298

7.4 Troubleshooting

7.4.1 Problems Recording Data

If “flat lines” or “fuzzy lines” are noted in data review, consult with your Sleep Study Resource.

1. “Loss of signals” (“flat-line”). This usually occurs because: sensors or connecting wires are damaged, or sensor disconnected from skin/scalp, or cable disconnected from recorder.

Solution: Inspect integrity of wires/sensors and their connections. Pay special attention to where sensors/wires inter-connect. Re-secure connections or replace any damaged equipment. Do a test session in the clinic/lab to ascertain sensor functioning appropriately.

2. “Artifact” (“fuzzy lines”). This includes:
 - a) 60 Hz artifact, from: High impedances; Unequal impedances; Poor electrical contacts; Electromagnetic environmental fields (includes electric blankets, hearing aides); Electrical leakage currents
 - b) Mixed frequency artifact, from: Poor electrical contacts; Electromagnetic environmental fields; Electrical leakage currents
 - c) Electrode “popping” (bursts of signals), from: Electrodes loose -- lift off skin; Poor placement; Participant lies on sensors
 - d) Strong ECG signals on other channels, from: Long electrode distances; Horizontally displaced heart or obese neck (in obese people)
 - e) Sweat artifact (rolling artifact seen with breathing)

Solutions: Lower and equalize impedances: Better skin prep (abrasion), more careful application of conductive gel. Keep any unnecessary electrical appliances away from bed (electric blankets). Avoid soft (fatty) tissues when applying electrodes (bony areas near mastoid). Encourage use of a fan or air conditioner if hot. Arrange leads in a way to minimize pulling/tugging (popping).

3. Low amplitude of respiratory signals or poor oximeter signal: Usually these are related to poor placement of sensors (too tight, too loose, or positioned poorly).

Solution: Check positioning. Always place sensors snugly but not too tight.

4. No data, or data stopped after short recording time: A short recording time usually results from incorrect setting of the automatic clock, a battery failure, a disconnect of a main cable, or that the participant prematurely turned off the monitor. However, if the montage is changed, the polygraph configuration may require more megabytes per hour, resulting in less time fitting on a 20MB flashcard. This will be evident if the study is 19-20 MB but only contains 5-6 hours of data.

Solution: Check that the montage has not been altered.

If duration of study is noted as “0,” the study will indicate “number of epochs detected” rather than “epochs completed.” This generally indicates that the headbox cable and recorder were not properly connected.

Solution: Check the cable connections.

Another pattern of missing data is a study that sequentially loses data from channels in the order that they appear on the PIB.

Solution: Check the cable connections -- those to the PIB are especially vulnerable. If a PIB cable connection that has been soldered appears loose, it will need to be re-soldered. Contact the RC and return PIB and cable connection to Compumedics.

If several studies stop inexplicably around epoch 700 (± 50), there may be a problem with the current BIOS version. This is a problem with compatibility between the BIOS and the flashcard format.

Solution: Notify the RC immediately if this occurs.

5. Battery reads 0.3V (or other obviously wrong voltage). This probably means a recorder failure.

Solution: First check that problem is not duplicated with a different fully charged battery. If not, contact the RC.

6. PIB heats up during testing. This indicates a faulty PIB.

Solution: Contact the RC and return equipment to Compumedics.

7. Respiratory inserts loosen and are no longer usable.

Solution: Notify the RC and return unit to Compumedics.

8. Metal safety bar on PIB loosens.

Solution: Replace screw (brass replacement from Compumedics preferable). (Can use a rubber band to secure temporarily.)

9. Plastic connector to respiratory bands disconnects too freely.

Solution: Carefully secure this connection using an adjustable wrench, just more than “finger tight.” Do not use glue.

10. Position sensor starts to give incorrect values. This usually means that the mercury in the sensor is stuck, or dispersed.

Solution: Check that dipswitch is set properly. Then, gently jolt PIB. If unsuccessful, contact RC.

7.4.2 On-site Troubleshooting Procedures

If problems recording data are noted that are not resolved with the aforementioned steps (7.4.1), attempt to isolate the problem to the portable unit or PIB by using the “swapping” technique below. If problem source still unclear, use procedures 7.4.2.1 (Portable Quick-cal) or 7.4.2.2 (PIB Quick-cal) below or both to determine if problem resides in portable unit or PIB.

1. Swapping: Attempt to isolate the problem (to sensors, PIB, monitor, or cable) by sequentially “swapping” parts until the problem is resolved. (Exchange PIBs, batteries, flashcards, etc.) For example, if a problem is noted with the thorax/abdomen channels, first insert new respiratory bands in the problem system. If problem is resolved, then the problem likely is due to faulty bands. If it persists, exchange PIBs. If problem is resolved, the problem was due to a faulty PIB, not monitor, etc. If still unresolved, exchange portable units, etc.
2. After this preliminary assessment, Contact the RC. (Jeff Winters or Susan Surovec at 216/791-3800, ext. 4771).
3. If problem is still not resolved, complete a Fault Report form, send a copy to the RC, keep a copy for your records, and send a copy to Compumedics along with the complete system (Portable, PIB, flashcard, and battery).

When units are shipped to Compumedics for repair, be sure to indicate on the packing slip “For Repair/ Under Warranty.” This will prevent Customs charges.

7.4.2.1 Portable Quick Calibration Procedure

This is to be used to assist in identifying if a faulty Portable unit is responsible for problem data. This procedure can also be used in the home during hook-up if a problem is noted with any given channel. Consider doing this if you have extra PIBs or monitors that can be “swapped” during a problematic hook-up.

Equipment: Compumedics Potable Recorder with battery, calibration box, and large test lead (PIB cable with red/black leads).

Procedure:

1. Set Calibration box as follows:

Bank.....B	Switch.....7
Scale..... μ V	Impedance.....OFF
Speaker.....OFF	Power.....ON

2. Connect the test cable between the Portable and the Calibration box (RED=Output, BLACK=Reference).
3. Turn on the Portable.
4. Select CHANNEL, [Next], [Next], then VIEW CHANNEL.
5. Observe sine wave for the following:

EEG(sec)	ECG	EMG	EOG(L)
EOG(R)	EEG	SOUND	AIRFLOW(Channel 17)

6. Change the Scale on the Calibration box to mV.
7. View sine wave for the THOR and ABDO channels.

If you are able to successfully view appropriate waveforms, the problem is unlikely due to a faulty monitor; proceed with PIB check.

7.4.2.2 PIB Quick Calibration Procedure

This is to be used to assist in identifying if a faulty PIB is responsible for problem data. This procedure can also be used in the home during hook-up if a problem is noted with any given channel. Consider doing this if you have extra PIBs or monitors that can be “swapped” during a problematic hook-up.

Equipment: Compumedics Portable Recorder with battery, PIB w/cable, calibration box, and PIB test lead (electrode plug connector and red/black leads).

Procedure:

1. Set Calibration box as follows:

Bank.....B	Switch.....7
Scale..... μ V	Impedance.....OFF
Speaker.....OFF	Power.....ON

2. Connect the test cable between EEG(sec) on the PIB and the Calibration box (RED=Output, BLACK=Reference).
3. Turn on the Portable.
4. Select CHANNEL, [Next], [Next], then VIEW CHANNEL.
5. Observe sine wave for EEG(sec).
6. Move the electrode plug to the next channel (ECG).
7. Select [Next] on the portable.
8. Observe sine wave for new channel (ECG).
9. Repeat 6 - 8 for the following:

EMG	EOG(L)	EOG(R)
EEG	AIRFLOW (Channel 17)	

If you are able to successfully view appropriate waveforms, the problem is unlikely due to a faulty PIB. Consider problems with cables.

7.5 Care and Maintenance of Equipment

CAUTION: NEVER LEAVE ANY EQUIPMENT (OR SHHS MATERIALS) UNATTENDED IN A CAR OR OTHER VEHICLE, OR IN A PRIVATE RESIDENCE. KEEP AWAY FROM EXTREME TEMPERATURES. Do not soak or immerse Compumedics Recorder or PIB in any liquid. Do not use autoclave, acetone-based solutions, or abrasive cleaning agents to clean any of the sensor's electrodes.

Computer and flashcard: Keep away from extreme heat or cold. Keep away from magnetic fields. Always insert flashcard in direction of arrow, never force into computer. Keep flashcard in plastic carrying box at all times when not directly being used.

Cartridges: Cartridges are similar to your computer hard drive. They store the data you have collected, and if they are damaged then your data will likely be lost. You should protect them as you would your data. The cartridges need to be protected from both physical and electrical damage. Hard impacts, such as from falling, banging, or crushing, can ruin cartridges beyond repair. They should always be stored in their protective plastic case. Be sure that they are inserted into the plastic case so that the metal slide goes into the case's hinge. Never force them into either the case or the drive. The cartridges should be mailed in padded envelopes or sturdy cardboard boxes. If shipped in boxes, please be sure to provide plenty of padding. Cartridges can be damaged electrically if they are permitted to come in contact with electrical or magnetic fields. Electrical wires, speakers, and magnets are all potential sources of damage. Electrical or magnetic fields will irretrievably erase data from your cartridges. This damage will not be apparent until someone tries to read the cartridges. As your collection of cartridges ages, your

computer may report errors with your cartridges by giving you messages about “bad sectors” or “corrupt files.” Should you experience such problems, please contact either Jeff Winters (Reading Center) or Dan Boren (Coordinating Center) for help.

Oximeter Probe (non-disposable): May be cleaned with 70% isopropyl alcohol or an antibacterial cleaner on a soft cloth. **(Do not use acetone-based cleaning agent, as damage to the sensor will occur.) Disposable: discard sensor after each use.**

Airflow sensors: Should be disposed of after one use.

Non-disposable Lead Wires with Snaps: May be cleaned with an antibacterial cleaner (VIONEX wipes) or a soft cloth. Do **not** use an alcohol-based or acetone-based cleaning agent, as damage to the wires may occur. (Disposable snap electrodes should be disposed of after one use.)

Gold Cup Electrodes with Attached Leads: Soak electrodes in warm water with mild detergent (such as Tide), then rinse electrodes in sterile H₂O and air dry. Clean with toothbrush and warm soapy water (Gold Cup EEG electrodes may also be soaked in a sterilizing disinfecting solution such as Cidex -- check manufacturer instructions before using this product).

Sleeves for chest and abdomen bands: Wash in warm soapy water after each use.

Vest: Wash at least weekly (warm soapy water -- machine washable), and more often as needed.

Do not soak or immerse headbox or PIB in any liquid to prevent damage to the unit.

7.6 SHHS Every Other Month Calibration Verification Procedure (60 minutes)

The following procedure should be completed every other month on each unit, to ensure that the amplitude of signals are correctly recorded and filtered by each portable unit. This will be accomplished by recording test voltages, generated by your Calibration Box, on a flash card used for creating a “TEST STUDY.” The adequacy of signal processing and recording will be tested by:

- a. Viewing each signal on the portable recorder (LED display).
- b. Recording the impedance values of each channel (other than oximetry, bands, light, position).
- c. Producing a paper record of your test study (screen dumps), measuring by hand the excursions of each signal.

You will need to copy Table 1 and maintain copies of these tables in a log book at your clinic site. In this log, also keep all screen dumps used to record the excursions of each channel.

Equipment:

Compumedics Calibration Box
Main Calibration cable (connects PIB main interface to Calibration box)
PIB Calibration cable (connects one electrode socket to the Calibration box)
Portable monitor w/battery and flashcard
PIB w/cable
Computer w/Portable Mgr. and Windows Replay
Portable Unit Manual, Appendix D (dip switch diagrams)

Procedure:

1. Connect the Main Calibration Cable between the Calibration Box and PIB:
 - a) insert the **red** plug into the **0.5xOUTPUT** socket of the Calibration box
 - b) insert the **black** plug into the **REFERENCE** socket of the Calibration box
 - c) insert the **grey** electrode plug into **EEG(sec)** on the PIB
2. Connect the PIB and Portable w/the PIB cable
3. Turn on the Portable and the Calibration box
4. Verify noise level by selecting CHANNEL,[next], [next] then VIEW CHANNEL. The channel should be free of noise.
5. Start Recording by selecting **[BACK]**, **RECORDING**, and **START RECORDING NOW**.
6. Verify the signal amplitude and impedance (see Diagram):
 - a) go to **CHANNEL** and then **VIEW CHANNEL** on the monitor
 - b) using the arrow keys and the **[SCALE]** and **[SPEED]** options, adjust the speed and gain appropriately (refer to the Portable Settings column of the diagram for the correct settings for each given channel). (e.g. EEG(sec) should be at 250 uV, with a speed of 20mm/s)
 - c) verify that the height of each signal (amplitude) matches the description on the below diagram (e.g., EEG(sec) just touches top and bottom of screen).
 - d) turn **IMPEDANCE ON** on the Calibration box (found above signal output) and also select **IMPEDANCE** on the Portable monitor (by selecting **[BACK]**, **IMPEDANCE**)
 - e) verify the **RED** pin is in **0.5xOUTPUT**. Ascertain that the screen on the Portable monitor reads **5k**. Record this value in column 5 (Impedance 5k) on Calibration Form. If impedance <4 or >6 contact the RC.

-
- f) return the **RED** pin to **1.0xOUTPUT**. Ascertain that the screen on the Portable monitor reads **10k**. Record this value in column 6 (Impedance 10k) on Calibration Form. If impedance <9 or >11 contact the RC.
 - g) turn the **IMPEDANCE OFF** on the Calibration Box
 7. Move the grey pin connector to the next channel (**ECG**).
 8. Verify the signal amplitude and impedance (see Diagram):
 - a) go to **CHANNEL** and then **VIEW CHANNEL** on the monitor
 - b) using the arrow keys and the [SCALE] and [SPEED] options, adjust the speed and gain appropriately (refer to the Portable Settings column of the diagram for the correct settings for each given channel).
 - c) verify that the height of each signal (amplitude) matches the description on the below diagram.
 - d) turn **IMPEDANCE ON** on the Calibration box (found above signal output) and also select **IMPEDANCE** on the Portable monitor (by selecting [BACK], IMPEDANCE)
 - e) move the **RED** pin into **0.5xOUTPUT**. Ascertain that the screen on the Portable monitor reads **5k**. Record this value in column 5 (Impedance 5k) on Calibration Form. If impedance <4 or >6 contact the RC.
 - f) return the **RED** pin to **1.0xOUTPUT**. Ascertain that the screen on the Portable monitor reads **10k**. Record this value in column 6 (Impedance 10k) on Calibration Form. If impedance <9 or >11 contact the RC.
 - g) turn the **IMPEDANCE OFF** on the Calibration Box
 9. Move the grey pin connector to the next channel (**EMG**).
 10. Verify the signal amplitude and impedance (see Diagram):
 - a) go to **CHANNEL** and then **VIEW CHANNEL** on the monitor
 - b) using the arrow keys and the [SCALE] and [SPEED] options, adjust the speed and gain appropriately (refer to the Portable Settings column of the diagram for the correct settings for each given channel).
 - c) verify that the height of each signal (amplitude) matches the description on the below diagram.

- d) turn **IMPEDANCE ON** on the Calibration box (found above signal output) and also select **IMPEDANCE** on the Portable monitor (by selecting [BACK], IMPEDANCE)
 - e) move the **RED** pin into **0.5xOUTPUT**. Ascertain that the screen on the Portable monitor reads **5k**. Record this value in column 5 (Impedance 5k) on Calibration Form. If impedance <4 or >6 contact the RC.
 - f) return the **RED** pin to **1.0xOUTPUT**. Ascertain that the screen on the Portable monitor reads **10k**. Record this value in column 6 (Impedance 10k) on calibration Form. If impedance <9 or >11 contact the RC.
 - g) turn the **IMPEDANCE OFF** on the Calibration Box
11. Move the grey pin connector to the next channel (**EOG(L)**).
12. Verify the signal amplitude and impedance (see Diagram):
- a) go to **CHANNEL** and then **VIEW CHANNEL** on the monitor
 - b) using the arrow keys and the [SCALE] and [SPEED] options, adjust the speed and gain appropriately (refer to the Portable Settings column of the diagram for the correct settings for each given channel).
 - c) verify that the height of each signal (amplitude) matches the description on the below diagram.
 - d) turn **IMPEDANCE ON** on the Calibration box (found above signal output) and also select **IMPEDANCE** on the Portable monitor (by selecting [BACK], IMPEDANCE)
 - e) move the **RED** pin into **0.5xOUTPUT**. Ascertain that the screen on the Portable monitor reads **5k**. Record this value in column 5 (Impedance 5k) on Calibration Form. If impedance <4 or >6 contact the RC.
 - f) return the **RED** pin to **1.0xOUTPUT**. Ascertain that the screen on the Portable monitor reads **10k**. Record this value in column 6 (Impedance 10k) on Calibration Form. If impedance <9 or >11 contact the RC.
 - g) turn the **IMPEDANCE OFF** on the Calibration Box
13. Move the grey pin connector to the next channel (**EOG(R)**).
14. Verify the signal amplitude and impedance (see Diagram):
- a) go to **CHANNEL** and then **VIEW CHANNEL** on the monitor

- b) using the arrow keys and the [SCALE] and [SPEED] options, adjust the speed and gain appropriately (refer to the Portable Settings column of the diagram for the correct settings for each given channel).
 - c) verify that the height of each signal (amplitude) matches the description on the below diagram.
 - d) turn **IMPEDANCE ON** on the Calibration box (found above signal output) and also select **IMPEDANCE** on the Portable monitor (by selecting [BACK], IMPEDANCE)
 - e) move the **RED** pin into **0.5xOUTPUT**. Ascertain that the screen on the Portable monitor reads **5k**. Record this value in column 5 (Impedance 5k) on Calibration Form. If impedance <4 or >6 contact the RC.
 - f) return the **RED** pin to **1.0xOUTPUT**. Ascertain that the screen on the Portable monitor reads **10k**. Record this value in column 6 (Impedance 10k) on Calibration Form. If impedance <9 or >11 contact the RC.
 - g) turn the **IMPEDANCE OFF** on the Calibration Box
15. Move the grey pin connector to the next channel (**EEG**).
16. Verify the signal amplitude and impedance (see Diagram):
- a) go to **CHANNEL** and then **VIEW CHANNEL** on the monitor
 - b) using the arrow keys and the [SCALE] and [SPEED] options, adjust the speed and gain appropriately (refer to the Portable Settings column of the diagram for the correct settings for each given channel).
 - c) verify that the height of each signal (amplitude) matches the description on the below diagram.
 - d) turn **IMPEDANCE ON** on the Calibration box (found above signal output) and also select **IMPEDANCE** on the Portable monitor (by selecting [BACK], IMPEDANCE)
 - e) move the **RED** pin into **0.5xOUTPUT**. Ascertain that the screen on the Portable monitor reads **5k**. Record this value in column 5 (Impedance 5k) on Calibration Form. If impedance <4 or >6 contact the RC.
 - f) return the **RED** pin to **1.0xOUTPUT**. Ascertain that the screen on the Portable monitor reads **10k**. Record this value in column 6 (Impedance 10k) on Calibration Form. If impedance <9 or >11 contact the RC.
 - g) turn the **IMPEDANCE OFF** on the Calibration Box

17. Move the grey pin connector to the next channel (**AUX**).
18. Verify the signal amplitude and impedance (see Diagram):
 - a) go to **CHANNEL** and then **VIEW CHANNEL** on the monitor
 - b) using the arrow keys and the [SCALE] and [SPEED] options, adjust the speed and gain appropriately (refer to the Portable Settings column of the diagram for the correct settings for each given channel).
 - c) verify that the height of each signal (amplitude) matches the description on the below diagram.
 - d) turn **IMPEDANCE ON** on the Calibration box (found above signal output) and also select **IMPEDANCE** on the Portable monitor (by selecting [BACK], IMPEDANCE)
 - e) move the **RED** pin into **0.5xOUTPUT**. Ascertain that the screen on the Portable monitor reads **5k**. Record this value in column 5 (Impedance 5k) on Calibration Form. If impedance <4 or >6 contact the RC.
 - f) return the **RED** pin to **1.0xOUTPUT**. Ascertain that the screen on the Portable monitor reads **10k**. Record this value in column 6 (Impedance 10k) on Calibration Form. If impedance <9 or >11 contact the RC.
 - g) turn the **IMPEDANCE OFF** on the Calibration Box
19. Remove the grey pin connector.
20. Connect the oximeter, resp bands, and light sensor to the main unit. Follow instructions in Table 2-B (Calibration of Effort, Position, and Light) and complete log (description of channels).
21. Verify signals on all remaining channels using Table 2-B
22. End recording by selecting [**BACK**], **RECORDING**, and **STOP RECORDING NOW**.
23. Download file from flash card to computer using Portable Mgr.
24. Using Windows Replay, do a print screen of one epoch for each channel recorded:
 - a) In Replay, Select Options|Config Polygraph from the File menu.
 - b) Set the polygraph as follows, using Add and Delete:

<u>Channel</u>	<u>Size</u>	<u>Color</u>	<u>Grid</u>	<u>Zoom</u>	<u>Channel</u>	<u>Size</u>	<u>Color</u>	<u>Grid</u>	<u>Zoom</u>
EEG(SEC)	6	Black	ON	x1	ECG	6	Black	ON	x1
EMG	6	Black	ON	x1	EOG(L)	6	Black	ON	x1
EOG(R)	6	Black	ON	x1	EEG	6	Black	ON	x1
AUX/AIR	6	Black	ON	x1	THOR	6	Black	ON	x1
ABDO	6	Black	ON	x1					

- c) Save the montage to button #9 (or any other free layout) by pressing the button number under the Save column on the far left.
- d) Press OK.
- e) Page through the study to the recorded channel.
- f) Select File|Print and press OK.

Note: Be sure that you are printing in “landscape” mode. Do this by selecting Print Setup from the File menu, and set Paper Size to Landscape.

*****Warning:** *Be sure to change your polygraph setting back to normal when you are finished.*

- 25. Compare the printed copies to the figures below.
- 26. Measure the height of 10 wave forms per channel. Do this with a clear ruler, measuring the VERTICAL height, assessed from nadir to peak. Keep the ruler perpendicular to a horizontal line drawn between peaks and nadir points (see example below). Measure the vertical height between respective grid lines (see example). Average the heights of the 10 waves that you have measured and record this in the appropriate column in Table 1. Divide by the distance between grid marks and record this value next to the preceding value. Ascertain that this ration is 0.95-1.05. Notify the RC if signal morphology does not match the described wave form (e.g., ECG looks like a QRS complex), and if the average height of the signals differ by > 5% of the maximum deflection (between grid lines; ratio <0.5, >1.05).

Table 1

Calibration Procedure Checklist								
Portable # _____				PIB # _____				
Channel #	Channel Label	Noise levels low? (Y/N)	Signal viewed on LED matches description?	Impedance values displayed (write the actual value)		Signal viewed in Replay matches description? (Y/N)	Average amplitude displacement (from printouts)/	Comments (eg describe differences, excessive noise)
1	SaO ₂	---		---	---			
3	EEG(sec)							
4	ECG							
7	EMG							
8	EOG(L)							
9	EOG(R)							
10	EEG							
11	Sound/Mic			---	---			
13	THOR			---	---			
14	ABDO			---	---			
15	Position	---		---	---			
16	Light	---		---	---			
17	Aux/Air							

Conclusion: This portable unit, PIB, and PIB cable **passed/did NOT pass** the Calibration Check.

Tech:

/ /

Site:

Date:

Table 2 - A Calibration Box Settings

For PIB channel:	Set Calibration Box to:				Set the Portable to:		Signal just touches the top and bottom of the screen?
	Bank	Number	Scale	Output	Scale (uV)	Speed (mm/s)	
3 - EEG	B	6	mV	0.5	250	20	Yes
4 - ECG					625		No*
8 - EOG (L)					250		Yes
9 - EOG (R)					250		
10 - EEG					250		
7 - EMG	B	4	uV		31.3	5	No*
13 - THOR	B	7	mV		x 8	20	
14 - ABDO					x 8		
11 - SOUND					x 1		Yes
17 -	B	7	uV		62.5	5	No*

*there should be approximately 2mm gap on the top and bottom

Table 2 - B Calibrations for Effort, Position, and Light

Sensor:	Procedure:	Output: (View channel)
Oximeter (ch. 1)	apply probe to finger with no respiratory disorder (observe normal application procedure)	>95%
Resp. Bands (ch.15 & 16)	Stretch bands approximately 1mm and then back 10 times, 2 seconds each time.	0.5 Hz sine wave taking up full screen (+/- 10%) Peaks may go off screen.
Position (ch. 18)	Place headbox in four positions, simulating patient: back, front, left, and right	Observe the words BACK, FRONT, LEFT, and RIGHT, corresponding to the headbox position
Light (ch. 19)	Expose sensor to light, then cover	observe the words LIGHTS ON and LIGHTS OFF

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SLEEP HEART HEALTH STUDY MANUAL OF OPERATIONS

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8.1 Cardiovascular Events

8.1.1 Endpoints

The following *incident* events will be considered endpoints for the SHHS:

- a) hospitalized acute MI (HAMI)
- b) coronary surgical intervention -- percutaneous transcatheter angioplasty (PTCA), coronary stent placement, coronary artery bypass grafting (CABG)
- c) angina pectoris (AP) -- at CHS and FHS only
- d) coronary heart disease death
- e) any coronary heart disease (CHD) -- summary variable which includes a - d above.

The following *recurrent* events will be considered endpoints for the SHHS:

- a) HAMI
- b) coronary surgical intervention

8.1.2 Ascertainment

Cardiovascular events will be ascertained at least every two years and at least once by the end of Grant Year 3 (August, 1998). Each investigative center will identify potential outcome events and obtain the relevant hospitalization, outpatient procedure, and physician records. Protocols vary for the different parent study cohorts, and are summarized below.

8.1.2.1 Framingham

Very few of the FHS subjects participating in the SHHS will have a follow-up clinic visit prior to August, 1998, so the majority of events will be ascertained during a structured telephone or home interview. Subjects who undergo sleep studies between October, 1995 and August, 1996 will be visited in the home two years after the PSG. During this visit blood pressure will be measured in a standardized fashion and a modified ARIC Annual Follow-up Questionnaire form will be administered. Subjects who undergo sleep studies between September, 1996 and March, 1997 will not be due for their two-year-post-PSG BP measurement until Year 4 of the study; therefore, the modified Annual Follow-up Questionnaire Form will be administered over the telephone between June and September, 1998. Any potential outcome events identified will be referred to the FHS medical records department to complete data collection and allow the event to be adjudicated. Consent to obtain copies of medical records is granted by the FHS members as part of their participation in the parent study.

8.1.2.2 Johns Hopkins

In the ARIC portion of the cohort, events will be ascertained every twelve months either by annual phone calls with administration of the Annual Follow-up Questionnaire Form or during a structured history at the tri-annual clinic visit. Hospitalization records for potential outcome events will be obtained and abstracted by trained personnel. All DRG discharge codes are

recorded. ECGs will be photocopied and classified by the Minnesota coding system. Consent to obtain copies of medical records is given as part of the overall consent for participation in ARIC.

In the CHS portion of the cohort, potential events will be ascertained every six months by phone calls alternating with clinic visits. Hospitalization and outpatient procedure records will be obtained and abstracted by trained personnel. ECGs will be photocopied and classified by the Minnesota coding system. Consent to obtain copies of medical records is given as part of the overall consent for participation in CHS.

8.1.2.3 Minnesota

Ascertainment procedures and abstraction forms for potential events will be identical to those used by the Johns Hopkins ARIC Cohort (see 8.1.2.2).

8.1.2.4 NYU/Cornell

Potential CHD events in the New York City cohorts will be ascertained two years after PSG or at the end of Grant Year 3 (whichever is earlier). Participants who undergo PSG during Grant Year 1 will return to the clinic for follow-up blood pressure measurements and administration of a modified ARIC Annual Follow-up Questionnaire form during Year 3. Those participants who undergo PSG during Year 2 will be administered the follow-up questionnaire over the telephone in the last 4 months of Year 3, and return to the clinic for a blood pressure measurement during Year 4. Hospital and outpatient procedure records from any potential outcome event will be obtained and abstracted using the CHS forms. NYU and Cornell personnel will be trained in record abstraction for epidemiologic research. Subjects will give consent to obtain copies of medical records at the time of event ascertainment.

8.1.2.5 Pittsburgh/Sacramento

These CHS Cohorts will ascertain events, and obtain and abstract medical records in an identical fashion as the Johns Hopkins CHS Cohort (see 8.1.2.2).

8.1.2.6 Tucson/Strong Heart

Events occurring in subjects from the Tucson Epidemiologic Study of Obstructive Airways Disease (TES) and the Tucson Health and Environment Cohort (H&E) will be ascertained two years after the PSG or at the end of Grant Year 4 (whichever is earlier), using a modified ARIC Annual Follow-up Questionnaire form, administered either over the telephone or during a clinic visit. Hospital and outpatient procedure records from any potential outcome event will be obtained and abstracted using the CHS forms. Tucson personnel will be trained in record abstraction for epidemiologic research. Subjects will give consent to obtain copies of medical records at the time of event ascertainment.

Events occurring in Strong Heart Study participants will be ascertained at the time of a follow-up clinic visit, using the protocols and forms established at SHS. Copies of medical records for potential events will be obtained and abstracted.

8.1.3 Adjudication

Each parent study will adjudicate potential cardiovascular events which occur among its participants. Based on the quality assurance procedures of the parent studies and the results of the HAMI Comparability Study (summarized below), it is expected that the adjudicated results from ARIC, CHS, FHS, and SHS will be both valid and in close agreement with one another. The NYU/Cornell and Tucson centers will establish their own Cardiovascular Events Adjudication Committees. A sample of events reviewed by these committees will be re-reviewed by the SHHS Morbidity and Mortality Committee to assure comparability with the other parent studies.

8.1.3.1 Results of the HAMI Comparability Study

The SHHS Morbidity and Mortality Subcommittee conducted a comparability study for the outcome HAMI during the May, 1995 Steering Committee meeting. A sample of hospital records and accompanying data abstraction forms which had been previously reviewed and adjudicated by the parent studies were re-adjudicated by nine SHHS physician investigators. FHS, CHS, ARIC, and Strong Heart Study sites each contributed 26 cases. Cases were selected which had a discharge diagnosis of MI or coronary artery disease. Three cases were excluded from the results of the review; for two cases the SHHS review committee did not have the complete parent study record, and one case was inadvertently missed during the adjudication session. The ARIC criteria for HAMI were used to guide event classification; however, clinical judgement could override these guidelines.

RESULTS	SHHS Adjudication	
	Not MI	MI
Parent Study Adjudication		
Not MI	45	7
MI	2	47

The observed agreement between the parent studies and the SHHS reviewers for the classification of HAMI was 91%, with a kappa statistic of 0.82, indicative of excellent agreement. Of the 9 disagreements, the SHHS reviewers classified as MI three uncomplicated post-CABG patients with elevated cardiac enzymes and two CPK bumps after a cardiac arrest which were not classified as MI by the parent studies. In the majority of disagreements, the parent study was more conservative than the SHHS committee, suggesting that by accepting the parent study adjudication we will maintain high specificity at the expense of missing a few potential cardiovascular events.

8.1.3.2 Cohort-specific protocols for cardiovascular event adjudication

HAMI -- All parent studies rely on a combination of chest pain, ECG tracings and myocardial enzyme profiles to define MI. For the SHHS both incident and recurrent HAMI will be adjudicated at all sites. At ARIC sites, abstracted data including the Minnesota codes for serial ECGs will be entered into a computer algorithm; the result will then be reviewed by the Events Committee. CHS centers also will abstract the hospital record and Minnesota code the ECGs, but no computer algorithm will be used. Both CHS and ARIC code HAMI events as definite or probable (counted as MI in analyses), or suspect or no MI. FHS reviews will not use abstracted data (only a copy of the medical records), and ECGs will not be Minnesota coded; however, the ECG from the FHS clinic visits before and after the potential event will be considered. At FHS, HAMI is classified as definite (the only cases used in analysis), maybe and no MI. At Strong Heart, medical records are abstracted, but ECGs are not Minnesota coded; events are classified as definite MI (the only events used in analyses), suspect MI and no MI. The New York City and Tucson investigative center Adjudication Committees will adopt the CHS abstraction forms and event criteria. A random sample of records reviewed at these sites will be re-reviewed by the SHHS to assure comparability with the other sites.

Coronary Surgical Intervention -- All studies will review hospital records to identify incident and recurrent coronary interventions. Each parent study will likely adjudicate these hospitalizations for HAMI, angina pectoris or cardiovascular death; however, documentation of a CABG or PTCA during the hospitalization will be adequate to assign this outcome for the SHHS without specific adjudication.

Angina Pectoris -- Incident AP will be an adjudicated outcome only at CHS sites and at Framingham. In CHS, the outcome of angina is assigned to all subjects who have coronary disease. Criteria for “definite angina” include an exercise stress test diagnostic for ischemia, coronary angiography demonstrating 70% narrowing of an epicardial coronary artery, or the occurrence of a surgical intervention. Subjects who receive a diagnosis of HAMI are also classified as having “definite angina”. At the inception of the CHS cohort, a classification of “possible angina” was made for those subjects in whom the diagnosis could not be confirmed. “Possible angina” will not be a SHHS outcome. At FHS syndromes of coronary ischemia are classified as either “angina pectoris” or “coronary insufficiency”. For the SHHS these outcomes will be combined into the AP category. Both diagnoses rely on clinical criteria and ECG findings, augmented by catheterization and stress test results. These outcomes are coded as “definite” and “maybe” at FHS. Only the “definite” events will be utilized by the SHHS. Some of the adjudicated AP outcomes will not be available until after the FHS Offspring Cycle 7 or Omni Cycle 2 exams, after the end of the SHHS funding period.

Cardiovascular Death -- All participant deaths will be reviewed by the parent study Events Committees. At ARIC, CHS, and FHS copies of recent hospitalizations, death certificates and autopsy results are obtained, and abstracted at ARIC and CHS. In addition, the subject’s physician and family or other proxy is interviewed to obtain additional data regarding the death. Each committee determines whether or not the death was due to coronary heart disease, and whether the death was sudden or not. The Tucson and New York City investigative centers will adopt the CHS abstraction forms and event criteria. The SHHS will perform a comparability study for mortality (all-cause, coronary heart disease and cerebrovascular disease) similar to the HAMI comparability study.

Any Coronary Heart Disease -- This will be a summary variable including all subjects who receive an adjudicated diagnosis of any of the other cardiovascular outcomes.

8.2 Congestive Heart Failure

8.2.1 Endpoints

Incident clinical CHF will be an endpoint for all SHHS subjects except for ARIC participants. In the CHS and FHS cohorts, routine echocardiograms are performed on all participants. The continuous variables of left ventricular mass and left ventricular ejection fraction will be endpoints for the SHHS participants from these parent studies.

8.2.2 Ascertainment

Ascertainment for potential CHF events will occur using the same forms during the same interviews as ascertainment of potential cardiovascular events at FHS and CHS. (See 8.1.2.1 and 8.1.2.2). At the NYU/Cornell and Tucson sites, medical records for any potential episode of CHF ascertained during the follow-up questionnaire will be obtained and sent to the Cardiovascular Events Adjudication Committee.

For FHS participants follow-up echocardiograms will be performed at the clinic visit following the PSG. The FHS Offspring Cycle 7 and Omni Cycle 2 exams will not be completed before the end of Year 4, so these data will not be available for all participants in this funding cycle.

8.2.3 Adjudication

Incident CHF will be adjudicated by the Events committees. CHS criteria for CHF include decreased systolic cardiac function, a report of cardiomegaly and pulmonary edema on chest X-ray, or an appropriate response to pharmacologic treatment for CHF. Framingham criteria include a combination of clinical signs and symptoms such as rales, edema, dyspnea, or orthopnea, and physiologic tests demonstrating decreased systolic function. For the SHHS endpoint of incident clinical CHF only measurements of systolic cardiac function obtained for clinical purposes will be utilized. NYU/Cornell and Tucson will adopt the CHS criteria.

The variables of left ventricular mass and left ventricular ejection fraction will not be adjudicated. Only the echocardiograms performed at the Field Centers and interpreted by CHS and FHS investigators (not tests performed for clinical purposes) will contribute to this data base.

8.3 Cerebrovascular Events

8.3.1 Endpoints

SHHS cerebrovascular endpoints will comprise all strokes, both incident and recurrent, and hospital admission for carotid endarterectomy. Strokes will be subclassified as hemorrhagic and non-hemorrhagic, and as fatal or nonfatal. Hemorrhagic strokes will be further subclassified as subarachnoid or intracerebral hemorrhage. Non-hemorrhagic strokes may be subclassified by specific etiology (such as embolic, lacunar, or atherothrombotic) if a planned comparability study demonstrates substantial agreement between studies on these details.

8.3.2 Ascertainment

Ascertainment of cerebrovascular endpoints will be conducted at the same time and with the same follow-up forms as ascertainment of cardiovascular endpoints (see 8.1.2).

8.3.3 Adjudication

Stroke is broadly defined as a constellation of neurologic symptoms with a sudden onset which lasts at least 24 hours or until death. The SHHS will use the parent study adjudication results for stroke (assuming that a planned comparability study reveals a high degree of agreement between sites). The NYU/Cornell and Tucson centers will establish their own Cerebrovascular Events Adjudication Committees. A sample of events reviewed by these committees will be re-reviewed by the SHHS Morbidity and Mortality Committee to assure comparability with the other parent studies.

For the carotid endarterectomy endpoint, documentation of this procedure during a hospitalization will be adequate to assign this endpoint without adjudication.

8.3.3.1 Site-specific protocols for cerebrovascular adjudication

ARIC (Johns Hopkins and Minnesota sites) -- Hospital records for potential cerebrovascular events will be obtained, and abstracted onto ARIC forms. A computer algorithm which includes symptoms, physical findings, the presence of a non-carotid embolic source, the results of CT scans, cerebral angiograms and lumbar punctures, and pathology reports will initially classify the event. Computer classifications will be reviewed by the Events Committee. ARIC classifications for stroke will correspond to the following SHHS endpoints:

ARIC Endpoint	SHHS Endpoint
Subarachnoid hemorrhage	Any stroke, hemorrhagic stroke, subarachnoid hemorrhage
Brain hemorrhage	Any stroke, hemorrhagic stroke, intracerebral hemorrhage
Thrombotic brain infarction	Any stroke, non-hemorrhagic stroke
Non-carotid embolic brain infarction	Any stroke, non-hemorrhagic stroke
Undetermined type	Any stroke

All fatal strokes will be classified both by the most specific etiology determined and as “fatal stroke.”

CHS (Johns Hopkins, Pittsburgh and Sacramento sites) -- When potential cerebrovascular events are identified, the medical records will be abstracted, the patient or family proxy will be interviewed, copies of brain images will be obtained, and all data will be reviewed by a study neurologist. If the diagnosis is not apparent from these data, the neurologist will discuss the case with the subject’s physician or examine the patient. The full record, including the report of the study neurologist and the MRI obtained as part of the baseline CHS exam, will then be reviewed by the Cerebrovascular Disease Endpoint Committee. CHS classifications for stroke will correspond to the following SHHS endpoints.

CHS Endpoint	SHHS Endpoint
Hemorrhagic, subarachnoid	Any stroke, hemorrhagic stroke, subarachnoid hemorrhage
Hemorrhagic, intra parenchymal	Any stroke, hemorrhagic stroke, intracerebral hem.
Hemorrhagic, indeterminate	Any stroke, hemorrhagic stroke
Ischemic, lacunar	Any stroke, non-hemorrhagic
Ischemic, cardioembolic	Any stroke, non-hemorrhagic
Ischemic, atherosclerotic	Any stroke, non-hemorrhagic
Ischemic, other (arterial dissection or arteritis)	Any stroke, non-hemorrhagic
Ischemic, unknown	Any stroke, non-hemorrhagic

All fatal strokes will be classified both by the most specific etiology determined and as “fatal stroke.”

FHS -- When potential cerebrovascular events are identified, medical records will be obtained, and the subject will be invited to a special exam in the Neurology Clinic at the FHS. The findings of this exam, the medical record, copies of brain-imaging studies and results of spinal fluid analyses are reviewed by the Stroke Endpoints Committee. FHS classifications for stroke will correspond to the following SHHS endpoints.

FHS Endpoint	SHHS Endpoint
Subarachnoid hemorrhage	Any stroke, hemorrhagic stroke, subarachnoid hemorrhage
Intracerebral hemorrhage	Any stroke, hemorrhagic stroke, intracerebral hemorrhage
Embolic stroke	Any stroke, non-hemorrhagic stroke
Atherothrombotic	Any stroke, non-hemorrhagic stroke

All fatal strokes will be classified both by the most specific etiology determined and as “fatal stroke.”

NYU/Cornell -- When potential cerebrovascular events are identified medical records and copies of brain imaging studies will be obtained and abstracted onto CHS forms. The subject or proxy will be interviewed using the CHS protocol. The Cerebrovascular Endpoints Committee will then review the data and classify the event into one of SHHS categories.

Tucson and Strong Heart Centers -- When potential cerebrovascular events are identified medical records and copies of brain imaging studies will be obtained and abstracted onto CHS forms. The subject or proxy will be interviewed using the CHS protocol. The Cerebrovascular Endpoints Committee will then review the data and classify the event into one of SHHS categories.

A random sample of events reviewed by the Tucson and NYU Cerebrovascular Endpoints Committees will be re-reviewed by the SHHS Morbidity and Mortality Committee to assure a high degree of agreement between the parent studies.

8.4 Hypertension

8.4.1 Endpoints

SHHS will define incident hypertension as a new physician diagnosis of hypertension, beginning treatment with anti-hypertensive medications, or a systolic BP > 160 or a diastolic BP > 95. In addition, SHHS will use the continuous measures of blood pressure taken on the evening of the PSG as an endpoint in cross-sectional analyses and the change in blood pressure 2-3 years after the PSG in longitudinal analyses.

8.4.2 Ascertainment

During follow-up contacts, SHHS participants will be asked about physician-diagnosed high blood pressure and about all medications prescribed and taken. Both the initial and follow-up blood pressures will be measured with the subject in the seated position as detailed in Section 6.6.1.3 of the Manual of Operations. All of the initial blood pressure measurements will be performed in the subject's home, prior to setting up the PSG equipment. Follow-up blood pressures will vary by investigative site. In some centers, follow-up blood pressures will be measured in the subject's home two years after the PSG. In other centers, blood pressures will be measured in the clinic when the subjects return for their follow-up exams.

8.5 Mortality

8.5.1 Endpoints

Mortality endpoints will include all-cause mortality, cardiovascular mortality, cerebrovascular mortality and all vascular mortality.

8.5.2 Ascertainment

When subjects cannot be contacted for their scheduled follow-up, every attempt will be made to determine whether or not they are deceased. All known contacts for the subject will be called to determine the subject's vital status, and both local death registries and the National Death Index will be searched for their name or social security number. When a death has been ascertained, the parent study will obtain records from any hospitalization within one month of the death, a copy of the death certificate, and an autopsy report, if performed. In addition, the subject's physician and the family member or other proxy who was with the subject when they passed away will be interviewed to obtain details of the circumstances of the death. ARIC, CHS, and FHS centers will use their respective forms; Tucson and NYU will adopt the CHS forms and protocol.

8.5.3 Adjudication

All investigative centers will adjudicate all ascertained deaths using the forms and protocols established by each parent study. Events which meet the criteria for a cardiovascular or cerebrovascular outcome which also result in death will be coded as death due to cardiovascular or cerebrovascular disease. Tucson and NYU will adopt the CHS protocols.

8.6 Quality of Life

8.6.1 Endpoints

Quality of Life will be evaluated using the summary score and 8 specific domains of the SF-36 Health Survey.

8.6.2 Ascertainment

The SF-36 will be re-measured in SHHS participants two to three years after their PSG. Participants will complete the Health Survey themselves at most centers; however, some Strong Heart participants for whom an appropriate translation is not available will have the instrument administered by an interviewer.

8.7 Transfer of Adjudicated Results from the Field Centers to the Coordinating Center

During the follow-up phase of the study, self-reported and adjudicated events will be reported to the Coordinating Center every month. The Coordinating Center will issue to each Field Center a list of ID numbers of those participants whose PSG was completed two years earlier. The study coordinator will confirm that the follow-up contact has occurred or determine when follow-up is scheduled. Any self-reported symptoms or hospitalizations which have triggered parent study review and adjudication will be reported back to the Coordinating Center. Software will be developed to track these potential events from ascertainment through the collection of all relevant medical records to final adjudication for those centers which do not already have a tracking system. Periodically, each Field Center will determine the status of any incident outcomes for the

whole SHHS cohort, as some events may be ascertained during earlier or later parent study contacts. The parent study coordinating centers will be asked to send parent study adjudication results for SHHS participants to the SHHS Coordinating Center annually.



SLEEP HEART HEALTH STUDY MANUAL OF OPERATIONS

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CHAPTER 9 - STUDY ADMINISTRATION AND DATA MANAGEMENT

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The Coordinating Center has primary responsibility for study administration and data management. These are outlined below.

9.1 Study Administration

The Coordinating Center works with the Steering Committee and Project office to administer the study, including such diverse tasks as overseeing the study's day-to-day activities and monitoring overall study progress to ensure that goals are being met.

Many of these administrative activities fall under the rubric of communication, which is one of the Coordinating Center's most important functions. The Coordinating Center is to be the primary conduit for communication between all sites, the Steering Committee, and the Data and Safety Monitoring Board (DSMB). Clear, frequent, and complete communications are vital to the successful operation of a collaborative study. In some instances communications will originate at the Coordinating Center, and in other instances communications originating from another site will be sent to the Coordinating Center to be disseminated to all other sites. Communications range from formal written documents such as manuals and steering committee reports to informal communication via telephone or e-mail. Communications facilitated by the Coordinating Center will be of several forms, including the following:

Routine communications: The Coordinating Center will routinely distribute announcements regarding deadlines, upcoming meetings, decisions made by the Steering Committee, minutes from Steering Committee and DSMB meetings, etc. Depending in the nature of a particular message, these communications may be sent to Field Center PIs or Study Coordinators, the Steering Committee, or the DSMB. In general copies of all communications will be sent to the Program Office.

Routine reports: During the recruitment and data collection phase of the study, the Coordinating Center will distribute reports to Field Center PIs and Study Coordinators and to the Program Office each week summarizing recruitment progress to date and data completeness. Monthly for the first year of the study and quarterly thereafter, the Coordinating Center will distribute Quality Control reports to Field Center PIs and Study Coordinators and to the Program Office. These reports will summarize technician performance and identify any potential problems. Outlying data values will also be returned to the Field Centers to be checked. Comprehensive reports summarizing study progress will be prepared and distributed before each Steering Committee meeting and each DSMB meeting, approximately 2-3 times per year.

Special reports: Any time problems arise with data completeness or quality, Field Center performance, or in other areas, special reports will be prepared. Depending in the nature of the problem, these reports may be distributed to the entire Steering Committee or just the PI involved, along with the Program Office. In rare circumstances these reports would be distributed to the DSMB as well. Follow-up reports documenting the resolution of the problem will be prepared as well. Other special reports, including statistical reports and special progress reports will be prepared as needed or at the request of the Program Office or Steering Committee.

Documentation: The Coordinating Center will also prepare, duplicate, and distribute study manuals and other policy documents as needed.

These communications are summarized in Table 9.1 below.

Another major function of the Coordinating Center is study oversight. This includes monitoring study progress in areas such as recruitment and data completeness, identifying problems that arise, and working with Investigators and Study Coordinators to resolve the problems. In its relationship with the Field Centers, the Coordinating Center views itself not as a policeman looking for wrongdoing but rather as a collaborative supporter whose job it is to provide the Field Centers with the tools and support necessary to enable them to do their jobs efficiently.

Study oversight also includes quality assurance and control. The Coordinating Center will work with the Quality Control Committee and the Sleep Reading Center to establish quality assurance policies (activities undertaken before data are collected to assure high quality), including requirements for technician certification and observation, and equipment maintenance. The Coordinating Center will then take primary responsibility for monitoring that these policies are carried out. The Coordinating Center will also perform quality control activities (activities undertaken after data are collected to ascertain actual data quality). These will take the form of statistical reports in which data quality will be analyzed both as a whole and at the individual site and technician level. (See Chapter 11 for a detailed description of Quality Assurance and Control activities.)

Table 9.1 Coordinating Center Communications

		Time frame	Sent to:			
			FC*	SC*	PO*	DSMB*
1.	Routine communications: Deadlines, meetings, announcements, decisions, etc.	as needed**	X	X	X	X
2.	Routine reports:					
	Recruitment	weekly	X	X	X	
	Data completeness	weekly	X	X	X	
	Quality Control	monthly	X	X	X	
	Steering Committee	2-3/year		X	X	
	DSMB Report	2/year		X	X	X
3.	Special reports:	as	X	X	X	X
	Problem identified	needed				
	Problem resolved					
	Special progress report					
	Statistical reports					
	etc.					
4.	Minutes from meetings	as needed	X	X	X	X
5.	Documentation	as needed	X	X	X	X
	Manuals					
	Other policy/procedure documents					

* FC = Field Center; SC = Steering Committee; PO = Program Office;
DSMB = Data Safety and Monitoring Board

** Communication types identified as “as needed” will be sent only to those groups to which that communication pertains. Under various circumstances, this may or may not pertain to all groups indicated. For example, Routine communications regarding meeting announcements would only be sent to the DSMB if the meeting being announced was the DSMB meeting.

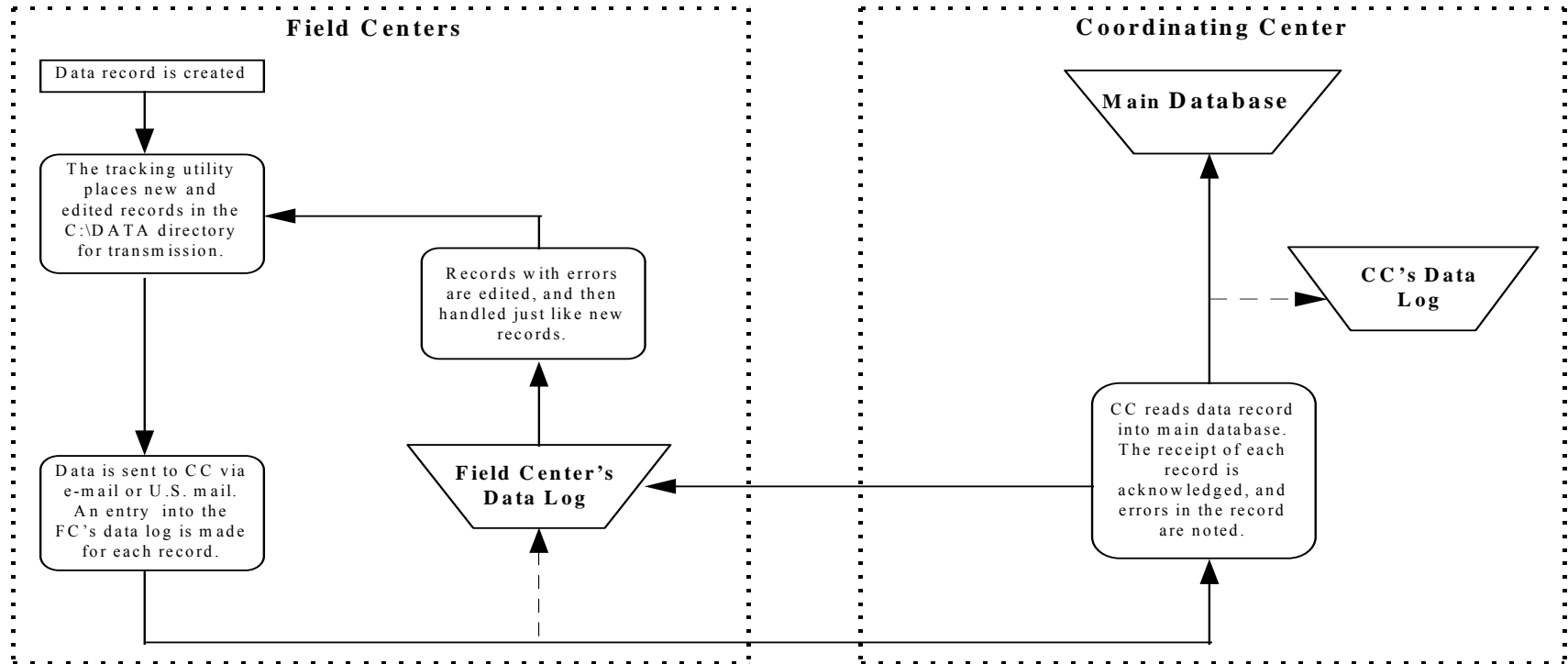
9.2 Data Management

9.2.1 Overview of Management Software

SHHS provides a software package to help in the creation, editing, and management of data that is collected for the study. Our data comes from two main sources: sleep studies and questionnaires. In order to make the handling of the data as simple (and therefore reliable) as possible, all data are handled the same way whenever possible. The software package consists of the following components:

- Recruitment - This is used to monitor and manage your recruitment of participants into the study. Reports are available to help you plan your recruitment in order to meet the study's goals on gender and race. Data entry of the Contact Form and the Sleep Habits Questionnaire is performed using this module.
- Home Visit Data - This is a package of forms that you use to enter, edit, and review data that is collected on SHHS participants during the home visit.
- Tracking - This program performs several functions to help you keep track of your data. It is used to send data that you have entered or modified to the field center. When you receive a receipt for your data, you use this program to read it in and verify that the data you sent was indeed received as intended. This program will also help you to identify records in which errors occurred and therefore must be edited and re-sent. It will help you answer questions about your data, such as when a given piece of data was sent, whether or when it was received, and whether any errors occurred. This program will also help you track and manage your Zip cartridges.
- Compumedics Software - These programs were written by the makers of the sleep monitors. They are used to initialize the flashcards before performing a study, to review the results of a study the morning after it is performed, and to copy the studies to the IOmega Zip cartridges prior to sending it to the Reading Center in Cleveland.

9.2.2 General Data Flow



This diagram shows the basic flow of sleep study or questionnaire data from the Field Centers (FC) to the Coordinating Center (CC). The goal is to move each record from the FC to the main database at the CC. The data logs permit the Field Center or the CC to see the status of each record at any time. For example, a center will be able to use the data log to see when a given record was sent to the CC, whether and when it was received at the CC, and whether any errors occurred when it was added to the main database. Operators at the Field Centers use the data log to identify records that need to be re-transmitted, whether because of errors during data entry or because they were not received at the CC.

9.2.3 Data Entry and Tracking Specifications

9.2.3.1 Sources of Data

There are several sources of data for SHHS. They are as follows:

- Recruitment Data - There are two questionnaires that are collected for participants in their parent studies and who may or may not eventually become SHHS participants: the Contact Form and the Sleep Habits Questionnaire. The Contact Form will be obtained for all persons for which recruitment was attempted. The Sleep Habits Questionnaire will be collected for all participants in all of the parent studies.
- PSG Data - An SHHS participant will have a polysomnograph (PSG) study performed using the Compumedics sleep monitors in their home visit. PSG data is collected by the sleep monitors.
- Home Visit Data - This data is collected on forms and questionnaires at the time the PSG study is performed. It consists of blood pressure and anthropometric data, medications, a cohort-specific Health Interview, a Morning Survey, an Adverse Events Form, and a Quality of Life Survey (when necessary). There are also two short summary forms filled out after the Home Visit while reviewing the PSG data: the Signal Verification form and a Sleep Data Retrieval form.
- Clinic Visit Data - this consists of the ankle/arm data and the spirometry data which needs to be collected by some parent studies and will be collected at a clinic visit.
- Parent Study Data - this consists of all parent study participants and their comparability data.

This section of the manual (9.2.3) deals only with the entry and management of the first three sources of data. Entry of medications data is covered in Section 9.3, The SHHSMEDS Program. It is assumed that all data have been cleaned and coded per instructions provided in the questionnaire/form-specific sections (see Chapters 4 and 6).

9.2.3.2 General Data Entry Procedures

Before actually entering data into the computer, there are a few general things you need to know about the process. This section will cover procedures that you will use for all forms that you deal with.

Your computer may boot up to the DOS prompt. If so, you should begin by running Windows. At the C:\ prompt, simply type WIN and hit enter. When Windows has loaded, you will see a series of icons representing groups of programs on the screen. One of them is labeled SHHS Data Management. This group contains the three parts of the SHHS software.

Although there are several different forms which will need to be data entered, the general procedure will be the same for all of them. In order to minimize keying errors, all forms are entered twice. For a given form, you will open the appropriate data entry form and key in the

entire form once. When you reach the end of the form, the computer will ask you if you are ready to begin entering the same data a second time, which we call *verifying* the form. When you begin to verify the form, the computer will hide all of the data that you just entered and go back to the top of the form. As you fill in each field the second time, the computer will compare the data you put in the first time with the data you put in the second time. If a mismatch is found, a dialog box will appear alerting you to the problem. At this point you should carefully check to be sure that you put in the data that was entered on the form. Since the computer cannot possibly know whether the error was made on the first pass or the second, it will accept whatever you put in after a mismatch is found, so please take a moment to check the value you key in against the value listed on the form.

The procedure for entering data into each field is always the same. Using either the numeric key pad or the keyboard, you type in the data exactly as it appears on the paper form, and then hit the <enter> key or the <tab> key to move on to the next field. As you proceed from one field to the next, the screen will scroll down automatically from time to time. If you find that you have made a mistake and wish to go backwards to correct it, you can hit <shift><tab> to go backwards one field. You may also use the mouse to go to a different field; simply move the mouse cursor over the desired field and click the mouse button once. If you need to go backward to a field that has already scrolled off the screen, you can use <page up> and <page down> to move as desired.

Please note that it is best to try to move from one field to the next in the normal order and without a lot of jumping around. As you enter data, the computer will check to be sure that the value you entered is acceptable, and may skip certain questions depending on the answers you gave to other questions. If you jump around on the form, the computer may become confused and will not behave predictably. Keep in mind that this is the computer's shortcoming, not yours; you have to use care when working with dumb machines.

In most cases, you will begin entering a form by entering the ID number of the participant whose data you are entering. After keying it in and hitting <enter>, the computer will check to see if it knows about a person with that number. It will not let you enter data for a person if it does not already have his or her ID number in its database. This is the one and only validity check that is performed on the participant ID. If the computer complains about an ID number that you are sure you have entered correctly, you should either call the Coordinating Center so that we can track down the problem, or create a record for the new participant (see below). Once the ID number has been accepted, the computer will automatically fill in the appropriate field center ID, and go on to the first question on the form. You will only have to enter the ID number and the field center once; when you make the verification pass you skip the ID number and field center and begin with the first question on the form.

There are a couple of reasons that you might need to create a record for a new participant. First, while doing practice studies in the initial stages of the study, you will be using special, temporary participant ID numbers. Second, for two of the field centers (New York and Framingham), enrollment is ongoing and so new ID numbers will need to be added on a regular basis. See section 9.2.3.3 under *Looking at the Participants' Personal Data* to learn how to add a participant to your database.

The data you enter will fall into one of four types: numbers, strings, dates, and times. Each deserves special mention.

- **Numbers** -- Most of the data you enter will be integers. You simply key in the number and hit <enter>. In some cases you may have a real number (one that contains a decimal) listed on the form. However, the computer expects an integer (even though a person might have said that he slept for 2.5 hours). In this case, if you enter “2.5” the computer will not accept the data. It will ask for an integer value. Follow coding instructions for the question for which such data has occurred (see Chapter 4 or 6).
- **String fields** -- String fields can contain letters, numbers, spaces, and any printable characters. The entry of string fields is straight forward-- type in the data and hit <enter>. On the verification pass, however, string fields behave differently from other data types. Your first response is not cleared as it would otherwise be, but is left on the screen. When verifying a string field, you should simply visually check the data against the paper form, and hit <enter> if no changes need to be made. You are not required to type it in a second time. If you need to correct the data, use the cursor keys, <backspace>, and <delete> to make your changes and then hit <enter> to go on to the next field.
- **Dates** -- Dates can be entered in a variety of formats. The general form for a date is *mm/dd/yy*, although you can use either a “/” or a “-” to separate month, day, and year. The year can be entered as two or four digits. You need not enter leading zeros for single digit numbers. Thus, the following are all acceptable ways to enter the date September 7, 1995:
09/07/95
9/7/95
09-07-95
9-7-1995
- **Times** -- All times are entered using a 12 hour format, and are broken down into three separate numeric fields. The first part is the hour, and it must be between 1 and 12. The second part is the minute, which must be between 0 and 59. The third part is a coded version of *AM* or *PM*, where *AM* is represented as 1 and *PM* is represented as 2. Midnight should be entered as 12:00 AM (12, 0, and 1), and noon as 12:00 PM (12, 0, and 2).

At the bottom of each screen used for data entry, you will find three fields giving the date a record was created, last edited, and last sent to the coordinating center. The data in these fields is locked, which means that you cannot edit it directly. It is there to inform you of the status of a particular record, and other parts of the software use this information to determine whether a record needs to be sent during the next transmission of data.

9.2.3.3 Tracking

Overview

As you recruit participants into the study, you can use this software to help you track your progress. For all persons in your parent study, you will attempt to collect a Sleep Habits Questionnaire. Then, for each person you attempt to enroll, you will fill out a Contact Form which will detail the results of your contacts with the participant. You can then use the data entry

forms provided to enter the data from the forms into a database on your computer. This data will be sent to the Coordinating Center at a predetermined interval, but this procedure is covered later in this chapter. To guide you in your selection of potential participants to contact in the future, you can print out reports which breakdown the participants you have recruited by age, gender, and race.

Opening the Recruitment Program

When you want to enter either a Contact Form or a Sleep Habits Questionnaire, you should begin by opening the Recruitment program in the SHHS Data Management group in Windows. Do so by double-clicking the icon labeled *Recruitment* in the SHHS group in Program Manager. When the program opens, you will be presented with the main menu, which is pictured in Figure 1.

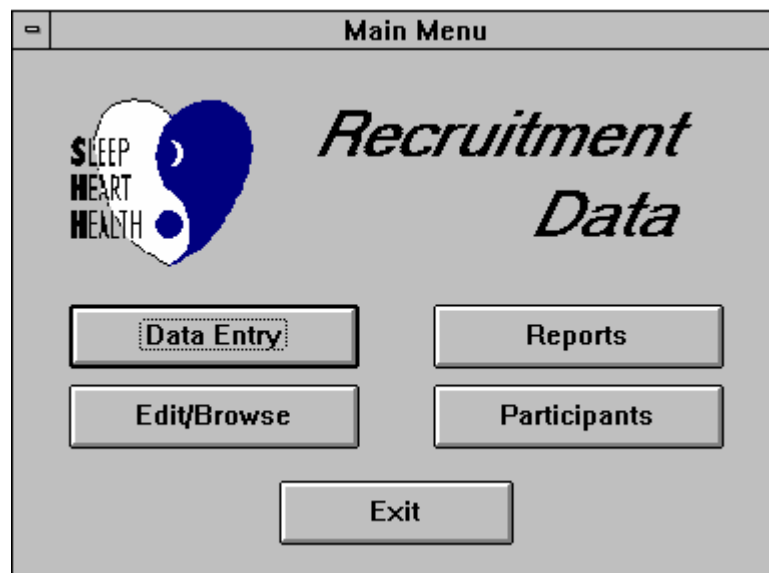


Figure 1

Entering Tracking Information

When you wish to enter one or more Contact Forms or Sleep Habits Questionnaires, you begin by clicking the button labeled *Data Entry* on the main menu. A new dialog box will appear asking you to select the form you wish to enter (see Figure 2). Open the desired form by clicking on the appropriate button. There is a distinction between *Data Entry* and *Edit/Browse* which will be explained more fully in the next section. At this point, it is important to know that when you begin by choosing *Data Entry* you will only be able to enter new data, and not look at data you have already entered.



Figure 2

When entering data in the Recruitment program, it is assumed that you will want to enter many copies of the same form. For example, you may wish to have a session in which you enter several *Contact Forms* all at once. This means that you will enter the first form, then re-enter (verify) it, and then the form will present you with a new, empty record so that you can proceed to enter the second form. You proceed in this way until you have no more forms to enter, and then you close the form by double-clicking the gray system menu box with a short, white, horizontal bar at the extreme upper left hand corner of the form.

You do not need to do anything special to save your data. This is done automatically, either when you move to a new record or close the form at the end of an editing session. Although you will find a menu item called *Save* under the File menu, it does not save the data you are entering. It is used to save changes to the form itself, if you had made any changes to it.

Examining or Editing an Existing Record

It will often happen that you wish to look at the data for a form that you have already entered, or perhaps even make changes to previously entered data. You can open the same forms that you used to enter the data the first time in such a way that they will let you do this. From the main menu, click *Edit/Browse*. You will then be prompted to select the form you wish to open.

When you open a form in this way you will only be able to examine or edit records that you have previously entered by choosing *Data Entry* from the main menu; you will not be able to create new records. It is important to note that when you are looking at a record like this, you have the ability to change nearly any data that you have entered. Your changes will be saved automatically, and the changes will be sent to the Coordinating Center the next time you transmit data.

When you first open any given form in *Edit/Browse* mode, you will see the first record of the given type that you entered. Within a single record, you can use <page up> and <page down> to scroll up and down the form, as well as using <tab> and <shift tab> to move from one field to the next.

You may also move from one record to the next by using the record selector bar at the bottom of the window. The buttons and their functions are shown in Figure 3.

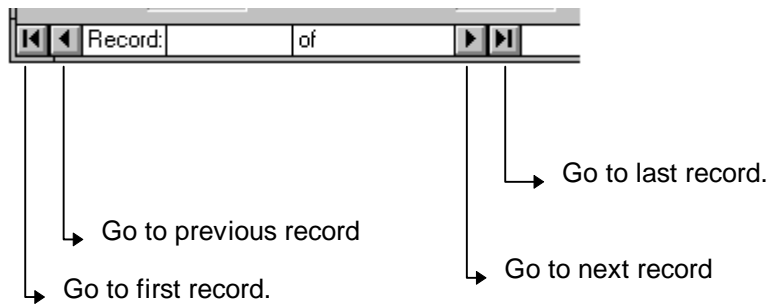


Figure 3

When you still have a small number of records in your database, using the record selector bar to move through the records will be an acceptable method, but as the number of records grows, it will become increasingly cumbersome. Soon, you will want to search for a particular record or find a particular piece of data. You can do this by going to the field that contains the data that you want to find, either by using the mouse to click on the field or by using <tab> and <shift><tab>. Then, pull down the **Edit** menu and select **Find**. A dialog box will ask you to fill in the data you want to find. Do so, and click OK. The program will then find the first record containing the requested data (if it can be found). Note that there are several options available for searching, such as case sensitive searching (for text fields), matching any part of a field, or matching exactly what you typed in. When it will be useful, hints on using these features will be given below.

For example, say that you want to find the Sleep Habits Questionnaire that you entered for the whose ID number is 90001. First, move to the Participant ID field by clicking on it with the mouse. Next, pull down the **Edit** menu and select **Find**. In the dialog box that appears, enter the number 90001, and click OK. The computer will find that participant's record and display it for you. You can then either look at it, or, if needed, make changes.

Changing Existing Data

From time to time you will find that some data that you have entered needs to be changed. You may discover an error on your own, or the coordinating center may contact you advising that a particular piece of data needs to be investigated.

The first step will be to locate the record using the techniques described in the previous section. Once the desired record is found, you can use the mouse and the keyboard to make changes. As was the case when entering data, you do not need to explicitly save your work; that will be done automatically when you move to another record or close the form. Accordingly, the field *Last Changed* at the bottom of the form will be updated after your changes are automatically saved. So, you will not see the date updated until you move to a new record and then come back to the one you just edited.

Reviewing Your Recruitment Progress

At present, two reports are provided to assist you in your recruiting. To run either of them, you should first click the *Reports* button on the main menu. You will then be asked to select the report you would like to see.

Recruitment Progress is a report which summarizes your recruitment efforts to date. It details the number of people you have contacted, how many you have recruited, and breaks down your participants by race, gender, and age. As the data in your database grows, this report may take several minutes to finish running, so please be patient once you have started it.

Scheduled Sleep Studies will let you list the PSG studies that have been scheduled between any two dates. When you select this report, you will first be asked to supply the beginning and ending dates for which the report should be run. By default, the beginning data will be the date as read by your computer's system clock, and the ending date will be one week later. You may change these dates if you wish, and then click OK to run the report. You can then click *Print Preview* to see a picture of what the report would look like, or if you have attached a printer to your computer, you can print the report by clicking *Print*.

Looking at the Participants' Personal Data

Your database contains a list of all the participants in your home study, along with certain personal information, such as their address, phone number, etc. From the main menu, you can click *Participants* to see a small form containing this information (see Figure 4).

The screenshot shows a window titled "Participant" with a "Participant Information" section. The form includes the following fields and options:

- ID:
- Sites:
- Name:
- Gender:
- Date of Birth:
- Race: 1 - White, 2 - Black
3 - Native Am/AK Native
4 - Asian/Pacific Islander
5 - Hispanic, 6 - Other
- Address:
- City: State:
- Zip:
- Home: Work:
- Notes:

At the bottom of the window, the status bar displays "Record: 4550 of 4550" with navigation icons.

Figure 4

With this form, you can find a particular participant in the same way that you found a specific *Contact Form* or *Sleep Habits Questionnaire*. You are not, however, restricted to finding a participant by ID number. To search for a participant by name, place the cursor in the name field and open the *Find in Field* dialog box by selecting **Find** from the **Edit** menu. To find a participant whose last name is Jones, for example, fill in "Jones" in the *Find What* dialog box, and then pull down the listbox next to the *Where* field and select *Any Part of Field*. Now, the computer will find all fields containing the word "Jones."

To add a new participant to your database, open the Recruitment program and click on the button labeled *Participants*. When the participant dialog boxes opens, you will see the first participant in your database. Using the record selectors at the bottom of the window, go to the *last* participant (see Figure 3 above for an explanation of the record selector bar). Then, click on the *next record* arrow to go to an empty record, and proceed to fill in the data for your new participant. There are two fields on this form that are required: the participant's ID number and the field center ID. If you try to leave either of these fields blank, the computer will complain and it will not save your new record. All of the other information is optional. You can fill it in now, fill it in later, or leave it blank for all time.

9.2.3.4 Handling of PSG Data

Overview

Once a participant has been recruited into SHHS, a sleep study will be performed on him or her. The sleep monitor used to perform this study initially stores the data on a flashcard. In order for us to use the data, it must then be downloaded onto an IOmega Zip cartridge. Two copies of each study will be made onto two separate Zip cartridges so that you can send one to the Reading Center in Cleveland, and keep the other at your field center as a temporary backup. Software to help you format the cartridges is provided. Once you have sent a cartridge, you can expect the Reading Center to send you a receipt for the data you sent. You can read this receipt into your database and ensure that all of your data was properly received. When the Reading Center has read and scored the studies contained on your cartridge, the cartridge will be sent to the Coordinating Center in Seattle, where the results will be read into the main database, and the studies will be archived onto laser disks. A few weeks after you send a cartridge to Cleveland, you can expect it to be returned from Seattle. Using the software, you can reinitialize (reformat) the cartridge along with the backup that you saved, and return them to your pool of available cartridges.

A Word on the Zip Cartridges

The Zip cartridges that we use to transfer PSG data are similar to floppy diskettes with a huge increase in storage capacity. Like floppies, you can add an electronic label to them, and write on the paper label on the cartridge itself. Although the use of these labels is not mandatory, it is **STRONGLY RECOMMENDED** that you use these features to help you manage and track your PSG data.

Two copies of each cartridge will be maintained in order to guard against losing data in the mail, the malfunction of computer equipment, or human error. Pairs of cartridges should be maintained

with similar labels. The electronic label on a Zip cartridge can be up to 12 characters long. The label can contain numbers, letters, and a few other printable characters (such as an underscore), but cannot contain spaces. We recommend a labeling scheme which identifies the field center to which a cartridge belongs, some sort of serial number, and the matching cartridge. For example, the New York field center might create its first pair of cartridges labeled NY0001_A and NY0001_B, a second pair labeled NY0002_A and NY0002_B, and so forth (see the next section for details on doing this). When the electronic label has been written to the cartridge, you should write this label on the paper label on the cartridge.

Initializing Cartridges

When using new Zip cartridges, no initialization is necessary since the cartridges are sold pre-initialized. However, it is a good idea to format them anyway so that you can add an electronic label onto the cartridge and erase the README.TXT file that comes pre-writing on new Zip cartridges. When you later begin to reuse cartridges that have been sent away and returned to you, you will need to erase them before you can write new data onto them.

Be sure to use caution when you erase a disk. The operation is not reversible, and once you begin, all of the data on the cartridge will be gone forever. Double check the labels before you begin, and do not hurry.

To erase and initialize a cartridge, find the **Zip Tools** program group in Windows. Open it, and double-click the Tools icon. This will open the IOmega Tools program. Insert the cartridge you wish to initialize in the Zip drive, and click the button with a picture of a pencil erasing a diskette on it (the second button from the left). This will open a dialog box that you use to format the Zip cartridge. You should choose *Short Format*, ensure that the bootable disk option is NOT checked, and fill in the label you wish to write onto the cartridge. Click the OK button to begin. The process takes about 8 seconds, and the program will notify you when it has finished. You should then immediately write this label on the front of the cartridge.

Labeling Zip Cartridges

Besides using Zip Tools to label a cartridge when it is initialized, it is possible to label them directly from the DOS prompt. The general command is LABEL <drive> <label>. Assume that you wanted to label two cartridges NY0001_A and NY0001_B, and that your Zip drive is drive D:. To do this, insert the Zip cartridge in the Zip drive, and enter the following command:

```
C:\>LABEL D: NY0001_A
```

Then, insert the second cartridge and enter:

```
C:\>LABEL D: NY0001_B
```

Users of File Manager in Windows can also create or change the labels. With File Manager running, insert the cartridge in the Zip drive, and make the D: drive current by clicking on the D: drive icon. Pull down the *Disk* menu, and select *Label Disk*. Enter your label and click OK.

Copying Data From a Flashcard to a Zip Cartridge

Before you can review a PSG study, you will need to convert it from the flashcard to the Zip cartridge. You do this using the *Portable Manager* in the *Compumedics P-Series* program group under Windows.

Begin by inserting the flashcard into the reader that is located immediately above the floppy diskette slot in the front of your computer. Be particularly careful to put the flashcard in right side up, and push firmly but gently until the flashcard seats into the slot. When the flashcard is correctly inserted, the green light will flash briefly and you will hear a soft, single beep. If this does not happen, or if you hear more than one beep, something is wrong and you should try again. Above all, never force the flashcard into the reader. Next, place the Zip cartridge onto which you want to copy the study into the Zip drive. Finally, open the Compumedics P-Series program group and double-click the Portable Manager icon.

From the main screen that appears, select F5 (Convert Card to Disk) either by hitting the F5 key or by clicking on the button on the screen. Another screen will appear which details the identifying information found on the card. At the bottom on this screen there are two boxes that you can use to select the destination for the study data. Although the default value is always *Hard Drive*, you should always select *Optical Drive* (which really means Zip drive). When you have done this click OK to begin. A small dialog box will keep you informed as to the progress of the conversion, and this box will disappear when the conversion is complete. This process takes about 10 minutes. When you have finished, hit <Esc> to exit the portable manager and return to Windows.

You should make note of the studies that are contained on the Zip cartridge you are dealing with so that you can keep track of the whereabouts of each piece of data. In the near future you will receive software that will help you do this, but for the present it must be done by hand.

Study Manager Instructions

Study Manager is a program for copying studies back and forth between the hard drive and Zip drive. It is recommended that you follow the following protocol for the transfer and management of studies:

1. Download a study to the hard drive.
2. Insert a Zip disk into the Zip drive and start Study Manager.
3. Select which drive you wish to view in the bottom left corner.
4. Highlight the study you wish to copy by clicking on it, or “tag” several studies you wish to work with by double-clicking them or highlighting the studies and pressing the Tag button along the bottom.
5. Depending on whether you are viewing the hard drive or the Zip, the command for copy is either Backup/Backup✓ or Restore/Restore✓, respectively.
6. Press the appropriate button, wait for the study(s) to copy, and then **verify that the study took place.**

Sending Cartridges to the Reading Center

Each Zip cartridge should hold four PSG studies. When a cartridge is full, you should make a backup copy of it and then send it to the Reading Center in Cleveland. You will keep the backup copy in a safe place until you get the original back in the mail.

When you initialized the cartridges, you should have made a pair of matching cartridges. To make a backup copy, find the cartridge that matches the one that you will send to the Reading Center. You will then use a program called Copy Machine to copy your cartridge. Note that in the Copy Machine program the term diskette is often used interchangeably with the term cartridge.

Open the *Zip Tools* group in Windows, and double click the *Copy Machine* icon to start the copy program. When *Copy Machine* has opened, click the large button at the top labeled Single Drive Copy. In the next panel down, select drive E for the single drive copy. Click OK to begin. You will be asked to insert the source diskette (the full cartridge that you want to copy) and click Start. The program will briefly examine the source cartridge, and then ask you to remove it and insert the target cartridge. Finally, you will be asked to reinsert the source diskette. Copy Machine will read the contents of your cartridge, eject it, and then ask you once again for the target diskette. When the copy is complete, the target cartridge will be ejected and the program will notify you.

Handling Cartridges Returned From the Coordinating Center

When the data on one of your cartridges has been scored by the Reading Center, and then archived at the Coordinating Center, the cartridge will be returned to you along with a notice that the cartridge is ready to be reused. When this happens, you should find the matching cartridge and reinitialize (format) them together so that they can be reused. You can keep the same labels if you like, and you should make appropriate entries into any logs you have stating that the cartridges have been returned.

9.2.3.5 Handling of Home Visit Data

Overview

For each participant in the study, we will need to collect data by filling out various forms and questionnaires. Software is provided to help you enter the contents of these forms and send the data to the Coordinating Center. The Coordinating Center should send you back a receipt acknowledging receipt of your data, and you can read these receipts into your database. This database will help you to track your data, and to resolve problems as they arise. Should the Coordinating Center advise you that there is a problem with some of your data, you will be able to use the software to make corrections and send the changes you have made.

Entering Data

Entering home visit data is very similar to entering recruitment data. From the main menu, you click *Data Entry*. You are presented with the dialog box shown in Figure 5. Like the recruitment data, you may then select any of the available forms to enter. The form you select will open, and you enter and then verify the data for one or more participants.

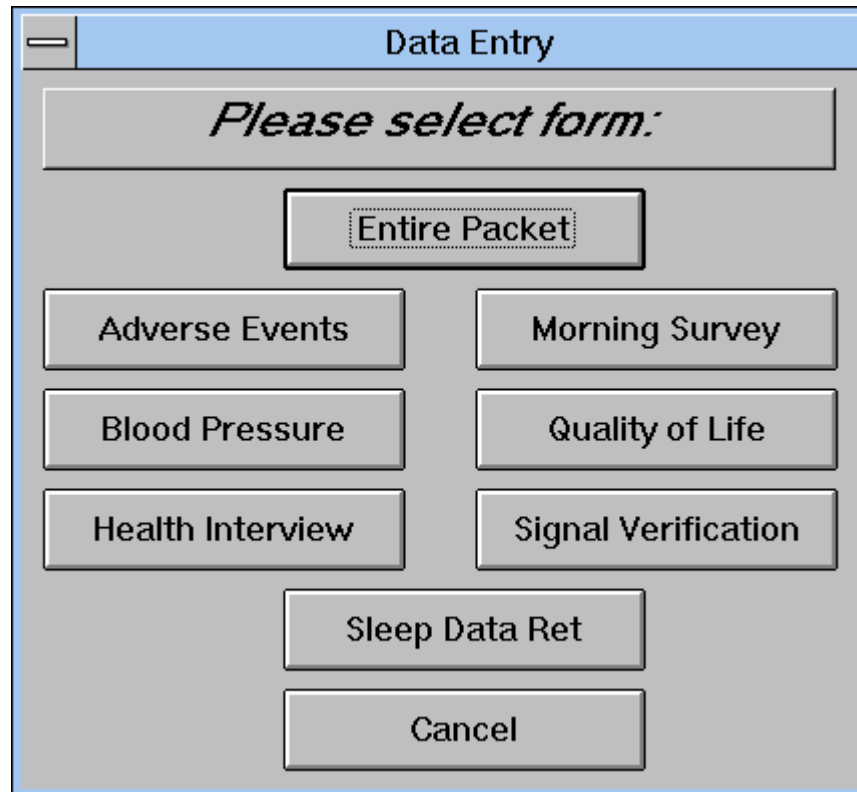


Figure 5

However, it will often be the case that you will want to enter an entire packet of forms containing all six forms from the home visit for one participant. Instead of having to open and then close each form in turn, you can click the button labeled *Entire Packet* on the *Form Select* dialog box. First, the *Adverse Events* form will come up. You will enter the participant's ID number, and then enter and verify the form as normal. When you have completed the form, a dialog box will appear saying *Next Form...* Click the OK button, and the *Blood Pressure* form will come up next. This time it will have gotten the ID number and field center ID from the *Adverse Events* form, and you will immediately begin to enter data into the computer. After it has been verified, you will proceed to enter the *Morning Survey*, *Quality of Life*, *Signal Verification* and *Sleep Data Retrieval* forms.

Resolving Errors and Editing Data

Making changes to the home visit data is done in exactly the same way as with the recruitment data. From the main menu, click on *Edit/Browse*, and then select the desired form. Notice that the *Entire Packet* button is disabled in this case. You must select one form to open.

9.2.4 Using the Data Tracking Utility

Overview

As your work progresses in the study, you will collect a large quantity of information. The Tracking program is a tool to help you track your data in order to ensure that it arrives at its destination as intended. Each time you send your home visit data to the Coordinating Center, a record of what you sent is automatically added to the Data Log. Shortly after your data arrives at its destination, you should get a receipt which acknowledges that your data arrived safely and describes any errors that may have occurred. You can read these receipts into the data log so that all of the data you sent can be marked as having been received properly.

The Data Tracking utility will help you to perform the following tasks:

- See which data has been collected and sent for a given participant
- Read in data receipts from the Coordinating Center
- Extract new or changed data so it can be sent to the Coordinating Center
- Identify data that you have sent but which has not been received
- Identify data in which errors have occurred and which need to be edited and re-sent

Opening the Data Tracking Utility

Assuming that you have Windows running and the program manager is active, you should open the SHHS group. There, you will find an icon labeled Tracking. Double-click the Tracking icon to open the Data Tracking utility. You should be presented with the main menu, which is pictured in Figure 6.

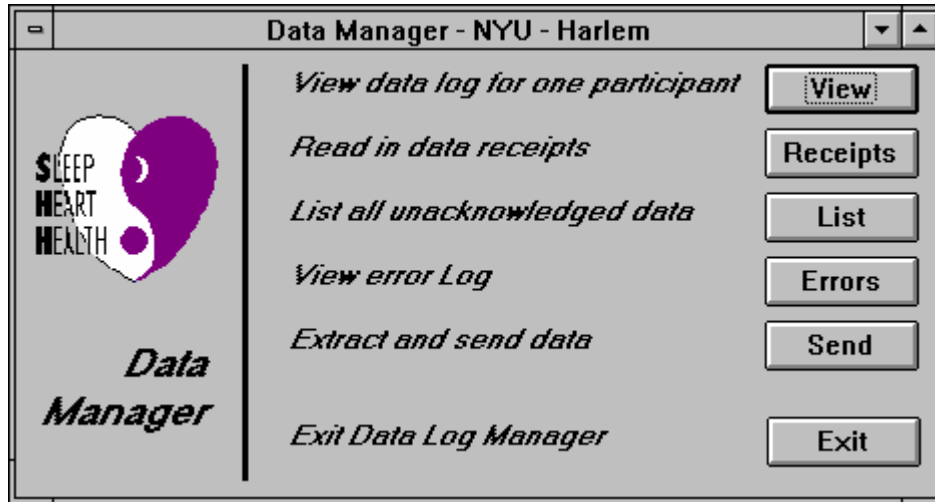


Figure 6

Viewing a Participant's Data

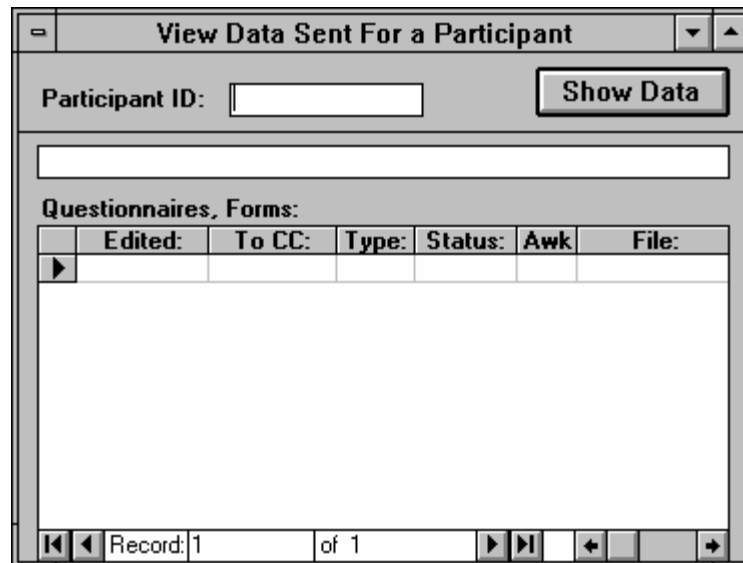


Figure 7

Perhaps the most common type of question you will need to answer will be questions regarding which pieces of data have been sent to the Coordinating Center for a given participant. You can do this by clicking the button labeled *View* on the main menu. You will see a dialog box like the

one in Figure 7. To see a summary of all the data for a particular participant, enter his or her ID number in the field labeled *Participant ID* and then click the button labeled *Show Data*. The computer will search the data log for all records for this participant and will list them in the grid in the dialog box. The grid will list the questionnaire or form for this participant. You should see one row in the grid for each record that has been sent. The labels at the top of the grid tell what data is contained in each of the columns. These are:

- **Edited:** The date on which the record was entered.
- **To Coordinating Center:** The date on which the record was sent to the coordinating center.
- **Type:** The type of record that was sent. The record types are numeric, but their meaning is listed at the bottom of the dialog box.
- **Status:** A record's status will be *New* for new records that were created and sent. The status will be *Re-sent* when a record has been edited and re-sent, as would be the case when the original record contained an error which you corrected before sending the record again.
- **Awk:** This will be either Yes or No, depending on whether you have received acknowledgment from the Coordinating Center for this record.
- **File:** The name of the file in which this record was sent to the Coordinating Center.

If there are more records than can be displayed in the given space in the grid, scroll bars will appear on the right side of the grid. You can use them to scroll to whatever piece of information you would like to see. When you are done with the information on the screen, you can enter a new ID number in the *Participant ID* field and click the *Show Data* button again to review the information for a different participant. Or, you can close the dialog box and return to the main menu by double clicking the system menu in the upper left corner of the dialog box.

Remember, the data will appear on this page only after it has been sent to the Coordinating Center. Thus, if you enter a packet of information and then immediately use this tool to see the participant's data, it will not show up.

Reading in Data Receipts

When you receive a receipt for your data from the Coordinating Center, you should read it into the data log so that you can balance what you have sent against what the Coordinating Center has received. The receipts that you will receive will be contained in a file. The information in these files will look like a simple report which details the pieces of data that were received. You can look at or even print out these files, but you should never edit or change them since they are in a format that the data tracking utility knows how to read. A typical receipt file might look like this:

DATA RECEIVED AT SEATTLE

DATE: 8/17/95

FROM: KETCHIKAN

OK (NO ERRORS)

PPTID ENTERED REC

```
-----  
90001 08/17/1995 CF  
90001 08/17/1995 SH  
90001 08/17/1995 HI  
90001 08/17/1995 MS  
90001 08/17/1995 SD  
90001 08/17/1995 SV
```

WITH ERRORS

PPTID ENTERED REC FIELD PROBLEM

```
-----  
90001 08/17/95 BP CUFFSZ20 CUFF SIZE IS MISSING
```

This receipt indicates that for participant 90001, the Coordinating Center received a Contact Form (CF), Sleep Habits Questionnaire (SH), Health Interview (HI), Morning Survey (MS), Sleep Data Retrieval (SD), and Signal Verification (SV), none of which had any errors. For the same participant, a Blood Pressure (BP) record was received, but it contained an error in the field CUFFSZ20 (Cuff size), which was missing.

When you receive data receipts, you should always put them somewhere safe, as you may wish to refer to them in the future. You should either print them out and store them in a 3-ring binder, or save them on a floppy diskette, or both.

To read them in, click the button labeled *Read* on the Data Manager menu. A dialog box will appear asking you to choose which file to read in (Figure 8). Select the appropriate file, and click OK. Another dialog box will appear showing you the progress as your receipt is read (see Figure 9). When it has finished, you can click the OK button to dismiss the dialog box.

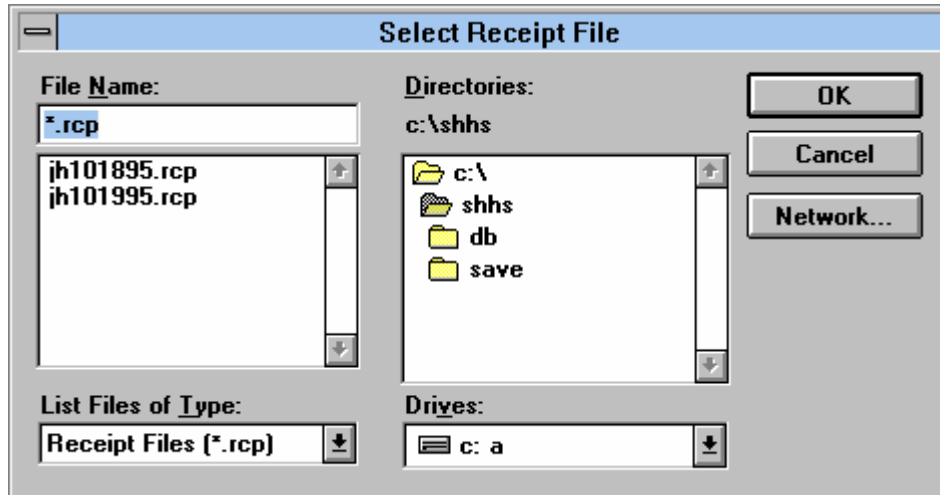


Figure 8

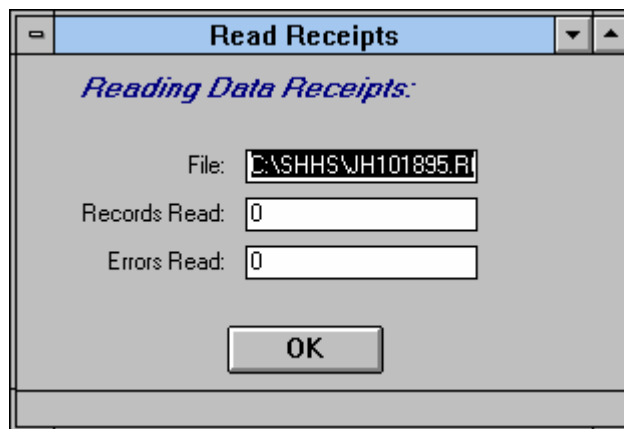


Figure 9

Listing Unacknowledged Data Records

At some point, you may wish to know what data you have sent but which has not been acknowledged by the Reading Center or the Coordinating Center. To get a listing of such data, click the *List* button on the main menu. You will see a dialog box like the one in figure 10. The information is presented in two grids, which are like the *View Data ...* dialog box (Figure 7) except that there is no column telling whether each record was acknowledged. You may either browse this information on the screen, or if you wish, click the *Print* button at the bottom of the dialog box to get a hard copy.

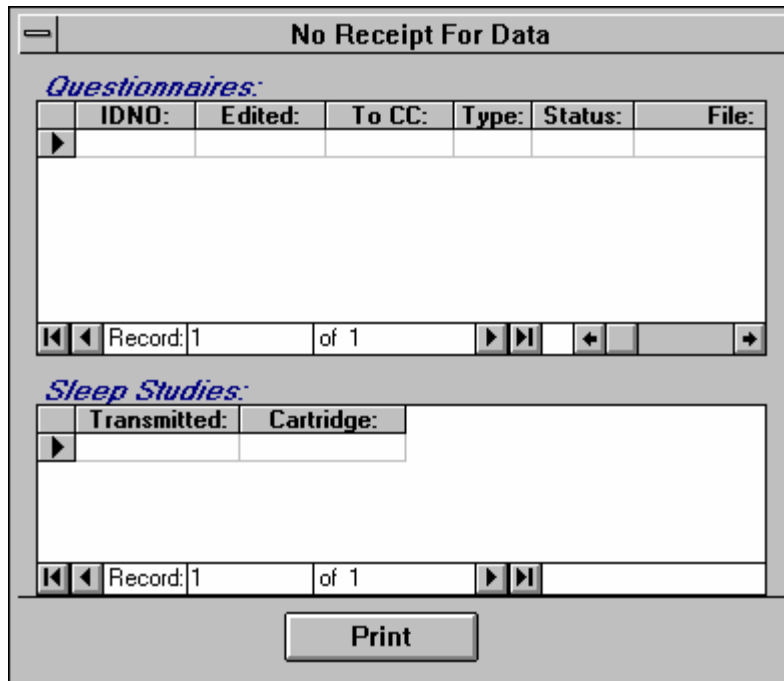


Figure 10

Viewing the Error Log

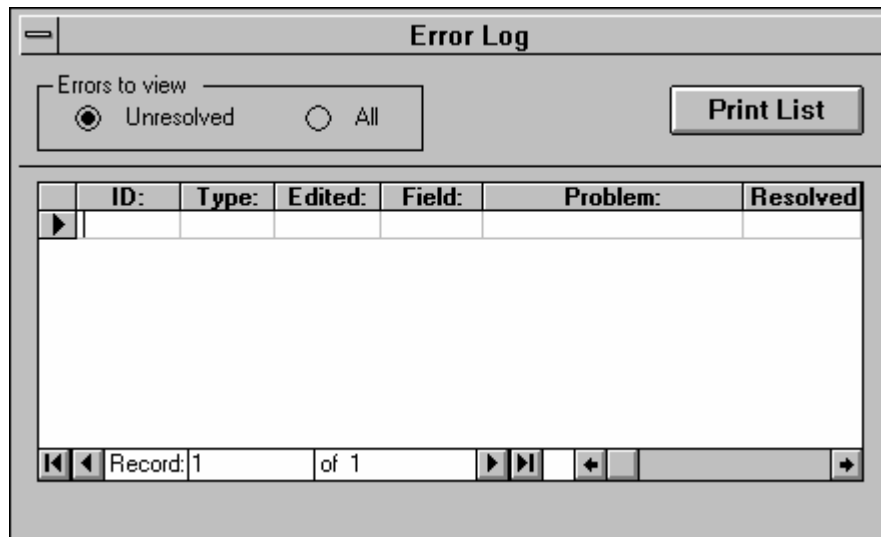


Figure 11

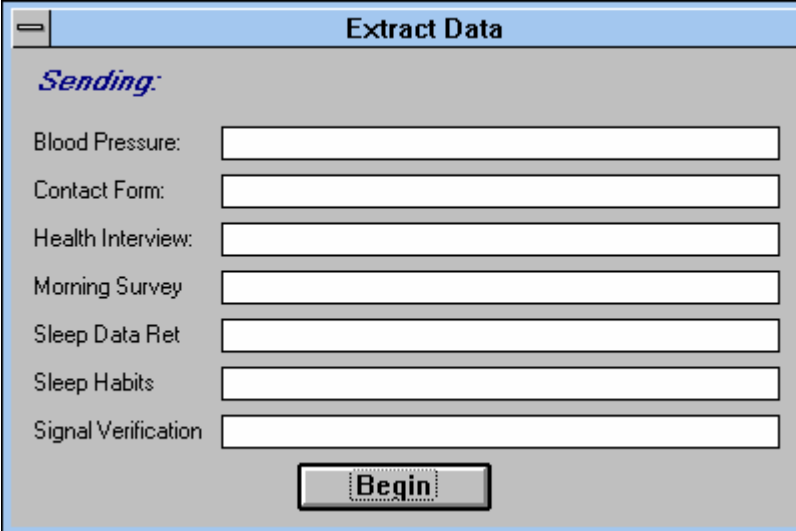
Inevitably, data will be sent that contains errors that must be fixed. Your receipts will list any such records, and you can view and print out the list to guide you in cleaning your data. After you have made changes and re-sent the records that were in error, the error log should automatically be updated to show the records were fixed. Thus, you do not need to (and in fact you cannot) manually mark errors as having been resolved.

To see the error log, click the button labeled Errors on the Data Manager menu. You will see the dialog box shown in Figure 11. By default, you will only see a listing of the errors that are not yet resolved. If you want to see all errors that have ever been received, click the radio button labeled *All* at the top of the dialog box. If you wish, you can print out a listing of the errors by clicking the *Print* button.

Sending Data to the Coordinating Center

Once a week, usually on Fridays, you will need to send the data you have entered to the Coordinating Center. To do this, you use the data manager to extract all of your new or changed data and write it into a file, which you will then mail to Dan at the Coordinating Center in Seattle.

From the main menu, click on the button labeled *Send*. A dialog box will appear that looks like the one shown in Figure 12. Click the button labeled *Begin* to proceed. As your data is extracted, the dialog box will inform you of its progress by listing the number of each type of record it has extracted and the filename to which they were written. When the process has finished, the label on the button at the bottom will change from *Begin* to *OK*. Click on *OK* to dismiss the dialog box.



Extract Data

Sending:

Blood Pressure:

Contact Form:

Health Interview:

Morning Survey

Sleep Data Ret

Sleep Habits

Signal Verification

Begin

Figure 12

At this point, your data is in the C:\TRANSMIT directory on your hard disk. You must now send it to the Coordinating Center. Eventually, these files will be transmitted over e-mail. For now, copy all files from C:\TRANSMIT onto a floppy disk and mail them to the Coordinating Center.

Dan Boren
SHHS Coordinating Center
1501 Fourth Ave, Suite 2105
Seattle, WA 98101-1662.

Once you have done this, you need to make a backup copy of your data and remove it from the C:\TRANSMIT directory. It is recommended that your data be backed up into an archival directory on your hard disk, as well as to a floppy disk, and that these two copies be stored in different places. One strategy that works well is to create a special subdirectory that is named according to the day on which the data transmission took place. That week's data are copied to the directory, and then removed from C:\TRANSMIT.

For example, say that you have just extracted last weeks data and that the date is 9/8/95. Go to the C:\DATABACK directory, and create a subdirectory named after the date. Change into that subdirectory, and then copy all of the files that were written during extraction:

```
C:\>cd \databack
C:\DATABACK>md 090895
C:\DATABACK>cd 090895
C:\DATABACK\090895>copy c:\transmit\*.*
```

Do the same thing again with a floppy disk (there is no need for a DATABACK subdirectory on the floppy disk):

```
C:\DATABACK\090895>a:  
A:> md 090895  
A:\>cd 090895  
A:\090895>copy c:\transmit\*.*
```

If no errors occurred, you now have two copies of the data, and you can now clean up the C:\TRANSMIT directory by deleting all of the files in it. *Be very careful when you do this so that you do not unintentionally delete something you did not intend to!* Please make sure that you erase all files in C:\TRANSMIT each week so that duplicate files are not re-transmitted to the Coordinating Center the following week.

9.2.5 Weekly Backups

As part of your weekly maintenance, it is strongly recommended that you back up your hard disk to guard against losing your work. A batch file is included that will back up all of the SHHS data to floppy disk. Please note that this utility will not back up your entire hard disk; it will only protect your SHHS data. To use it, exit Windows. Have a blank, formatted floppy disk ready, and insert it into the A: drive. At the DOS prompt, type SHHSBACK and hit <enter>.

9.3 The SHHSMEDS Program

The entry of data from the form entitled "Medications - Prescription and Over-the-Counter" is performed using a separate DOS program. The same program is used to enter data from the medication portion (question 8) of the Morning Survey. Unlike the other data entry software, SHHSMeds only supports single entry of data, so you will not have to enter everything twice. At some point in the future, this program will be replaced by a Windows version that will perform just like the rest of the data entry software. For now, however, you must use this version.

Running SHHSMEDS

SHHSMEDS.COM is a compiled program, and it has been placed in a subdirectory called MEDS on the hard disk of your data entry computer. You must first exit Windows, if it is running, and then go to the MEDS subdirectory of the C: drive. Run the program by typing MEDS at the DOS prompt:

```
C:\> CD MEDS  
C:\MEDS> MEDS
```

After displaying the logo, SHHSMeds searches the active directory for its database files and their index files. If they are not found, the most likely reason is that you called Meds from the wrong subdirectory.

The First Screen

The initial screen will appear as illustrated in Figure 13. The number of records in use in the upper right hand corner refers to the number of medicines in the database. Entering the letter "E" will enable you to enter a participant's medication data, and entering the letter "X" will allow you to exit from the program.

```
-----  
SHHS Meds: Data Entry for Medicines      16197 Medicines in database  
-----
```

```
-----  
Select: E)nter patient medicines, eX)it?  
-----
```

Figure 13

Editing Commands in SHHSMeds

SHHSMeds converts all letters to uppercase. The following table lists the editing commands available in SHHSMeds. The control commands are taken from WordStar (sic!). To use them, you hold down the control key and press the lettered key.

Key Pad	Control Commands	Function
Up Arrow	^E	Moves the cursor one field up or one field to the right.
Down Arrow	^X	Moves the cursor one field down or one field to the left.
Left Arrow	^S	Moves the cursor one space to the left.
Right Arrow	^D	Moves the cursor one space to the right.
Home	^A	Moves the cursor to the beginning of the current field.
End	^F	Moves the cursor to the end of the current field.
Del	^G	Deletes the one character at the cursor.
backspace	^H	Back spaces and deletes one character
<Enter>	^M	Moves the cursor to the next field (one field down or to the right).
	^Y	Deletes the entry for the current field.
	^C, ^Z	Exits from the current field to the bottom of the screen.

The Second Screen: Entering Preliminary Information

Once you have entered an "E," the following screen appears:

```
-----  
SHHS Meds: Data Entry for Medicines          16197 Medicines in database  
-----
```

SHHS ID number: _____

Your ID number:

1. All the meds? [Codes: 0=N, 1=Y, 2=Took none, 9=Refused]

morning Survey or Meds form (enter S or M)?

Comment:

```
-----  
Select: E)nter patient medicines, eX)it?  
-----
```

Figure 14

SHHSMeds indicates the width of the field by the use of underscore () characters. SHHSMeds cannot look up the ID number to verify that it is valid, and so you must take care to enter it correctly. The program will force you to enter your ID number. The question "All the meds?" refers to the question in section A of the Meds form. There is no corresponding question on the Morning Survey, so this part of the screen is superfluous. Just enter a 0 and go on to the next question. Next, you must tell the program whether you are entering data from the Morning Survey or the Medication form. Enter an "S" for the Morning Survey, or an "M" for the Medications form. Be careful, as you might easily enter an "M" for the Morning Survey. Finally, you have the opportunity to enter a comment. For the Medications form, this corresponds to the reasons for refusal. You have up to 60 characters.

The Third Screen: Entering Prescription Meds, Morning Survey Meds

The next screen allows you to enter prescription meds, and corresponds to section B of the Medications form, or question 8 of the Morning Survey.

```

-----
SHHS Meds: Data Entry for Rx Meds           16197 Medicines in database
-----
                Pills    Pills
N --Medicine-- --Dose-- Rxd/D Prn Tkn/D
1 _____

```

```

-----
Select: Edit entries [Y/N]? n
-----

```

Figure 15

As on the Medication form, the field for medicine allows up to 12 characters, and the field for dose up to 8 characters. By default, the number you enter in the column for "Pills Rxd/D" refers to the number of pills prescribed per day. You may, but need not, enter "/D." If the prescription indicated a particular number of pills per week or per month, then you must enter the number and then "/W" or "/M." The column for "Prn" indicates whether or not the medicine was to be taken as needed, and the only allowed responses are "Y" and "N." The data-entry requirements for "Pills Tkn/D" are the same as those for "Pills Rxd/D."

The columns "Pills Rxd/D," "Prn," and "Pills Tkn/D" are not collected on the Morning Survey but the program expects data. Simply enter a 1 for "Pills Rxd/D" and "Pills Tkn/D," and an "N" for "Prn."

When you have entered the name of a medicine and pressed the ENTER key, SHHSMeds checks the name of the medicine against the names in the database. If it is found there, the cursor moves to dose. You may notice a slight lag as the program searches the database, but the process usually takes less than one second. SHHSMeds does the same sort of checking to make sure that the dose is correct as well. The program allows entry of up to a total of 15 prescription medicines.

If SHHSMeds cannot find the entered name of the medicine (or the dose) in the database, then the screen appears as illustrated below (Figure 16). The cursor is at the “_” in the window. By using the keys “N” for next and “P” for previous, you may scroll through the database one page at a time. The entry in the main screen, “ENDURIN,” is misspelled, and the program was unable to find it in the database. The particular screen that appears in the window to the right depends on the spelling of the entered item. If an entry is misspelled late in the word (as in this example), then SHHSMeds can come close to finding the right item in the database. If, on the other hand, the first letter is in error, SHHSMeds is not likely to bring up a screen that is helpful.

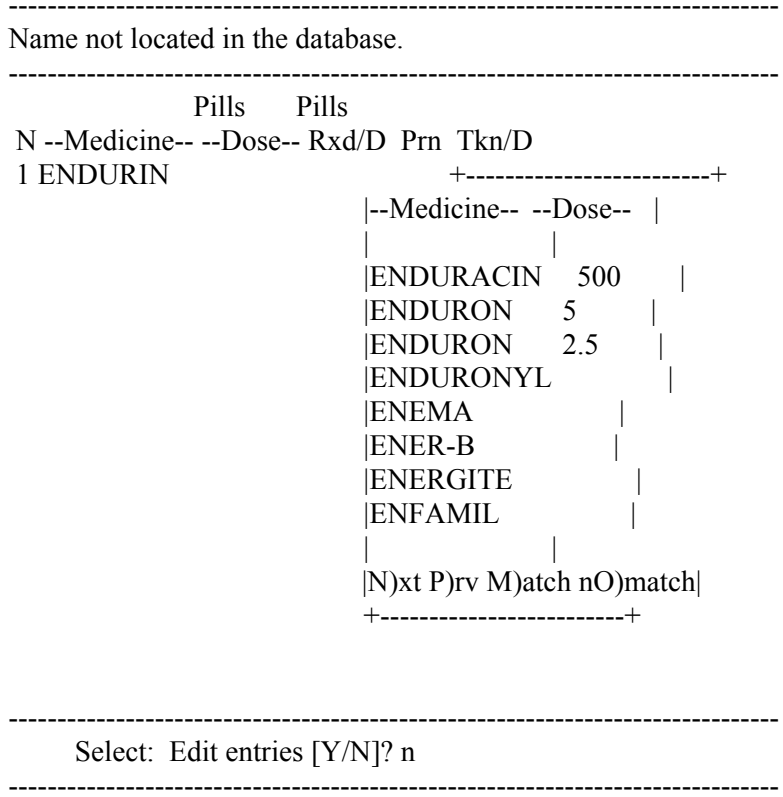


Figure 16

SHHSMeds also checks the dose of the medicines. The program distinguishes between the letter, “O,” and the number “0.” The letter “O” in a dose such as “O.125” rather than (0.125) will produce a non-match.

Once you have found the correct item, then enter an “M” for “Match” and SHHSMeds brings the cursor back to the item that was in error on the main screen. The window at the right remains just as you left it. You can correct the entry, and then move on to the next item. SHHSMeds will verify the entry and code it automatically.

In all instances, you should try to find a match. You may need to refer to a PDR to verify some of the matches. For instance, quinidine may be listed as quinidine sulfate or quinidine gluconate, and clonidine may be listed as clinidine JCL. (The database will only have the first 12 characters of these names, and the program deletes blanks that separate words such as in “quinidine

sulfate.”) If the Medication Form lists “QUINIDINE SU” and the database “QUINIDINESU,” these terms are a match.

In some instances, you will not be able to find a match. One example may be the generic name of a prescription medicine that is still on patent. When you are unable to find a match, you should enter “O” for “no match” in the window at the right. This will permit you to enter a non-matching term and proceed with data entry.

When you come to the last medicine on the list, then simply press the ENTER key. The program will ask you the number of medicines that could not be transcribed. The last item on this screen inquires whether you want to edit any of the entries. If so, you enter the number of the medicine that you want to edit. If not, you move to the next screen.

The Fourth Screen: Entering OTC Meds (Medications Form Only)

```

-----
SHHS Meds: Data Entry for OTC Meds          16197 Medicines in database
-----
                                Pills
N --Medicine-- --Dose--          Tkn/D
1 _____

```

```

-----
Enter <CR> to continue or medicine number to edit entry:
-----

```

Figure 17

The next screen lets you enter over-the-counter medicines, which are listed in section C of the medication form. If you are entering meds from the Morning Survey, this screen will be skipped. This part of the program works just like the prescription medication part, except that there is no entry for “Pills Tkn/D.” As you enter the names and doses of meds, they will be looked up in the database in exactly the same way as the prescription meds.

The Final Screen

SHHS Meds: Data Entry for Medicines 16197 Medicines in database

Date [MMDDYY]: _____
Interviewer code:

Comment:

Codes: 0=No, 1=Yes, 9=Unknown

Figure 18

The final screen corresponds to the bottom of the second page of the medications form. If you are entering data from the Medications Form, you will be entering the data found at the bottom of the second page. You should enter the date of the interview, the ID number (or code) for the interviewer, and any comments that have been written (subject to the 60 character limit). You will notice that there is no place to enter the times of the first and second edits. If you are entering Morning Survey Data, please fill in the Interviewer or reviewer ID found at the bottom of page 3, as well as the date. The Comment field should be left blank.

When you have finished with the last field, you will be asked whether you wish to make any changes. When you have finished with this screen, you will receive one (in the case of Morning Survey data) or two (for prescription meds) messages telling you that your data is being written to disk. The data will be written to the C:\TRANSMIT directory, just like all of the other data you enter. It should be backed up, transmitted, and then deleted just like the rest of your data.

9.4 Data Management within the Coordinating Center

9.4.1 Field Center Data

Each week a set of data files will be transmitted from each Field Center to the Coordinating Center over the Internet. These raw files will be copied onto backup diskettes before any processing occurs. Next the files will be read into the Access database. A set of routine programs will run to check the data in the following ways:

- Are data from all forms included in the data set for each participant represented? If not, the program will generate a list to be sent back to the Field Center.
- Are any files present that the database is unable to accept due to improper format, file corruption, or other problem? If so, the program will generate a list to be sent back to the Field Center.
- Do any data values lie outside of acceptable ranges or fail internal consistency checks? If so, the program will generate a list to be sent back to the Field Center.

The program will also generate a receipt file to be returned to the Field Center. This file will be read into the Field Center's local database so that records will be flagged as having been received at the Coordinating Center (see Section 9.2).

All of these lists will be combined into a weekly report which will include the number of participants seen and a summary of forms received, in addition to any problems noted as above.

9.4.2 Reading Center Data

Each week, the Reading Center will send the Coordinating Center a list of all studies received that week. The Coordinating Center will match this list against the data received from the Field Center that week, to ascertain that all studies arrived as they should. If any problems are noted, lists will be generated and sent to the Reading Center and the Field Centers asking them to resolve the discrepancies. This will include both expected studies that did not arrive at the Reading Center and unexpected studies that did arrive.

In addition, the Reading Center will send the Coordinating Center data cartridges each week containing studies that have been read so that they can be permanently archived onto CD at the Coordinating Center. The Reading Center will also send the Coordinating Center data files each week containing participant results files. The participant results files will be read into the Coordinating Center database, with programs checking for the following potential problems:

- Data files that arrive for participants for whom we have no other home visit data
- Data files that cannot be read into the database due to incorrect format, file corruption, etc.
- Data values that are extreme in value or fail internal consistency checks

In addition, a program will check for any participants for whom the Coordinating Center has not received a participant results file within 60 days of the home visit.

If any of these problems are noted, lists will be generated that will be sent to the Reading Center or the Field Center, as appropriate, for resolution.

Responses to these weekly lists are expected before the next weekly report is generated. Any problems not resolved will appear again on the next week's report. Any problems which remain unresolved after one month will be followed-up with the PI and the Program Office.

9.4.3 Backups and Data Security

9.4.3.1 Backups

Raw PSG data will be sent to the Coordinating Center from the Reading Center on zip cartridges. These will be archived permanently onto CDs, with new CDs being created approximately twice per month for each site. Each CD will contain data from only one site. One set of CDs will be kept in permanent storage at the Coordinating Center (should this be offsite, or will we access the CDs regularly?) and another set will be returned to each site, containing only data from that site.

Home visit data, recruitment data, and participant result files from the Reading Center will be backed up onto tape weekly at the Coordinating Center. The Coordinating Center is on a network that is backed up every week. Some tapes are kept as permanent archives, others are rotated monthly. An updated backup tape is taken off site monthly. In addition, raw data transmitted from the Field Centers and Reading Center will be saved onto diskettes as a secondary backup.

Covariate information received from the parent studies will also be backed up onto tape and kept as a permanent archive.

9.4.3.2 Data Security

The Coordinating Center is located in a secured building which allows no access by unauthorized individuals after office hours. The computer network is secured by use of passwords so that no unauthorized individuals (including unauthorized staff) have access to the SHHS database. Sensitive information such as participant names and addresses are kept in a separate database accessible only to the database administrator. Any participant hospital records received at the Coordinating Center are kept in locked file cabinets.

9.4.4 Database Management and Reporting

Microsoft Access will be used for all database management functions at the Coordinating Center. A set of programs for data checking and reporting will be written which will be run weekly by a data processor. SPSS and SAS will be used to generate statistical reports.

9.5 Reading Center Procedures

1. Objectives

The Sleep Reading Center for the SHH Study will:

- a) Provide centralized training for aspects of SHHS related to the performance of sleep studies.
- b) Provide ongoing technical support for the performance of sleep studies; including maintaining a supply of back-up sleep monitoring devices, providing “second line” advice regarding troubleshooting of problem studies (after consultation with local resources), and acting as a liaison with the equipment supplier.
- c) Provide timely review (for quality and medical alerts) and scoring of all records, generating reports needed for participant feedback and data files for Coordinating Center processing. Reports will provide the key sleep data, collected uniquely for the SHHS.
- d) Participate in on-going quality assurance efforts to maintain high levels of scoring accuracy and technical performance of tests at the field sites.

2. Structure

The Reading Center will be directed by Susan Redline, M.D., M.P.H. She will hire and assist in the training of an Administrative Assistant, a Chief Polysomnologist, and polysomnology scorers, and be ultimately responsible for all goals specified above.

Two physician investigators (Carl Rosenberg, M.D. and Kingman Strohl, M.D.) will assist in the development of scoring procedures. They will participate in weekly staff meetings that discuss issues with scoring and quality control.

The Chief Polysomnologist will be directly responsible for training and certifying scorers and centrally trained field research assistants. She will participate in the development of teaching materials for training and for procedures for certifying scorers and assuring high levels of accuracy and reproducibility of scoring procedures. She will review each PSG record within 72 hours of its receipt at the Reading Center, identifying medical alerts, and providing quality codes. She will triage studies for formal scoring to the scorers, monitoring their performance, and providing support for interpreting ambiguous studies. She will implement on-going procedures for assuring accuracy and reproducibility of scored procedures.

Three to five scorers will be charged with the responsibility of directly scoring all records. They will be charged with the task of scoring 2-3 records per day and participating in scoring QA procedures.

3. Overview of Scoring

The Compumedics software system will be used to process all records, and provide preliminary estimates of the AHI. Scorers will review the record, on an epoch by epoch basis (on screen), marking each sleep stage, each arousal, and each respiratory event.

Analysis software will be used to link the various channels after scoring to provide summary measures of sleep-disordered breathing and sleep staging. (Report provided in Appendix of Reading Center Manual of Operations.) Software will also provide overall summary measures of desaturation and heart rate variation.

Sleep stages will be characterized by modified Rechtschaffen and Kales criteria (Rechtschaffen A, Kales A. A Manual of Standardized Terminology Techniques and Scoring System for Sleep Stages in Human Subjects. Washington, DC: US Government Printing Office, 1968.) and arousals by the ASDA criteria (The Atlas Task Force, EEG Arousals: Scoring Rules and Examples. Sleep 1992; 15:173-84.) .

Apneas will be identified if the amplitude (peak to trough) of the airflow signal decreases to below (approximately) 25% of the amplitude of “baseline” (identified during a period of regular breathing with stable oxygen levels), if this change lasts for ≥ 10 sec.

Hypopneas will identified if the amplitude of the airflow or chest wall movement decreases to below (approximately) 70% of the amplitude of “baseline” (identified during a period of regular breathing with stable oxygen levels), if this change lasts for ≥ 10 sec.

“Central” events will be noted if no displacement is noted on either the chest or abdominal inductance channels. Otherwise, events will be noted as “obstructive.” All hypopneas will be considered obstructive (because any effort, including that needed to generate >25 displacement of the airflow signal, is considered obstructive).

Periodicity will be noted “manually” if marked waxing and waning of respiration occurs in a regular cyclic pattern. This requires at least 5 consecutive cycles of such a breathing pattern, lasting at least 10 consecutive minutes.

Computer analysis (multiplexing) of the data from the respiratory channels (airflow, chest, abdominal) will provide the following:

The main “predictor” variable considered will be AHI, defined as the number of apneas and hypopneas per sleep hour, identified if at least a 3% desaturation or an arousal occurred in association with a change in breathing (as above). The desaturation that is linked with any given respiratory event will be based on the nadir desaturation reached within 30 sec. of the end of the event. The magnitude of the desaturation for an event is the difference between the greatest saturation level observed

during the event and this minimum. Arousals will be linked with events if they begin within 3 secs. of the termination of the respiratory event.

The other variables will be assessed as to any differences in their predictive ability to identify cardiovascular or other morbidities. Other measures:

Summary AHI values, based on requiring > 2%, 3%, 4%, and 5% desaturation levels, occurring within 30 seconds of the termination of the event.

Summary AHI values based on an associated arousal, occurring within 3 sec. of the termination of the respiratory event. Summary AHI values and based on all combinations of arousal and the five levels of desaturation.

Percent sleep time in apnea (obstructive or central, including events with at least a 3% desaturation +/- arousal). Percent sleep time in hypopnea (including events with at least a 3% desaturation +/- arousal). Percent sleep time in desaturation (<95%, <90%, <85%, <80%, <75%). Number of desaturations/hour of sleep (unlinked with respiratory events) of 2%, 3%, 4%, 5%. These "dips" are based on a slope detection algorithm (see Appendix of Reading Center Manual of Operations).

Sleep summary data include: percent time in each sleep stage; arousal index; number/hour stage 1 shifts; upward shifts; and wake shifts; sleep efficiency; sleep latency; REM latency (defined both as time from lights off to first REM and from onset of sleep to first REM).

Heart Rate data: (Averaged values) of maximum, minimum and mean heart rate noted associated with respiratory events and arousals (in REM and NREM separately), and also averaged over the entire NREM and REM sleep recording period (see Appendix for Reading Center Manual of Operations for algorithm).

A full description of criteria for all scoring can be found in the Reading Center Manual of Operations.

9.6 Data Management within the Reading Center

9.6.1 Preliminary Report Generation

Each study will be first reviewed for quality of signals. The Chief Polysomnologist (or her designee) will code each channel of information according to duration of artifact free signal, and also give an overall QA grade to each study. The total duration of the study and the total duration of scorable data on each channel will also be indicated.

A preliminary determination will be made of the overall best EEG channel for sleep staging and best channel for respiratory amplitude detection. Initial parameters will be set for sleep staging and respiratory event detection. The report then will be visually scanned for oxygen saturation

artifact. A preliminary report then will be generated with report of: sleep latency, time asleep in REM and NREM, baseline heart rate, number of oxygen dips >3%, number of respiratory events with >3% desaturation.

A (final) preliminary report that includes time spent in desaturation will be generated for any study with frequent desaturations or dips (>40/hr dips or AHI>40). If time in desaturation of <70% for >10% TST, a Medical Alert will be generated. If a preliminary AHI or dip rate > 40 are identified, the report will be triaged for immediate complete respiratory (within 48 hours) scoring. If the final AHI > 50, a Medical Alert will be generated.

Other criteria for Medical Alert: Any study with a heart rate > 150 BPM or < 30 BPM for > 2min will be identified as a Medical Alert after the Chief Polysomnologist and Study Investigator determine that such data were not a result of ECG artifact.

See Reading Center Manual of Operations (page 6) for step-by-step procedures.

9.6.2 Medical Alert Generation

Once a Medical Alert is identified, a physician investigator will be asked to review the study. If the medical alert is ascertained, it will be logged into a Medical Alert Log and the Clinic Coordinator at the Field Center will be immediately called (within 72 hrs of the study's receipt in the Reading Center). This call will also be documented into a Medical Alert Log. The final report will be faxed to the site and to the Coordinating Center.

9.6.3 Final Report Generation

After the study has been scanned for meeting minimal criteria of adequacy, and a preliminary report generated, the scored file will be copied back onto the original zip cartridge. A scorer will be assigned that study for final scoring.

The scorer will scan each study to determine:

The approximate number of hours of EEG data that are contiguous respiratory data).

The scorer should note any of the following (note in gray box on P/QA Report):

- a. Abnormal awake EEG
- b. Frequent alpha intrusions
- c. Abnormal eye movements
- d. Periodicity

(See Section VII of Reading Center Manual of Operations for examples; when identified, these need to be reviewed with the Chief Polysomnologist or physician investigator.)

The scorer will determine whether the study meets minimal criteria for sleep staging (3 hours of readable EEG) and if respiratory and sleep staging need to be done in 2 or more passes. This will be indicated in the gray box.

The study will then be processed as:

- a. The adequacy of the initial settings for respiratory events and sleep staging will be reviewed. If a major difference exists between the settings chosen by the Chief Polysomnologist and that favored by the scorer, this should be discussed with the scorer.
- b. Automatic sleep staging will be re-run if necessary. Then, the study will be reviewed on an epoch by epoch (30 sec.) basis (using the hyponogram and sleep parameters), with re-coding of sleep stages per scoring rules (see Reading Center Manual of Operations).
- c. All 30 sec. epochs marked as sleep will be reviewed for arousals.
- d. The respiratory data (airflow/abd/chest/saturation/sat status) and primary EEG channel will then be reviewed in 5 min. epochs during periods of sleep. Events will be edited (see Reading Center Manual of Operations).

Additionally, the following will be noted AFTER scoring the record:

- a. The primary channel used for scoring respiratory events (thermistry, thorax, abdomen, mixed).
- b. Inappropriate lights on/off.
- c. Need to score respiratory events separately from sleep.

A final report will be generated. The data are to be reviewed manually and by a computer outlier program for overall internal consistency, outliers, and any evidence of medical alerts not previously identified. NOTE: Outliers and/or inconsistencies (these may be real, but require double checking):

% Stage (other than II) > 50%.
Sleep efficiency >98% or < 20
HR < 20 or >200
Saturation <40% or >99%
%REM >NREM
Arousal index <10% of AHI (unless no EEG data)
Arousal index 4-fold > AHI
AHI <5 and desaturation index > 30
Desaturation index (3%) 20% > AHI(3%)
AH duration < 9sec. or >125 sec.

If the final report appears correct, the final report and scored files are copied onto original cartridge. When all studies/cartridge have attached final reports, they are logged out and sent to the Coordinating Center. An electronic receipt is updated.

**CHAPTER 10 - PUBLICATION AND PRESENTATION POLICIES
AND PROCEDURES**

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Publication and Presentation Policy

10.1 Administrative Structure

The SHHS Steering Committee shall appoint a Publications and Presentation (P&P) Subcommittee and select a chairperson.

The Publications and Presentations Subcommittee shall report to the SHHS Steering Committee on all matters relating to the publications or presentations of SHHS material.

This P&P Subcommittee shall serve in an advisory capacity to the SHHS Steering Committee which shall have final authority for approval or disapproval of all recommendations of the Publications and Presentations Subcommittee. Where consensus is not reached by the P&P Subcommittee the matter will be referred to the Steering Committee.

10.2 Objectives

To stimulate scientific presentations and papers from SHHS investigators and to assure that abstracts, presentations, and publications based on SHHS material are accurate and objective, and do not compromise the scientific integrity of this collaborative study;

To assure and expedite orderly and timely reports to the scientific community of all pertinent information resulting from SHHS;

To assure that all investigators have the opportunity to participate and be recognized in the study-wide SHHS papers;

To assure that membership in Writing Groups for SHHS papers will serve as an opportunity to participate in the writing of manuscripts;

To establish procedures that allow the SHHS Steering Committee and the NHLBI to exercise review responsibility in a timely fashion for SHHS publications and presentations;

To maintain current list of all SHHS presentations and publications, and to distribute such lists to SHHS investigators and parent studies periodically.

10.3 Definitions

There are thirteen field centers that contribute study subjects.

There are six investigative centers; several consist of more than one field center.

There are nine study units consisting of the six investigative centers, the Reading Center, the Coordinating Center, and the Project Office.

Types of studies

- Mainline -- These are studies which deal with the primary hypotheses of SHHS and with data collected at all investigative centers.
- Secondary -- These are studies which deal with non-primary hypotheses of SHHS or with data collected at more than one but not all of the six investigative centers.
- Local -- These are studies which deal with data collected only at one investigative center.

Types of Publications

- Papers
- Abstracts

Types of Presentations

- Invited presentations at meetings for which no abstract is published
- Press Releases
- Lectures, seminars, or work-in-progress presented in local settings

Analysis Responsibility

- Central -- done by the coordinating center
- Local -- done at the investigative center proposing the publication or presentation

10.4 Submission of a Proposal for a Paper or Abstract

This should consist of a formal proposal to the P&P Subcommittee and must include as a minimum:

- 1a. Full Title
- b. Abbreviated Title [Length, total of 26 letters + spaces]
2. Lead Author
3. Timeline [Target start and finish dates, assuming P&P approval and Coordinating Center availability for analysis]
4. Rationale
5. Hypotheses
6. Data [variables, time window, source, inclusions/exclusions]

[information above this line will be used to obtain ARIC approval]

7. Type of Study: [Mainline Study], [Secondary Study], or [Local Study]
8. Type of Publication: [Journal Article], [Abstract] or [Other: _____]
9. Analysis Responsibility: [Coordinating Center] or [Local]

Please attach or include:

10. Introduction
11. Brief Analysis Plan [Include list of variables to be used, time frame of data, source of non-SHHS data, and probable statistical method.]
12. Summary Section
13. References

For a Local Paper, the submission may also contain suggested writing group members.

The SHHS proposal format is available on disk from the Coordinating Center or can be provided via email.

It is assumed that all proposals are submitted with the knowledge of the field center P.I.

Publication and presentation proposals shall be submitted to the Presentation and Publications Subcommittee in care of the SHHS Coordinating Center.

The proposal will be reviewed by the P&P Subcommittee to ascertain that the proposal format has been followed. In addition, the P&P Subcommittee will determine if there is overlap between a proposed publication and any other papers or abstracts that have been proposed or are in progress. In such cases the investigator will be encouraged to collaborate on the existing project.

Upon approval by the P&P Subcommittee, a paper proposal will be given a number and entered in the Paper Schedule Matrix.

The proposal shall be submitted to the SHHS Steering Committee for review and, for a paper, Writing Group nominations. This review process should take no more than 2 weeks. In the event it is not possible to suggest or determine a nominee within two weeks, approval may be given with the notation "nominee to follow."

All proposals for manuscripts and abstracts will be sent to the ARIC, CHS, Strong Heart, and Framingham parent studies after they have been approved by the SHHS P&P Subcommittee and the SHHS Steering Committee. In the event approval is withheld by any parent study, work on that manuscript will cease.

A brief 1-2 paragraph description may be submitted for inclusion in the Description of SHHS Papers Document. The description should include the objective, design, subjects and variables, and main analyses anticipated for the paper. The descriptions will be made available to all P.I.s as a record of ongoing papers. If none is submitted, the description will be taken from the proposal submitted.

An investigator may have only two papers proposals in which he or she is the Writing Group Chair approved and pending start at a time. Only one can be active at a time. A second manuscript will be eligible to start after the penultimate draft of the first manuscript is approved (Local papers are exempted.)

10.5 Writing Groups

10.5.1 Selection of Writing Group Members

Guidelines for composition of writing groups for papers or abstracts:

Mainline study

One member from each unit of the SHHS proposed by PI from each unit

Secondary study

One member from each study unit of the SHHS contributing data, the CC, Reading Center, NHLBI, plus investigators from other sites with special expertise in area.

Local Study

Additional members may be proposed by other SHHS study units with special expertise and by P&P Subcommittee. The chair of the writing group must approve the inclusion of these additional members.

For a Mainline publication each study unit may have a representative on the Writing Group. The study unit P.I. will decide whether his/her unit will participate and may nominate one person. A second Writing Group member from the same study unit may be nominated by a P.I. on manuscripts where it is necessary to take advantage of unique expertise and/or to justify the amount of work performed on behalf of a manuscript. The P.I. must write to the P&P Subcommittee requesting the addition of a second author and justifying the addition.

The Publications & Presentations Subcommittee will review the nominees to ascertain if any investigator able to significantly enhance the Writing Group should be added, or, when it is in the best interest of publication, a smaller Writing Group may also be recommended.

Based on the nominations, the Publications & Presentations Subcommittee will select Writing Group members and add the Writing Group names to the paper description in the Descriptions of SHHS Papers Document.

In general, the proposer would be designated as the Chairperson and first author and will receive written notification of all Writing Group members and his/her responsibilities as Chair.

A P.I. may add an author to a writing group if the paper has not yet begun and if there is not already a representative from that unit on the writing group.

When a start date for a manuscript has been determined by the P&P Subcommittee, the Chairperson of the Writing Group will be notified of the start date. The Writing Group Chairperson should contact each member of the Writing Group to discuss the outline of the paper, data request, and the responsibilities and assignments for each member.

10.5.2 Responsibilities of Writing Group

The **Writing Group Chairperson** is responsible for all phases of manuscript preparation, from conception through publication. Responsibilities include:

1. preparation of outlines, the identification of data analyses needed from the Coordinating Center, interim status reports and for their submission to the P&P Subcommittee;
2. assignment of tasks to Writing Group members with clear deadlines for completion of these tasks and determination that the tasks are completed on schedule;
3. manuscript approval by each Writing Group member before submission of its penultimate Draft to the P&P Subcommittee;
4. determination of the order of authorship on the manuscript. A major criterion shall be the effort and contribution made by the members of the Writing Group in preparation of the manuscript.

Disagreement about the order of authorship which cannot be resolved by the Chairperson of the Writing Group will be resolved by the Publications and Presentations Subcommittee, with the Steering Committee as the final arbitrator.

5. choice of a journal to which the manuscript should be submitted;
6. correspondence with co-authors, communication with the Coordinating Center and the P&P Subcommittee, responses to the NHLBI review, and to journal editors.

Members of the Writing Group are responsible for performance of tasks assigned by the Chairperson within the allotted time period. Each member is expected to actively participate in the preparation of the report.

If a Writing Group member does not accomplish the tasks assigned to him/her and has not contributed to the manuscript, he/she can be removed from the Writing Group. The Chairperson of the Writing Group must address a letter to the P&P Subcommittee requesting the removal of a particular Writing Group member.

10.5.3 Modification of Writing Groups

The P&P Subcommittee may change the composition of the Writing Groups that have failed to produce a manuscript according to the schedule originally agreed upon by the Writing Group and the P&P Subcommittee. When a delay develops, the Chairperson of the Writing Group will be notified by the P&P Subcommittee. A recommendation to remove or reassign the responsibility of Writing Group members will be made by the P&P Subcommittee. A recommendation to disband a Writing Group will be made by the P&P Subcommittee. These decisions will be reported to the SHHS Steering Committee for their approval.

10.6 Schedule for Manuscript Preparation

The expected schedule for the development of a manuscript is described below. Any deviation from this schedule must be approved by the P&P Subcommittee. Failure to adhere to this schedule will prompt review of circumstances. If it is determined that someone is negligent, this is the basis for replacing either the Chairperson and/or replacing members of the Writing Group who may cause the delay, or for disbanding the Writing Group.

The letter codes which appear in the SHHS publication schedule and which denote the time table for each stage in the preparation of the manuscripts are described below:

D. After notification by the P&P Subcommittee of the start date for the paper, the Writing Group will have 4 months to prepare a first draft. A first draft will consist, at a minimum, of an Introduction, Methods and Results Sections. This draft should be sent to the members of the Writing Group with a copy to the P&P Subcommittee assistant.

P. The penultimate draft becomes due 3 months after the first draft is distributed to the Writing Group. A penultimate draft should be sufficiently developed for subsequent submission to the Steering Committee for review and subsequently to NHLBI. After review of the penultimate draft by Writing Group members, and all Writing Group members have signed off, the Penultimate draft should be sent to the P&P Subcommittee with a cover letter stating that this penultimate draft is ready for review. A layman's summary must also be provided at this time for submission to Strong Heart Study P.I.s in order to obtain approval from the Tribal Councils and IHS.

R. The P&P Subcommittee has 14 days to review the manuscript. All members of the P&P Subcommittee will review each manuscript followed by a discussion during a regular P&P conference. Afterwards the author will be sent a summary of any pertinent reviewer's comments.

If the manuscript is not approved by the P&P Subcommittee, the draft will be returned to the Writing Group Chairperson with comments regarding the necessary revisions before resubmission.

If it is approved, it will be forwarded to the SHHS Steering Committee for review within 30 days. After approval by the SHHS Steering Committee, the manuscript will be sent to NHLBI for review. NHLBI review will be completed no later than 30 days following receipt of the steering committee approved manuscript. The project office will assign each manuscript to a minimum of 2 appropriately qualified NHLBI staff members. Staff will be asked to comment on scientific, administrative and policy issues. The project officer will collect and compile all comments and provide a written response to the manuscript with a decision for either approval, approval with modifications or disapproval. In certain cases and where noted, the project office may wish to see the paper again before final submission to a journal. Expedited review will occur in these instances. NHLBI correspondence will be directed to the primary author with copies sent to co-authors and the P&P Subcommittee.

Simultaneous to SHHS distribution, the penultimate draft will be forwarded to the parent studies, as follows: the CHS and Framingham P&P Committees; ARIC Publications Committee Editor; and the Strong Heart Study P.I.s, for obtaining approval from the IHS and Tribal Councils.

The Coordinating Center will initiate verification of the results after approval by the P&P Subcommittee. Completion of verification is expected within 30 days and the P&P Subcommittee and the Writing Group Chairperson will be notified by letter.

J. Within 30 days of receiving Steering Committee, NHLBI and P&P Subcommittee comment and verification confirmation, the revised manuscript will be circulated to Writing Group members for final sign-off.

The manuscript should be sent to the journal, with a copy of the cover letter sent to the P&P Subcommittee in addition to all co-authors. The P&P Subcommittee should also be sent copies of all subsequent communications with the journal.

10.7 Priority Assignment for Publication-related Analyses

The P&P Subcommittee, in consultation with the Coordinating Center, will determine priorities for data analysis related to publications or presentations. Guidelines for investigators to use in dealing with Coordinating Center are:

1. Communicate with the Coordinating Center representative on the Writing Group for all requests and questions on analyses.
2. Be sure that data requests are made in a timely fashion; interactive analyses will be allowed within the window before and after the first draft.
3. Plan systematically for the analysis of your data.
4. If the results lead to a split of the original paper into more than one manuscript, a new proposal and description should be submitted to the P&P Subcommittee. The same committee members are usually retained on the second paper.
5. If the Coordinating Center falls behind, the Chairperson of the Writing Group should inform the P&P Subcommittee; if there is a problem, deadlines can be changed.

10.8 Local Papers

A Local Paper generally refers to one for which data is collected only at one investigative center (SHHS sleep study and questionnaire data along with the parent study data). The site must utilize its own resources for analysis. This includes subgroup analyses performed on a subset of SHHS cohort for whom specialized covered data is available.

Procedure for submission of a Local Paper:

1. A formal paper proposal indicating a “local” paper is sent to the P&P Subcommittee, following the directions given above for mainline papers. Committee members may also be suggested.

2. The proposal should include: (1) Title, (2) Introduction, (3) Specific Writing Group, if any, (4) Analysis Plan, (5) Summary Section, (6) References.
3. The approved proposal is sent to the SHHS Steering Committee for their information. If a study unit P.I. has someone with special expertise in the area of the proposed manuscript, they may make a nomination for the Writing Group.
4. The Chairperson of the Writing Group for the local paper will be notified after Steering Committee approval.

Local manuscripts are not required to follow a schedule or time line. The penultimate draft must be submitted to the P&P Subcommittee for review. After approval by the P&P Subcommittee, the penultimate draft will be sent to the SHHS Steering Committee and NHLBI for final review. Local papers will follow parent study review procedures as necessary.

After the review and approval is complete, the manuscript may be sent to a journal with a copy of the cover letter sent to the P&P Subcommittee. The Chairperson must notify the P&P Subcommittee when the paper is published.

10.9 Summary of the Paper Publication Process

1. Investigator submits a paper proposal in the standard format to the P&P Subcommittee in care of the SHHS Coordinating Center.\
2. P&P reviews the proposal and, if approved, sends to SHHS Steering Committee for approval and nominations of Writing Group members.
3. P&P finalizes Writing Group and notifies the Chairperson of the Writing Group who, in most cases, will be the investigator who submitted the manuscript proposal.
4. Manuscript proposals will be sent to the ARIC, CHS, Strong Heart, and Framingham parent studies after they have been approved by the SHHS P&P Subcommittee and the SHHS Steering Committee.
5. The P&P Subcommittee notifies the Writing Group Chairperson when the manuscript may be started. (Local papers may start at any time and set their own time schedule.)
6. The Writing Group has four months from the start date to submit a first draft. A copy of the first draft must be sent to the P&P Subcommittee assistant for him or her to maintain on file. (Local papers exempted.)
7. The Writing Group has three months after the first draft to submit the penultimate draft to the P&P Subcommittee for review. (Local papers submit when ready.)
8. The P&P Subcommittee has two weeks to review the penultimate draft. If it is not approved, the manuscript is returned to the Writing Group with comments indicating required revisions.

9. If the penultimate draft is approved, the results given in the penultimate draft are verified by the Coordinating Center. Upon completion of verification the P&P Subcommittee is notified and any corrections are given to the Writing Group Chair.
10. Upon approval of the penultimate draft, it is distributed to the SHHS Steering Committee for approval within 30 days.
11. The penultimate draft is also distributed to the parent studies for review, as follows: the CHS and Framingham P&P Committees; ARIC Publications Committee Editor; and the Strong Heart Study P.I.s, who will be responsible for getting approval from IHS and the participating Tribes for publication. A layman's summary must also be provided for the Strong Heart Study at this time.
12. After approval by the Steering Committee, the penultimate draft is given to NHLBI to review within 30 days.
13. The chair has 30 days to make the necessary final revisions, get approval from the Writing Group, and send the manuscript to a journal with a copy of the cover letter to the P&P Subcommittee.
14. The P&P Subcommittee should be kept informed of all subsequent communications with the journal including final publication.

10.10 Preparation and Submission of Abstracts for Meetings

No abstract shall be submitted to any national or international organization for consideration prior to approval by the SHHS Publications and Presentations Subcommittee, the SHHS Steering Committee, clearance by NHLBI, and review and approval by the parent studies. If approval is withheld by a parent study, the abstract will be withdrawn. After July 1, 1996, abstracts are expected to be based on active manuscripts. Abstract authorship will be the same as that of the manuscript.

If an abstract is based upon an existing penultimate draft which has been reviewed by the P&P Subcommittee, it should be submitted for review up to 30 days prior to the deadline if constructive feedback by the P&P Subcommittee is desired. Otherwise, it may be submitted within two weeks of the presentation but there is a risk of withdrawal of the abstract if not approved.

If it is based upon a preliminary manuscript draft for which there has been no prior P&P review, it must be submitted eight weeks prior to the deadline. The Writing Group Chair must obtain the approval of co-authors prior to submission for approval. Late submissions will be accepted only in special circumstances.

Abstract review procedure:

1. All abstracts should be sent to the P&P Subcommittee.
2. If possible, abstracts will be reviewed at a regular P&P conference call. If not, the abstract will be faxed to the P&P Subcommittee members and a response requested within 4 days.
3. If the P&P Subcommittee review is favorable, the abstract will be sent simultaneously to the Steering Committee, NHLBI members, and parent studies for review. The Steering Committee and NHLBI will have 4 days to review and respond to the abstract.
4. If an abstract is approved, the investigator will be notified by the P&P Subcommittee to submit the abstract. If any parent study withholds approval at a subsequent time, the abstract will be withdrawn.
5. A final copy of the approved abstract submitted to the meeting should be sent to the P&P Subcommittee.
6. If the abstract is accepted, one month before the date of the meeting, a copy of all visual aids (including tables and graphs) and text for the presentation are to be submitted to the P&P Subcommittee for approval. The one month time frame assumes that there will be no opportunity for the presenter to revise the materials if they are not approved. A two month minimum is suggested in case revisions are necessary.

10.11 Data Requests

If someone from a parent study wants data that SHHS has on the parent's own participants, the P&P Subcommittee will generally approve the request; however, SHHS would like to be able to review a proposal stating how the information is to be used.

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SLEEP HEART HEALTH STUDY MANUAL OF OPERATIONS

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CHAPTER 11 - QUALITY ASSURANCE AND CONTROL

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11.1 Quality Assurance

In the Sleep Heart Health Study, quality assurance (QA) includes those activities designed to assure data quality that take place prior to data collection. Quality control (QC) includes data quality monitoring efforts that take place at identified points during data collection and processing.

SHHS quality assurance activities include the following:

11.1.1 Detailed Protocol Development

A clear description of the SHHS protocol, including study design and data collection activities, is described elsewhere in this Manual of Operations. Each section of the manual provides detailed step-by-step procedures for implementing the protocol of each individual procedure.

11.1.2 Protocol Changes and Equipment Updates

The Coordinating Center maintains the responsibility for updating the SHHS Manual of Operations. Requests for protocol changes may be initiated by any Field Center and sent to the Steering Committee for review. Changes require approval by the committee. Instructions for each procedure are documented and all modifications are included.

Any changes that affect QA or QC procedures will be documented in this chapter.

In addition, the PSG Reading Center has a written manual for guiding technicians through the details of their specific procedures. The Reading Center notifies the Steering Committee whenever equipment updates and corresponding protocol changes are needed. All changes require approval by a majority of the committee.

11.1.3 Certification, Recertification, and Maintenance of Certification

Criteria established to examine the adequacy of an individual's training are included in this chapter. Individuals meeting these standards are certified to execute a protocol or protocol segment. In addition, requirements for maintaining certification are specified for each procedure. Periodic recertification is required to verify that an acceptable performance standard or adequate knowledge of material has been achieved. The Coordinating Center and Reading Center monitor technicians performing procedures to ensure that Field Center staff perform only those protocols or protocol segments for which they are certified and that recertification activities are implemented according to the criteria contained in this volume. When a technician fails to meet the certification requirements, the Coordinating Center notifies the Field Center that the staff member needs to be retrained.

All staff certifications are reported to the Coordinating Center using the SHHS Field Center Technician Certification Check List (see page 356), which is sent to the Coordinating Center along with routine Quality Control reports.

11.1.4 Training and Training Updates

Training is the transfer of the study goals, plans and protocol to the research staff, resulting in clarification of procedures and standardization of data collection. Training materials developed for SHHS also provide the basis for continuing education during the study period. Periodic refresher training sessions review the protocol and inform personnel of any changes that have occurred.

11.2 Quality Control

For quality control purposes, SHHS data collection is monitored by observation and by quantitative assessment using specific quality control procedures such as repeat measurements and statistical analysis of study data. Monitoring is performed by personnel within the Field Centers and during site visits. SHHS quality control includes the following:

11.2.1 Observation of Technicians

By regularly observing staff performing specific protocols, Field Center Supervisors (or the investigator[s] who wrote the protocol) may identify techniques that need improvement or activities that do not adhere to the protocol.

11.2.2 Site Visits

Each Field Center will be site-visited once during the first year of recruitment. Additional site visits will take place as needed. The site visit team will include representatives from the Project Office, Coordinating Center, Reading Center, Investigative Centers, and a Study Coordinator.

11.2.3 Early Feedback and Communication

Early feedback and communication are important in monitoring and correcting problems such as data entry and data transmission errors. Telephone calls (including conference calls) and electronic mail are used whenever possible to facilitate rapid communication between the Reading Center, Field Centers, and the Coordinating Center. The Coordinating Center provides a weekly review of the data to detect outliers or unreasonable data. Questionable data is returned to the Field Centers to be verified or corrected.

As part of the quality control communications system, the Reading Center sends routine reports to each of the Field Center Principal Investigators and Study Coordinators regarding any errors that were observed in data received from the Field Center's technicians. This report includes descriptions of the problem and of subsequent discussions with the technician, the name of the technician involved, and the solution or proposed solution. The report is sent whether or not problems were identified during that time period. This report will be distributed monthly for the first year of enrollment and quarterly thereafter. Special reports will be prepared if problems are identified in the interim.

11.2.4 Quantitative Monitoring

Actual study data are used to monitor performance quality. Mean and standard deviations of study variables by technician are monitored for differences among technicians and for trends over time. Digit preference in blood pressure measurement is monitored periodically. Results of these analyses are presented to the SHHS investigators quarterly.

11.2.5 Repeat Measurements

The home sleep monitoring will be repeated in a sample of participants to establish that any errors in the sleep data are not so large as to threaten the validity of conclusions.

11.2.6 Reporting Results

Two aspects of quality control reporting should be emphasized. First, results must be timely. When remedial action is required, reporting is prompt so that a return to an acceptable level of performance is not unnecessarily delayed. Second, the reporting format must be easy to understand. Tabular presentations and graphic displays are accompanied by a narrative interpretation of the data.

11.2.7 Action on Results

With conscientious trained staff, quality control reports provide an opportunity to praise a job well done. On the other hand, a poor performance requires some remedial action. Depending upon past performance, the degree of error, and personal circumstances, remedial action may consist of a simple discussion to encourage a better performance, observation and monitoring of performance, or random repeat measurements by another technician. At times, retraining and recertification may be appropriate.

11.3 Quality Control Subcommittee

The Quality Control Subcommittee, which consists of representatives from the Coordinating Center, Field Centers, and the NHLBI Program Office, has been charged with coordinating and directing all SHHS quality assurance and quality control activities. Working with the specialty subcommittees and the Coordinating Center, the Quality Control Subcommittee determines the areas of emphasis for each routine quality control report in response to priorities for quality assurance developed by the Steering Committee. The Subcommittee also reviews all reports with specific attention to deviations from protocol, recurrent problems and trends, and shifts in data over time.

The Quality Control Subcommittee prepares recommendations to the Steering Committee concerning quality assurance and control and contacts Field Centers, the Reading Center or Coordinating Center as needed to advise them of problems and to discuss mechanisms for correction. The Quality Control Subcommittee will meet monthly during data collection years, and then periodically thereafter.

11.4 Quality Control Data and Reports

11.4.1 Monitoring -- Database and Feedback

The Coordinating Center tracks data quality problems and solutions compiled from copies of the reports that the Reading Center sends to the Field Centers. The Coordinating Center maintains contact with Field Centers to confirm that the Field Centers have been notified of any problems and that corrective actions have been implemented.

11.4.2 Data Analysis and Reporting

The Reading Center provides data and reports on specific quality control activities to the Coordinating Center at specific intervals (see Table 11.1). As the repository for SHHS study data, the Coordinating Center is responsible for conducting quality control analyses as summarized in Table 11.2 and below.

11.4.3 Data Entry

Data is entered at the Field Centers and the PSG Reading Center and transmitted to the Coordinating Center. To reduce errors, the software developed by SHHS for data entry requires double-entry of all values. In addition, the Coordinating Center analyzes most variables in the SHHS database periodically by Field Center in terms of status of the variables for each participant record, and frequencies for categorical variables or means, standard deviations and selected percentiles for continuous variables.

11.4.4 Technician Performance

To monitor technician performance, the Coordinating Center periodically examines blood pressure, weight, and neck measures in terms of age- and sex-adjusted means by technicians. The Coordinating Center monitors trends in adjusted means and in variability after adjustment over time, and periodically analyzes measurements which involve a degree of subjective judgment for digit preference by technician. The goal of these analyses is to identify potential outliers. When outliers are identified, the Coordinating Center will work with the Field Center Study Coordinator to determine whether a true data quality problem exists; and, if so, why.

PSG data sent to the Reading Center is assigned a quality grade by the Reading Center. The Coordinating Center prepares monthly summaries of recorded quality grade, stratified by Field Center and technician within Field Center. The Coordinating Center also monitors how often each technician goes out to do a sleep study, comparing this frequency with the minimum number of exams required to maintain certification.

11.4.5 Quality Control Reports

Quality control activities generate a large number of reports. For a report to be of use in correcting problems in data gathering, it must be prepared frequently and as soon as possible after the end of the period covered.

The frequency of reports is determined by balancing the study's need for prompt and frequent monitoring with the available resources to generate such reports and with the need to accumulate enough data to have an adequate sample size. Currently, a quality assurance report is prepared monthly documenting that all technician monitoring activities have been completed, that frequency requirements of procedures have been met, and that equipment checks have been done. The report also includes other selected information. Quality control reports will be prepared by the Coordinating Center on a regular basis (see Table 11.2).

11.5 Report Distribution

Distribution of quality control reports and designation of persons or groups responsible for responding to the reports and implementing corrective action are summarized in Tables 11.3 and 11.4 and described below.

Each Field Center and the Reading Center is responsible for reading and responding to the reports in their respective area and for implementing corrective action. Monitoring reports for protocol deviations, recurrent problems, or temporal trends is the responsibility of the Quality Control Subcommittee. The Operations Subcommittee will be responsible for sampling/recruitment reports, adherence to certification and maintenance protocol, and the turnaround of data at the Reading Center. When the Reading Center identifies immediate quality control problems such as blank channels, they send notices for correction directly to the Field Centers, keeping records for themselves and forwarding copies to the Coordinating Center. When the Coordinating Center identifies problems by periodic monitoring, the Field Center, the Quality Control Subcommittee, and the Reading Center (if applicable) are notified for concurrent monitoring. Reports are distributed as follows:

- Technician-specific performance reports are sent immediately to the appropriate Field Center Principal Investigator, Study Coordinator, and to the Quality Control Subcommittee.
- Reading Center performance reports are sent immediately to the appropriate Principal Investigator and the Quality Control Subcommittee.
- Summary quality control reports without technician-specific data are sent to the Steering Committee through the Quality Control Subcommittee or Operations Subcommittee.

Responsibility for responding to reports is as follows:

Field Center PIs, Study Coordinators, Quality Control Supervisors and Trainers:

- review each quality control and monitoring report with technician-specific quality control data;
- identify solutions to each problem;
- implement corrective action;
- report corrective action to Coordinating Center.

Reading Center Director:

- review each quality control and monitoring report pertaining to the Reading Center;
- identify a solution to each problem;
- implement corrective action;
- report corrective action to Coordinating Center.

Quality Control/Operations Subcommittees:

- each subcommittee will review each quality control and monitoring report for which they are responsible with attention to deviation from protocol, recurrent technician or Field Center problems, and temporal trends;
- direct Field Center and Reading Center attention to problems and recommend additional corrective action if the problems persist;
- monitor the implementation of corrective action;
- contact and coordinate study agencies and investigators to review data quality problems and solutions;
- prepare summary reports and recommendations for the Steering Committee.

Steering Committee:

- review quality control summary reports;
- monitor data quality trends;
- direct the Quality Control Subcommittee in areas needing special attention;
- modify study protocol.

11.6 Polysomnography Studies

11.6.1 Field Center Technicians

11.6.1.1 Training and Certification

Personnel charged with the responsibility of participant hook-ups will be required to meet performance standards that indicate an understanding of sleep physiology, polysomnology, the study goals and methods, medical alert levels and responses, equipment use and sensor placements specific for the SHHS, and sensitivity to participant needs. Only personnel who meet these standards will be “certified” (and approved) to perform sleep studies for the SHHS.

Personnel will be required to attend a central training session at the Reading Center, or undergo local training by a centrally-certified technician.

Training will consist of:

- An overview of Sleep Physiology and Sleep Apnea
- An overview of the Study Protocol
- An overview of Polysomnology

Detailed training on use of the Compumedics SleepWatch PS, including hands-on activities.

Detailed training on all aspects of the SHHS protocol specific for performing and processing sleep studies.

Certification:

Demonstration of the requisite knowledge and adequacy of technical performance will be assessed with a written and practical examination (requiring a grade of >75%). After passing these examinations, personnel will be required to perform a minimum of 5 studies of acceptable quality (interpretable) on non-cohort volunteers. Those personnel trained locally also will be required to perform 5 studies under the supervision of a centrally trained technician prior to being authorized to perform a study independently.

Personnel who serve as “back-up” technicians (for illness, scheduling conflicts, etc.) will be required to do a minimum of 4 studies/month to remain certified.

Re-certification will be required of any personnel who fall below the pre-set levels of performance standards, or who obtain <90% acceptable sleep studies in any given month evaluation period (or, for “back-up” personnel, who obtain 2 or more inadequate studies in any given month). The Director of the Reading Center, after consulting with the PI of the investigative center, will determine whether local or central (Reading Center) re-certification is indicated.

11.6.1.2 Equipment Maintenance

CAUTION: NEVER LEAVE ANY EQUIPMENT (OR SHHS MATERIALS) UNATTENDED IN A CAR OR OTHER VEHICLE, OR IN A PRIVATE RESIDENCE. KEEP AWAY FROM EXTREME TEMPERATURES. Do not soak or immerse Compumedics Recorder or PIB in any liquid. Do not use autoclave, acetone-based solutions, or abrasive cleaning agents to clean any of the sensor's electrodes.

Computer and flashcard: Keep away from extreme heat or cold. Keep away from magnetic fields. Always insert flashcard in direction of arrow, never force into computer. Keep flashcard in plastic carrying box at all times when not directly being used.

Oximeter Probe (non-disposable): May be cleaned with 70% isopropyl alcohol or an antibacterial cleaner on a soft cloth. **(Do not use acetone-based cleaning agent, as damage to the sensor will occur.) Disposable: discard sensor after each use.**

Airflow sensors: Should be disposed of after one use.

Non-disposable Lead Wires with Snaps: May be cleaned with an antibacterial cleaner (VIONEX wipes) or a soft cloth. **Do not** use an alcohol-based or acetone-based cleaning agent, as damage to the wires may occur. (Disposable snap electrodes should be disposed of after one use.)

Gold Cup Electrodes with Attached Leads: Soak electrodes in warm water with mild detergent (such as Tide), then rinse electrodes in sterile H₂O and air dry. Clean with toothbrush and warm soapy water (Gold Cup EEG electrodes may also be soaked in a sterilizing disinfecting solution such as Cidex -- check manufacturer instructions before using this product).

Sleeves for chest and abdomen bands: Wash in warm soapy water after each use.

Vest: Wash at least weekly (warm soapy water -- machine washable), and more often as needed.

Do not soak or immerse headbox or PIB in any liquid to prevent damage to the unit.

11.6.2 Training and Certification of Reading Center Personnel

1. Certification of the Chief Polysomnologist

The Chief Polysomnologist will be an experienced polysomnologist (>5 years experience scoring). S/he will be required to:

Demonstrate a complete understanding of scoring rules and ability to articulate reasons for assigning epoch by epoch codes for sleep and respiratory staging.

Demonstrate a level of agreement (within 10% for summary AHI and sleep stages and 15% level of agreement for arousal index) with a second experienced polysomnologist (each scoring the same 10 records "blinded").

Demonstrate a within 5% level of agreement (with-in scorer reliability) by scoring the same 10 records, at least one week apart.

2. Certification of Scorers

Each scorer will be trained using the Reading Center MOP that provides a written and pictorial description of scoring rules, and individualized training by the Chief Polysomnologist, physician staff, and previously trained scorers. Training includes: required reading of the RC MOP, individualized scoring sessions with the Chief Polysomnologist, physician staff, and previously trained SHHS scorers, scoring of practice studies, and scoring of SHHS studies (with review of scored results.)

Scorers will be certified based on their ability to demonstrate a complete understanding of scoring rules and ability to articulate reasons for assigning epoch by epoch codes for sleep and respiratory staging. This will be judged by review of a minimum of 10 records with the Chief Polysomnologist, a physician-investigator, or an experienced SHHS polysomnologist (with > one year of experience scoring records for SHHS).

Each scorer will be required to score at least 10 records, achieving a minimum of a 10% level of agreement with the Chief Polysomnologist (or experienced, certified SHHS scorer) for respiratory events and sleep stages and a 15% level of agreement for arousals.

3. Ongoing QA of Scoring Procedures/Indications for Re-certification

The Chief Polysomnologist will review the first 20 records scored by each scorer after certification, and periodically thereafter according to individual needs (defined below).

Weekly-biweekly QA scoring exercises will be conducted at the RC, with dedication of between 1.5 to 3 hours of time per week for the scorers to meet and discuss scoring issues. The weekly exercises will be organized by the Chief Polysomnologist, with topics that will reflect ongoing needs as identified by the staff of by the CC/QA Committee. These exercises will include:

- scoring of randomly chosen epochs;
- scoring of problem records/epochs;
- discussions of any problematic rules/examples identified during scoring

Exercises will include individual scoring, with follow-up discussion of any discrepancies in assigned scores. A discussion, with participation of Drs. Redline and Rosenberg, will establish a "consensus" score for discrepant records. Results of any discrepancies between scorers or the Chief Polysomnologist and between any scorers will be reviewed at weekly meetings with Drs. Redline, Rosenberg and Strohl. The results of the deliberations will be kept on file. This will include copies of ambiguous records and a summary of any arbitration.

The Chief Polysomnologist will track data from these meetings, and calculate levels of agreement among scorers, and trends over time. Any scorer identified to deviate more than the others (>10% from the consensus statement) on 3 consecutive exercises will be “re-trained.” This will include individualized review of consecutive records by the Chief Polysomnologist and/or Drs. Redline/Rosenberg. “Re-training” will be considered successful if review of at least 5 additional studies demonstrates no deviation from scoring protocol, and the subsequent QA exercises show no deviations in performance compared to scoring assignments made by the other scorers.

The Coordinating Center and PSG and QA Committees will establish methods for tracking scoring reliability and drift. This includes re-processing of records for reliability exercises and generation of summary data for each scorer (See below). The overall mean AHI, sleep stage values and arousal indexes will be tracked for each scorer. If average values differ by > 15 % for any given scorer, those records will be reviewed by the Chief Polysomnologist. The RC Director will determine whether re-training and re-standardization are required.

4. QA of Scored Records

Prior to sending any scored record to the Coordinating Center, the record will be subject to computer analysis (“Outlier Program”) and the scored file will be manually reviewed to identify extreme values that could indicate physiological implausibility. These include: 0% and >90% of any given sleep stage, 0% oxygen saturation, AHI > 160; apnea index > 40, heart rate <25, > 150. Outliers identified by the program or by visual review of the scored file will be documented by the scorer on the PSG Notes Form, indicating of how the problem was resolved (e.g., reviewed with the Chief Polysomnologist and determined to be accurate).

Before transfer of records to the Coordinating Center, the RC Coordinator or Chief Polysomnologist will:

- review the paperwork for completeness and logic,]
- identify any records where the AHI determined by preliminary and final scoring differs by > 5 ,
- identify any records flagged by the scorer to be “problematic”.

These records will be reviewed by Dr. Redline or Rosenberg, with documentation of their disposition.

After transfer of records to the CC, data will be subject to further assessment of outliers. Records thus identified with outliers will be checked for documentation of a record review prior to transfer to the CC. Records identified at the CC with outliers in which documentation of outlier problems had not been made will be returned to the Reading Center for review and resolution.

5. Coordinating Center Procedures

The Coordinating Center will randomly select the PSG studies to be rescored through the period of data collection. All of these studies will be forwarded to the Reading Center to be assigned to different readers to establish inter-reader reliability. These studies will then be reassigned to the same reader at defined time periods to define intra-reader reliability.

The Coordinating Center will determine intra- and inter-reader differences in the summary data for AHI, % time in apnea, % time in desaturation, sleep efficiency, sleep stages, and arousal indices. The Coordinating Center will monitor intra- and inter-reader reliability to determine the threshold for requiring remediation including retraining or removing a reader.

Site visits, coordinated by the Coordinating Center, will occur, as directed by the Steering Committee. A Polysomnologist will review random records, interview scorers and review tracking procedures, to assure the accuracy and completeness of all scoring procedures.

11.6.3 Quality Assurance/Control

Quality control measures, implemented at several levels, will assure that all centers and personnel meet and maintain comparable and high levels of technical performance.

Quality control of sleep studies will occur:

1. By assuring that study personnel meet certification criteria (certification check lists).
2. By clear documentation of home hook-up procedures and their review (by an individual uninvolved in the hook-up, e.g., the Study Coordinator) soon after each study (based on Sleep Data Retrieval Form; Section 7.2.2).
3. By review of each study prior to its transfer to the Reading Center, with early identification of problems with equipment or sensor placement (based on Signal Verification Form; Section 6.9.2). A Sleep Study Resource (usually a certified or registered polysomnologist) will be identified for each Field Center who will be charged with the responsibility of ascertaining the sleep studies meet QA standards and who will provide “troubleshooting” support.
4. By review of all studies at the Reading Center, with grading of the quality of each signal, and overall study interpretability (based on Sleep Data Quality Assessment; Section 11.6.4).
5. By ongoing review of participant reports regarding the quality of interactions with study personnel and overall comfort ratings for sleep studies and hook-ups (based on Morning Survey).

The Coordinating Center will process all data collected as above. Monthly reports (specific to Field Center and technician) will be distributed to all PIs, the NIH Program Office, and the Chair of the Steering Committee.

The data that will be included are:

From the Signal Verification form:

1. Impedance values (mean, % >5 Kohms) for EEG, EMG, EKG, EOG.
2. Notes of any unusual events during hook-up.
3. Completeness of sensor checks (i.e., the number of channels with documented signal checks).
4. The duration of each home visit.

From the Sleep Data Retrieval form:

1. Occurrence of channels without data (not “flat-lined”).
2. Occurrence of channels with substantial artifact.
3. The number of studies that have > 4 hours of oximetry/airflow data.
4. The number of studies identified as needing to be repeated/number of studies actually repeated.

From the Sleep Data - Quality Assessment and Preliminary Report form:

1. Grades for the quality of each channel (based on the duration of each signal with sufficient amplitude and free of artifact).
2. Overall grade for study interpretability.

Local Quality Assurance

A Sleep Study Resource will be identified who will:

1. Review the first 5 “practice” studies and first 10 “cohort” studies performed by each technician performing home studies. If more than 2 of these 10 studies have problems determined to be related to sensor placement, additional batches of 10 (successive) studies will be reviewed until 80% of records are determined to be technically adequate.
2. Be available to reinforce the technical skills of any new personnel or any personnel identified by the Reading Center as exceeding the minimum standards for study acceptability.
3. Be available for ongoing review and trouble-shooting of technically problematic record (“flat lines,” “increase artifact,” etc.).

11.6.4 Sleep Data - Quality Assessment Forms Completed by the Reading Center

11.6.4.1 Quality Assessment and Preliminary Report

The Sleep Data - Quality Assessment and Preliminary Report form is completed by the Reading Center for each PSG study processed. It grades the quality of each channel (based on the

duration of each signal with sufficient amplitude and free of artifact) and overall grade for study interpretability. In addition, medical alerts are checked and preliminary RDI (respiratory distress index) is recorded.

General Coding Instructions

Each box must be completed. If a piece of data is missing, the field should be left blank. It will be assumed that quality assessment was not or could not be done.

Question by Question Coding Specifications

The upper right gray box should be completed with the following identification data:

Participant ID Number
Whether it is First study (code=1) or a Repeat (code=2)
Field Center ID Number: a 2-digit field
Technician ID Number: a 3-digit field
Monitor ID/Headbox ID: each a 2-digit field

The next box should be completed with the following identification data:

Date of Study: (use month, day, year format; each a 2-digit field)
Date Received at RC: (use month, day, year format; each a 2-digit field)
Assigned Scorer ID: (a 3-digit field)
Total Recording Time: (coding: Hours: 00-24; Minutes: 00-59)
Date Preliminary Report sent Originating Site: (use month, day, year format; each a 2-digit field)
Repeat Study Requested: If a repeat study was requested, enter the date the request was sent to the Field Center (use month, day, year format; each a 2-digit field).
If no repeat study was requested, leave the line blank.
Zip Cartridge number: (a 10-character alpha-numeric field)
Total Sleep Time: (coding: Hours: 00-24; Minutes: 00-59)

Section-Specific Instructions

1. Quality Assessment of Channels

For each channel score the following:

- Hours of scorable signal: 00-18 (2-digit field)
- Quality Code: A single-digit value. Check the appropriate box based on the hours of signal mostly free from artifact, and enter the corresponding numeric value:
 ≥ 6 hours = 4; ≥ 4 but less than 6 = 3; ≥ 2 but less than 4 = 2; $< 2 = 1$.

Comment field data are not entered into the data base.

2. Lights: Mark the box indicating whether lights were calibrated appropriately (code=0) or not (code=1).
3. Overall Study Quality

Coding:

Permissible codes: 1-7, where 1=G=Unsatisfactory to 7=A=Outstanding.

4. Medical Alerts

As the study is reviewed the following medical alerts should be checked for.

Heart Rate > 150 for at least 2 minutes.

Heart Rate < 30 bpm for \geq 2 minutes

Oxygen saturation < 75% for > 10% total sleep time (TST)

AHI > 50

Coding:

Permissible codes: 0 (=NO) 1 (=YES) 8 (=N/A)

YES indicates the medical alert occurred, NO indicates the medical alert did not occur, and N/A indicates that there is insufficient data to determine medical alerts (i.e., heart rate, oxygen saturation, or AHI).

5. Preliminary RDI is recorded. It is an 8-digit field allowing for 2 decimal places.
6. Date Entered: Complete with the date the data were entered, in month, day, year format; each a 2-digit field.

11.6.4.2 PSG Scoring Notes

This form is completed by the PSG scorer at the time the complete PSG scoring occurs.

The upper gray box should be completed with the following information:

Participant ID

Study Date: Date the PSG study occurred (use month, day, year format; each a 2-digit field)

Date Scored: Date the complete scoring was completed (use month, day, year format; each a 2-digit field)

Date Scored Data sent to Coordinating Center: (use month, day, year format; each a 2-digit field)

Scorer ID: a 3-digit field

Acceptable codes for body of form:

Items 1 through 5: Permissible codes: 0 (=NO) 1 (=YES).

Item 6 - Predominant ($\geq 75\%$) Channel for Scoring Respiratory: Permissible codes: 1, 2, 3, 4, 5, 6, 7

Item 7 - Sleep Latency: Permissible codes: 0 (=Unreliable); 1 (=Reliable)

Item 8 - Staging Notes: Permissible codes: 1, 2, 3, 4, 5, 6

Item 9 - Restricted: Permissible codes: 1, 2, 3, 4, 5

Item 10: Other: Written comments will be entered.

Final RDI is recorded. It is an 8-digit field allowing for 2 decimal places.

Date Entered: Record the date the data were entered (use month, day, year format; each a 2-digit field).

*PSG Scoring Notes form (11/8/96) inserted here.
One page inserted after this page.*



SLEEP HEART HEALTH STUDY

PSG SCORING NOTES

ID#: Site ID#: Study Date: Date Rec'd at RC: Date Scored: Date Scored Data sent Coordinating Center: Scorer ID

- 1. Abnormal Awake EEG
2. Alpha Intrusion/Alpha Artifact
3. Abnormal Eye Movements
4. Periodicity
5. Periodic Large Breaths
6. Predominant Channel for Scoring Respiratory
7. Sleep Latency
8. Staging Notes
9. Restricted Analyses
10. Results of Outlier Check

FINAL RDI: DATE ENTERED:

11.7 Seated Blood Pressure and Anthropometry

Each Field Center will be responsible for the routine quality control activities of equipment maintenance and calibration, and regular certification/recertification of technicians on study protocol. This section describes these activities for blood pressure, weight, and neck circumference measurement and the associated equipment maintenance. See *Manual of Operations*, Sections 6.2-6.4, for details of Field Center procedures.

11.7.1 Technician Training and Certification

11.7.1.1 Blood Pressure

Training and certification consists of a conference call (or readings), a written test, viewing of a video tape, one hour practice, and the final certification. The lead blood pressure person at each Field Center is certified first. This individual is then responsible for certifying their staff members. Prior to the certification session, anyone who has never taken a blood pressure before should practice applying the cuff to volunteers and listening for the Korotkoff sounds.

For all technicians employed by SHHS during December, 1995, the following certification procedure was used:

1. Conference call - during the conference call, Ms. Peg Meyer from the University of Pittsburg talks about measuring blood pressures in a research setting. This call is approximately 45 minutes long.
2. Written test - the conference call is followed by a written test covering Ms. Meyer's material (approximately 10 minutes).
3. Video tape - after the written test, the trainee will view a video tape which includes step-by-step instructions and 12 examples showing the mercury column falling while the viewers listen to the Korotkoff sounds.
4. Practice session - trainees will spend approximately one hour practicing, time based on the certifiers judgment. Those trainees who have no experience with measuring blood pressure are required to practice on 20 volunteers.
5. Certification - the lead blood pressure person is responsible for certifying their staff according to the protocol (double stethoscoping) set forth in this section. Results are documented. Deadline for certification is 2 weeks after the conference call.

For technicians hired after the conference call took place, the same training and certification procedures are used, except that Steps 1 and 2 are replaced by:

1. Review of Frohlich, et.al. (See Section 6.2.3) which all Field Centers obtained for the initial certification process and notes from the conference call.
2. Written test - written test covering materials reviewed for new Step 1.

11.7.1.2 Anthropometry

The Supervisor performs the entire measurement process for measuring neck circumference and obtaining an individual's weight. The trainee measures the neck circumference on 3 volunteers. If they get the same measurement as the Supervisor, they are certified for this procedure. Weight is to be obtained on one volunteer.

11.7.2 Equipment Maintenance

The following equipment is used to obtain measurements during the SHHS Home Visit:

- standard Littman stethoscope with bell and tubing no longer than 14 inches
- standard Baum manometer for determining maximal inflation level
- four standardized cuffs (from Baum)
- measuring tape
- scale

Cuff Sizes. The Field Center Supervisor verifies daily that the full range of blood pressure cuffs is available. Field Center staff report immediately to the Supervisor if all cuff sizes are not available.

Sphygmomanometers. Regular inspections of the sphygmomanometers are required. The Field Center Supervisor records the results of these checks, including comments on any problems found, on the Blood Pressure Check List. This log sheet is mailed to the Coordinating Center monthly.

Daily. Sphygmomanometers must be checked for correct zero before each use. Place the instrument flat on the table and disconnect the inflation system. With eyes level with the zero line, the top of the meniscus should be on the zero line. If the reading is either above or below the zero mark, the instrument should be sent to Baum for repair.

Monthly. Check that cap of manometer fits properly and tightly. Complete the procedure above to check for correct zero. Reconnect the inflation system. Roll the cuff around a plastic bottle or tin can and secure in place. Close the valve on the Air Flo system and inflate the instrument until the mercury rises to 240 mmHg. Slowly open the Air Flo valve and allow the mercury to fall to 200 mmHg. Close the valve. The mercury column should remain stable. If the column continues to fall, there is an air leak and the system should be reinflated until the column rises to 200 mmHg. Pinch the tubing at various locations to localize the area of the leak; then replace the leaking tubing, cuff, or valve.

With time, the mercury will become dirty and an oxide layer will be deposited on the inside of the glass tube. Do not attempt to clean the glass column with a pipe cleaner, as hazardous levels of mercury aerosol will be produced. Send the instrument to the local Baum supplier for repair.

Since mercury is a toxic substance, all maintenance procedures must be performed carefully. Do not perform any maintenance procedures that will expose mercury to air. A manometer specialist with expertise in handling toxic substances should be contacted (at Baum) to add or withdraw mercury from the instrument.

Maintenance instructions for the standard sphygmomanometer are adapted from those given for the MRFIT study in *Controlled Clinical Trials, Vol. 7, no. 3 (Supplement), Sept. 1986*.

Measuring Tape. The Field Center Supervisor checks the condition of the measuring tapes monthly and replaces any that are worn or stretched. The tapes are checked for stretching by comparing them with a height ruler. Two technicians perform the check:

- The first technician holds the zero mark of the tape against the height ruler at the 150 cm level.
- The second technician flattens the tape against the height ruler without stretching and records the heights of the 30 and 100 cm marks on the tape to the nearest half centimeter.
- If the measures fall outside the 119.5-120.5 or the 49.5-50.5 cm ranges respectively, the tape should be replaced.

Scale. The scale is checked at the beginning of each day to assure that it reads zero when there is no weight on it. The scale is to be calibrated monthly using a 50-pound known weight. If the scale is outside the range of 49.5-50.5 pounds, it needs to be serviced.

11.7.3 Technician Performance Monitoring

Maintenance. A technician must perform at least one measurement per week to maintain certification.

Every other month, the Field Center's designated Supervisor observes each technician perform the blood pressure, weight, and neck circumference measurement procedures on a volunteer and record the results of the observations on the appropriate Supervisor Check List. The Supervisor notes any problems with technique and discusses them with the technician after the examination has been completed.

Simultaneous Blood Pressure Measurements (double stethoscoping). To assess the accuracy and precision of blood pressure measurements, every other month each technician measures blood pressure simultaneously with another technician using a Y-tube. The following procedure is used:

- Each technician independently measures the arm circumference, and records that measurement on the Technician Form for Simultaneous Blood Pressure Observations.
NOTE: If the two technicians disagree on which blood pressure cuff to use, they remeasure the arm together and use the cuff size determined by that measurement. Each

technician notes this cuff-size disagreement on his or her Technician Form for Simultaneous Blood Pressure Observations.

- All blood pressure measurements are recorded on the individual technician's form.
- Both technicians submit their Technician Form for Simultaneous Blood Pressure Observations to the Field Center Blood Pressure Supervisor, who compares the results.
- The Field Center Blood Pressure Supervisor reviews the results of the duplicate examinations, calculates the disparity between the blood pressure measurements and records it on the Supervisor Form for Simultaneous Blood Pressure Observations.

The two technicians should agree on each systolic and diastolic measurement within 4 mmHg. The average blood pressure should agree within 3 mmHg. When this standard is met, a copy of all forms is sent to the Coordinating Center.

When the standard is not met:

- The technician pair repeats the simultaneous blood pressure measurement protocol and records as described previously.
- A copy of all forms is sent to the Coordinating Center.

Adherence to Blood Pressure Measurement Protocol Procedures. The specific blood pressure measurement procedures are found in Section 6.2 of the Manual of Operations. The Supervisor Check Lists (Table 11.10) included here are based on adherence to these procedures.

Adherence to Weight Measurement Protocol Procedures. The specific weight measurement procedures are found in Section 6.3 of the Manual of Operations. The Supervisor Check Lists (Table 11.10) included here are based on adherence to these procedures.

Adherence to Neck Circumference Protocol Procedures. The specific neck circumference measurement procedures are found in Section 6.4 of the Manual of Operations. The Supervisor Check Lists (Table 11.10) included here are based on adherence to these procedures.

11.7.4 Supervisor Response to Quality Control Analyses

The Coordinating Center periodically analyzes data from each technician for digit preference in reading systolic and diastolic blood pressure. The Coordinating Center reports these results to the Field Center Quality control Supervisor, who reviews the results with each technician. When data are missing, the Coordinating Center examines the entry procedures used to record the data. The Coordinating Center communicates with the Field Centers when problems are identified.

11.8 Field Interviews

Interviews are conducted at the time of the Sleep Monitor hookup in the home. These interviews include the Health History form and the Medications form. The interviews are then entered into the database after returning to the Field Centers.

11.8.1 Interviewer Training

All interviewers were given six hours of interviewer training at central training prior to the start of the study. This included two hours of general training in interviewing process, standardization of interviewing within the Field Center and between Field Centers nationally, two hours of review of the forms to be used, and two hours of medication interviewing and problem-solving. The subjects covered in this design included:

- a. Importance of interviewer skills, attitudes and behaviors, including:
 - reading questions as written in an even pace
 - not giving self-interpretations of the questions
 - adequate understanding of probing techniques
- b. Role-playing, including:
 - when interviewing the difficult respondent
 - problem-solving with the medications
- c. Discussion of quality control measures, including:
 - process for maintaining quality control
- d. Certification process

11.8.2 Certification Process

- a. All Study Coordinators complete one set of interviews and send those tapes to the Study Interviewer Certifier. When those tapes are reviewed and meet or exceed expected standards, the Study Coordinator is certified as the Field Center certifier (see Section 11.8.4).
- b. All interviewers trained at central training should complete one full interview in the home. These interviews may be completed on volunteers in the home. Those tapes will be reviewed by the Study Coordinator in each center. If those tapes are reviewed and meet or exceed expected standards, the Field Center Study Coordinator should certify the interviewer and notify the Coordinating Center of that certification.
- c. Assessment of interviewer's ability is judged on the following criteria:
 - ability to answer questions and concerns of study respondent
 - follows the instructions on forms and reads questions as written
 - administers interview in a neutral, even pace
 - follows skip patterns and records answers correctly
- d. Training for new personnel brought to the study following central training should be trained in accordance with the training outline in Section 11.8.3.
- e. Assessment of interview is based on the criteria as found in Section 11.8.4.

11.8.3 Training for New Interviewers

Training of new interviewers consists of the following four sessions and corresponding content:

Session One: three hours

- a. Introduction to SHHS - 30 minutes
 - Who is involved in the study?
 - What is the purpose of the study?
 - What is the purpose of the interviews?
- b. Characteristics of an Interviewer - 90 minutes
 - Why interviewers fail to standardize
 - Goals in conflict - truth vs. standardization
 - Problems of establishing rapport and collecting data
 - Inadequately trained interviewers
 - Standardized Interviewing Techniques
 - Reading questions as written with no changes
 - Recording answers according to instructions
 - Maintaining a nonjudgmental stance
 - Learning to probe ambiguous answers
 - Probing Techniques
 - What is an ambiguous answer?
 - Directive and non-directive probes
 - Silence
 - Repeating the question
 - Clarifying the answer
 - Understanding the “I don’t know” response
- c. Role Plays with the Forms - one hour

Session Two - three hours

- a. Medication Coding Form
 - Why is it used?
 - When to perform
 - Intricacies of the form
- b. Role Plays with various sets of medications
- c. Problems that will be encountered
 - Unmarked medications
 - Pills out of containers
 - Uncertain medication prescriptions
 - Use of PRN

Homework: Complete five interviews and five medication forms

Session Three: one hour

- a. Review the completed forms with the interviewer.
- b. Process any questions, concerns, problems encountered.
- c. Explanation of the editing process in all forms and the review process.

Homework: Secure three completed taped sets of interview and medication forms

Session Four: one hour

- a. Review the tapes
- b. Certify the Interviewer

11.8.4 Specific Criteria for Evaluation of Interviewer

The specific criteria used are based on both the ARIC¹ and the CHS² studies. These criteria have also been noted in Fowler and Mangione.³ A further adaptation was made by Edwards et al.⁴

- 4.1 Answers respondent concerns and questions appropriately.
- 4.2 Reads questions at steady, even pace
- 4.3 Maintains the focus of the interview
- 4.4 Follows the instructions on the questions as written.
- 4.5 Initiates appropriate non-leading questions.
- 4.6 Records and codes answers correctly.
- 4.7 Completes the editing process and reviews forms.

Each tape is reviewed on a scale of 1 through 5. Each category also has a “not applicable” grade in the event there is insufficient data to assess the specific category. The criteria established for the study are as follows:

N/A Not applicable

- 1 Unsatisfactory (failed to meet standards)
- 2 Below expectation (did not meet some standards)
- 3 At expectation (met all standards)
- 4 Above expectation (met all standards and in some instances exceeded them)
- 5 Outstanding (distinguished performance, consistently exceeded all standards)

References:

1. ARIC Manual No. 2 - Operations Manual, 1993.
2. CHS Operations Manual.
3. Fowler, FJ, Jr., Mangione, TM, Standardized Survey Interviewing: Minimizing Interviewer-Related Error, Sage Publications, 1990.
4. Edwards, S. et al., Objective System for Interviewer Performance Evaluation for Use in Epidemiologic Studies. American Journal of Epidemiology, Vol. 140, page 1020.

11.9 Field Center Certification

Criteria have been established that technicians must meet in order to be certified to begin doing the SHHS sleep monitoring. Prior to enrollment of parent cohort participants, each technician must also demonstrate that they can complete an entire home visit successfully and process resultant data according to SHHS protocol. Below is a checklist of requirements that a technician must meet (and be certified) prior to a Field Center beginning SHHS home study visits.

Certification requirements

1. Each technician must receive sleep certification from the Reading Center.
2. Each team must demonstrate that they can complete a home visit in 2 hours or less
3. Each team must complete a home visit under the supervision of the Study Coordinator or lead technician to demonstrate that the team can perform a complete home visit according to SHHS protocol.
4. Each Field Center must be successfully enter and send to the Coordinating Center the data from one practice home visit.

Pre-enrollment SHHS Technician Certification Checklist

The checklist establishing pre-enrollment certification must be completed prior to a Field Center beginning enrollment of parent cohort participants (see next page).

PRE-ENROLLMENT SHHS TECHNICIAN CERTIFICATION CHECKLIST

For each technician, check the appropriate line when certification is received. If that technician will not be certified in that area, write "NA" on the line. The person certifying that the specified criteria was met should fill in their initials in the field labeled "By."

Technician Name: _____ ID: _____ Field Center: _____

_____ Sleep Certification Received Date: ___/___/___

_____ Home visit completed within 2 hrs. Date: ___/___/___ By: _____

_____ Complete visit completed according Date: ___/___/___ By: _____
to SHHS protocol

_____ Data entered and sent to CC Date: ___/___/___ By: _____

TABLE 11.1

Study Agency	Quality Control Data Sent to the SHHS Coordinating Center			
	weekly	monthly	quarterly	as needed
Field Center				
Contact/recruitment data	x			
Sleep Habits Questionnaire	x			
Home visit data	x			
Signal Verification form	x			
Sleep Data Retrieval form	x			
Quality Control Supervisor Check Lists		x		
Response to QA and QC reports				x
PSG Reading Center				
Quality of PSG data	x			
PSG data	x			
Response to QA and QC reports				x

TABLE 11.2

Quality Control Analyses □

Procedure	Type of Analysis	Responsible	Frequency
Sampling/Recruitment	response rate recruitment table	Coordinating Ctr	weekly
Data entry/Transmittal	completeness and integrity of data	Coordinating Ctr	weekly
All Interview and questionnaire data	general screen*	Coordinating Ctr	quarterly
Blood Pressure, weight, and neck circumference	adjusted means digit preference	Coordinating Ctr	quarterly
Comfort of PSG monitor	frequency distr.	Coordinating Ctr	monthly
PSG data	condition on arrival quality grades % missing data overall data processing report repeat study frequency	Coordinating Ctr	monthly
Supervisor Check Lists	completeness	Coordinating Ctr	monthly

Most analyses will be stratified by Field Center, and by technician within Field Center.

*General screen for patterns by technician and center.

TABLE 11.3**Quality Control Reports: Source, Distribution and Response**

Type of Report	Source	Distribution	Response
Field Center Recruitment and Technician Certification	Coordinating Ctr	Field Center PIs Study Coord. Operations Subcommittee	FYI or resolution of issues
Field Center performance (technician specific) data integrity quality of PSG study comfort of PSG monitor	Coordinating Ctr	Field Center PIs Study Coord. Quality Control Subcommittee	corrective action monitor resolution
Reading Center Performance rate of scoring turnaround time	Coordinating Ctr	Operations Subcommittee	corrective action monitor resolution
Reading Center Performance QC of scores	Coordinating Ctr	Quality Control Subcommittee	report to Steering Committee
Summary Reports (without technician specific data)	Coordinating Ctr	Quality Control Subcommittee	report to Steering Committee

TABLE 11.4**Review and Responses to Quality Control Reports****Field Centers and****Reading Center** reports corrective action taken to Coordinating Center**Quality Control and****Operations Subcommittees**

reviews reports for all Field Centers and Reading Center

identifies need for corrective action

monitors resolution of Quality Control problems

maintains Quality Control summaries

prepares Quality Control overviews (for Steering Committee)

Steering Committee

reviews Quality Control summary reports from the Quality Control Subcommittee

reviews priorities for the Quality Control activities

initiates *ad hoc* Quality Control analyses and reports

TABLE 11.5**Blood Pressure, Weight, and Neck Circumference Master Schedule****Quality Control**

Supervisor Activities:	daily	monthly	bimonthly	quarterly
observation of technicians			x	
maintenance of equipment:				
blood pressure cuffs	x			
measuring tape		x		
standard sphygmomanometer		x		
scale		x		

**Coordinating Center Quality
Control Analysis and Reports**

Blood Pressure, weight, and neck circumference

adjusted means				x
digit preference				x

TABLE 11.6**Field Center Quality Control Supervisor Activities
Observation of Technicians**

	weekly	monthly	bimonthly	quarterly
Blood Pressure				
Supervisor Form of Simultaneous Blood Pressure Observations			x	
Neck Circumference			x	
Weight			x	

TABLE 11.7

Quality Control Responsibilities of Supervisors**1. Observation of technicians:**

Frequency: bimonthly for each procedure
Required reports: Supervisor Form for Simultaneous Blood Pressure Observations
 Blood Pressure Examination and Anthropometry Check List
Send reports to: Coordinating Center

2. Maintenance of equipment:

Name of machine/equipment **Blood Pressure Cuffs**
Frequency: daily
Action required: make sure all sizes of cuffs are available
Required reports: none
Send reports to: NA

Name of machine/equipment **Standard Sphygmomanometer**
Frequency: daily (before each use)
Action required: check for correct zero
Required reports: none
Send reports to: NA

Frequency: monthly; more often if problems suspected
Action required: check tube for oxide dust, check cap for tightness,
 check that mercury is at zero with no pressure,
 check inflation system
Required reports: Blood Pressure, Weight, and Neck Circumference Check List
Send reports to: Coordinating Center

Name of machine/equipment **Measuring Tape (for cuff size and neck circumference)**
Frequency: monthly
Action required: check for worn or stretched tape
Required reports: Blood Pressure, Weight, and Neck Circumference Check List
Send reports to: Coordinating Center

Name of machine/equipment **Scale**
Frequency: monthly
Action required: check for accuracy
Required reports: Blood Pressure, Weight, and Neck Circumference Check List
Send reports to: Coordinating Center

TABLE 11.8

Supervisor Form for Simultaneous Blood Pressure Observations

DATE:
 mo day year

Field Center:

Supervisor:

1st Technician ID#:

2nd Technician ID#:

Every other month each technician should, with a second technician, simultaneously measure blood pressure with a sphygmomanometer using a Y-tube on a volunteer, *not a participant*. Each technician should separately (and out of the other's view) record his or her measurements on a Technician Form for Simultaneous Blood Pressure Observations. The Blood Pressure Supervisor should then transfer the results to this form (Supervisor Form for Simultaneous Blood Pressure Observations), calculate the differences between the two sets of measurements, and record the results below. If the difference on any individual measurement is greater than 4 mmHg, or if the averages of the readings for each technician differ by more than 3 mmHg, the supervisor should take corrective action and continue testing until the technicians succeed. A copy of this supervisor form should be sent to the Coordinating Center.

	1st Tech	2nd Tech	Difference
● initial arm circumference (cm)	_____	_____	_____
● initial cuff size selected	_____	_____	_____
● palpated systolic pressure	_____	_____	_____
● first SBP	_____	_____	_____
● first DBP	_____	_____	_____
● second SBP	_____	_____	_____
● second DBP	_____	_____	_____
● average SBP	_____	_____	_____
● average DBP	_____	_____	_____

Overall Comments of Supervisor

Instructions to Technicians/Corrective Actions

Signature

TABLE 11.9

Technician Form for Simultaneous Blood Pressure Observations

DATE:
mo day year

Field Center:

Technician ID#:

Every other month each technician should, with a second technician, simultaneously measure blood pressure with a standard sphygmomanometer using a Y-tube on a volunteer, *not a participant*. Each technician should separately (and out of the other's view) record his or her measurements on a copy of this form. The Blood Pressure Supervisor should then transfer the results to the Supervisor Form for Simultaneous Blood Pressure Observations and calculate the differences between the two sets of measurements.

- initial arm circumference (cm) _____
- initial cuff size selected _____
- palpated systolic pressure _____
- first SBP _____
- first DBP _____
- second SBP _____
- second DBP _____
- average SBP _____
- average DBP _____

TABLE 11.10**Blood Pressure Examination and Anthropometry QC Supervisor Check List****DATE:**

mo day year

Field Center:**Technician ID#:****Supervisor:****Standard Sphygmomanometer:**

For each item, circle *y* or *n* (*yes* or *no*) to indicate whether the procedure is carried out correctly. Record any comments in the blank space between that item and the next. For certain items, specific parts of the procedure which are important are listed separately. Items are presented in the sequence of the examination procedure, but may require confirmation before or after the examination.

Procedures to be completed prior to measurement:

- y* *n* Technician sets up equipment.
- y* *n* Technician verifies that a chair is available.

The following items apply throughout the procedure:

- y* *n* Participant is kept warm, relaxed and comfortable.
- y* *n* Participant is discouraged from talking, except to voice discomfort or confusion about instructions.
- y* *n* Technician maintains a consistently calm, patient and reassuring disposition.

Preparatory steps

- y* *n* Measures arm circumference appropriately.
- y* *n* Assists participant in sitting in chair (if necessary).
- y* *n* Applies appropriate size cuff to arm.

Seated Blood Pressure Measurement

- y n** Measures the systolic blood pressure using the standard manometer:
Inflates cuff quickly to maximal inflation level
Deflates at 2mmHg/second to appearance of systolic pressure.
Deflates cuff quickly and completely.

Weight Measurement

- y n** Scale is positioned at zero.
- y n** Participant is not wearing shoes.
- y n** Participant's weight is equally distributed on both feet.
- y n** Participant is not supporting himself or herself.
- y n** Examiner's eyes are level with the point of measurement.
- y n** The measurement is recorded to the nearest 0.1 kilogram.

Neck Circumference Measurement

- y n** Participant is sitting upright with the head in the Frankfort Horizontal Plane.
- y n** The tape is applied around the neck just below the laryngeal prominence.
- y n** The measurement is made perpendicular to the long axis of the neck.
- y n** The tape is not too loose or too tight, but enough to maintain skin contact.
- y n** The measurement is completed in less than 5 seconds.
- y n** The measurement is recorded to the nearest 0.5 centimeter, rounding up.

Overall Comments of Supervisor**Instructions to Technicians/Corrective Actions**

Signature, Supervisor

TABLE 11.11

Blood Pressure, Weight, and Neck Circumference Equipment Check List

Field Center: _____

QC Supervisor: _____

Standard Sphygmomanometer(s):

Enter date checked in table

Sphyg. ID #	Check cap for tightness	Check that mercury is at zero with no pressure	Check inflation system	Check tube for oxide dust

Scale(s) for Weighing

- Set scale at zero mark. Place 50-pound known weight on scale. If weight falls outside 49.5-50.5 pound range, the scale should be serviced.

Scale ID #	Weight recorded	Date Checked

Measuring Tape(s) for Arm and Neck Circumference:

- Hold the zero mark on the tape against the 150 cm mark on a height ruler. If the 30 cm mark on the tape falls outside the range 119.5 to 120.5 on the ruler, the tape should be replaced.

Tape ID #	Point on height ruler where 30 cm mark on tape falls	Date Checked

List problems with any equipment and corrective action taken:

For unresolved problems, contact the Coordinating Center for instructions before proceeding. For repair information and shipping instructions, contact the manufacturer (for Baum sphygmomanometers, contact W. A. Baum Co., 626 Oak Street, Copiague, New York 11726; 516/226-3940).

Signature, Quality Control Supervisor

TABLE 11.12**Blood Pressure and Anthropometric Certification Maintenance**

To maintain certification, for each blood pressure, weight, and neck circumference measurement procedure a technician must:

- perform at least one measurement per week.
- successfully complete the bimonthly supervisor check list.



SLEEP HEART HEALTH STUDY MANUAL OF OPERATIONS

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A.1 Comparability Committee Evaluation of A-Variables by Parent Cohort

Following is the Comparability Committee's evaluation of A-variables by parent cohort.

Comparability Study ALCOHOL

- ARIC** 40. Do you presently drink alcoholic beverages? Y/N
 41. Have you ever consumed alcoholic beverages? Y/N
 42. Approximately how many years ago did you stop drinking? _____ years
 43. For how many years did you consume alcoholic beverages? _____ years
 44. a. How many glasses of wine do you usually have per week? (4 oz. glasses; round down)
 b. How many days in a week do you usually drink wine?
 45. a. How many glasses, bottles, or cans of beer do you usually have per week? (12 oz. glasses, bottles, or cans, round down)
 b. How many days in a week do you usually drink beer?

(continued on next page)

- CHS** 67. Do you ever drink beer? Y/N/DK
 a. About how often do you drink beer? daily; weekly; monthly; yearly; rarely/never
 b. How many 12-ounce cans or bottles of beer do you usually drink on one occasion? _____ cans or bottles of beer
 68. Do you ever drink wine? Y/N/DK
 a. About how often do you drink wine? daily; weekly; monthly; yearly; rarely/never
 b. How many medium, six-ounce glasses of wine do you usually drink on one occasion? _____ servings
 69. Do you ever drink liquor? Y/N/DK
 a. About how often do you drink liquor? daily; weekly; monthly; yearly; rarely/never
 b. How many drinks, equal to one shot of liquor, do you usually drink on one occasion? _____ servings

Framingham

Avg. number of drinks per week over course of year Number days drink per week On average, limit for number of drinks at one period of time

Beverage	Unit	Code 00=never, 01=1 or less, 99=unknown	Code 0-7 9=unknown	Code number 99=unknown
Beer	bottle, can glass(12 oz)	____ ____	____ ____	____ ____
Wine	glass (4 oz)	____ ____	____ ____	____ ____
Liquor	cocktail, highball	____ ____	____ ____	____ ____

Comparability Study ALCOHOL (cont'd)**New York Cardiovascular Center**

1. Do you ever drink alcoholic beverages? Y/N
2. How often do you drink alcoholic beverages?
rarely/once in a while (a few days a month)/one to three days a week/four to six days a week/every day/more than once every day
3. Which of the following alcoholic beverages do you drink? (Mark all that apply) (Please rank these beverages in order of consumption with 1 being the drink you most commonly have. For example if you drink beer every day, beer = 1; and if you drink wine 5 days a week wine = 2, etc.) (rank from 1-5) beer /wine/mixed drink or cocktail/scotch, whiskey, etc./liqueur (brandy, kaluha)
4. When you have alcoholic beverages how many drinks do you usually have at a sitting? (1 drink = can beer, 1 shot whiskey, 1 mixed drink, or 1 glass wine) 1-9+

(continued below)

- Tucson 39.** a. Do you drink any alcoholic beverages? Y/N
If yes to 39a:
- b. How many glasses of beer per week? (On the average.) _____ glasses
- c. How many glasses of wine per week? (On the average.) _____ glasses white wine _____ glasses
of red/rose wine
- d. How much hard liquor per week? (On the average.) _____ shots OR _____ pints
- e. Have you ever had a problem with your drinking? Y/N

ARIC (continued)

46. a. How many drinks of hard liquor do you usually have per week? (1.5 oz. shots; round down)
- b. How many days in a week do you usually drink hard liquor?
47. During the past 24 hours, how many drinks have you had?
48. For how many years have you consumed alcoholic beverages?
49. Thinking about the entire time you consumed alcoholic beverages, how many glasses of wine did you usually have per week? (4 oz. glasses; round down)
50. Thinking about the entire time you consumed alcoholic beverages, how many glasses, cans, or bottles of beer did you usually have per week? (12 oz. glasses, bottles or cans; round down)
51. Thinking about the entire time you consumed alcoholic beverages, how many drinks of hard liquor did you usually have per week? (1.5 oz. shot, round down)
52. Was there ever a time in your life when you consumed 5 or more drinks of any kind of alcoholic beverage almost every day? Y/N/Unknown

New York Cardiovascular Center (continued)

5. When you have an alcoholic beverage, where do you have them? (Mark all that apply) (Please rank in order, with 1 being the highest numbering only those that apply) (rank 1-6) at home /at work/at a friend's house/at a restaurant/at a bar/other
6. When you have an alcoholic beverage with whom do you have them? (Mark all that apply) (Please rank in order with 1 being the highest numbering only those that apply) (rank 1-4) with friends /with work associates/with family members/by yourself
7. On a work day that you have alcoholic beverages when do you have them? (Mark all that apply) (Please rank in order, with 1 being the highest numbering only those that apply) (rank 1-7) before work /at work/at lunch/after work/at dinner/after dinner/before bed
8. On a weekend day that you have alcoholic beverages when do you have them? (Mark all that apply) (Please rank in order, with 1 being the highest numbering only those that apply) (rank 1-6) before lunch /at lunch/before dinner/at dinner/after dinner/before bed
9. How many alcoholic beverages do you have per week during the following time? (rank 35 or more/25-34/15-24/10-14/5-9/1-4/0)
 - a. Monday thru Thursday evening only (total per week)
 - b. While at work only (total per week)
 - c. Friday thru Sunday (total for weekend)

Comparability Study ALCOHOL (cont'd)**New York Cardiovascular Center (continued)**

*For question number 10 please enter the total number of drinks reported between the categories in question 9. (For example: Someone who has 10 drinks on week nights (9a), 10 drinks during work days (9b), and 8 drinks on the weekend (9c), has a total of 28 drinks for the week.)

10. How many alcoholic beverages do you have per week total? (rank 0-9/0-9)
11. At the present time, do you consider yourself to be:
a light drinker a light to moderate drinker a moderate drinker a moderate to heavy drinker a heavy drinker
12. How long have you been consuming alcohol at your present level of intake?
0-6 months/6 months to 1 year/1-2 years/3-5 years/5-10 years/over 10 years
13. Do you ever binge drink? (heavy drinking for periods of at least 24 hours) Y/N
14. People drink alcohol for different reasons. Below are some statements people have made about why they drink. How important would you say that each of the following is to you as a reason for drinking: (Please mark the circle that applies for each statement.) (rank: not at all/not very much so/somewhat/very much so)
 - a. I drink because it helps me to relax
 - b. I drink to be sociable
 - c. I like the taste
 - d. I drink because the people I know do;
 - e. I drink when I want to forget things
 - f. I drink to celebrate special events
 - g. A drink helps me to forget my worries
 - h. A drink improves my appetite for food
 - i. I accept a drink because it is the polite thing to do in certain situations;
 - j. A drink helps cheer me up when I'm in a bad mood
 - k. I drink because I need it when tense and nervous (Please skip to #20)

The next section is for those who do not presently consume alcohol.

15. Was there ever a time when you consumed alcoholic beverages? Y/N (If no, skip to question #20)
16. For how many years did you consume alcoholic beverages? (rank 0-5/0-9)
17. At what age did you stop drinking alcohol? (rank 1-6/0-9)
18. When you were drinking alcoholic beverages how many drinks did you usually have at a sitting? (1 drink = 1 can beer, 1 shot whiskey, 1 mixed drink,
or 1 glass wine) (rank 1-9+)
19. When you were drinking, how many drinks did you consume on average each week? (rank 0-9/0-9)

Comparability Study CAFFEINE CONSUMPTION

ARIC

“In the past year, how often on average did you consume . . .”

- 61. Coffee, not decaffeinated; 1 cup
- 62. Tea, iced or hot, not including decaf or herbal tea; 1 cup
- 63. Low calorie soft drinks, such as any diet Coke, diet Pepsi, diet 7-Up; 1 glass
- 64. Regular soft drinks, such as Coke, Pepsi, 7-up, ginger ale; 1 glass
- 65. Fruit-flavored punch or non-carbonated beverages, such as lemonade, Kool-Aid or Hawaiian Punch; not diet; 1 glass

CHS

Coffee Cups per day / week / month
 Tea Cups per day / week / month

Framingham

Caffeinated				Decaffeinated			
	Unit	# per day	Method		Unit	# per day	Method
Coffee	cup	____ ____	____ ____	Coffee	cup	____ ____	____ ____
Tea	cup	____ ____	____ ____	Tea	cup	____ ____	____ ____
Cola	12 oz	____ ____	____ ____	Cola	12 oz	____ ____	____ ____

Method used predominantly: 0=Non drinker, 1=Filter, 2=Perc, 3=Boil, 4=Instant, 8=Other, 9=Unknown

New York Cardiovascular Center

- 20. Do you drink coffee? (Do not include decaffeinated) Y/N (If no, skip to #24)
- 21. On an average work day, how much coffee do you drink? (Please include coffee consumed at home as well as work.)
 saucer or teacup = 1; styrofoam cup = 1-1/2; take-out paper container = 2
 rank 1-9+
- 22. On an average work day, when do you drink coffee? (Mark all that apply)
 before work; at work; at lunch; after work; at dinner; after dinner
- 23. When you drink coffee what is it associated with? (Mark all that apply)
 waking up in the morning; eating; working; keeping awake at times that I feel tired; having a cigarette; taking a work break
- 24. Do you drink any other caffeinated beverages? (Including coke, diet coke, tea, etc.) Y/N
- 25. If yes, how many cans of soda, cups of tea, etc. do you have on an average work day? rank 1-9+

Tucson

Not applicable

Comparability Study EDUCATION

ARIC

54. What is the highest grade or year of school you have ever completed, including trade or vocational school or college? RECORD NUMBER OF YEARS FOR GRADES 1-12 _____ OR:

CIRCLE RESPONSE FOR HIGHEST NUMBER BELOW:

GED 13

COLLEGE

VOCATIONAL

1 Year 17

2 Years..... 18

1 Year 14.....

3 Years..... 19

2 Years..... 15.....

4 Years..... 20

3 Years..... 16.....

Graduate School or Professional School 21

Don't know 99

CHS

5. What is the highest grade or year of school you have ever completed, including trade school or vocational school, or college?
Grades 1 - 12 (record number): _____|_____ 0 - no schooling

GED: _____ Vocational School: 1yr/2yr/3yr College: 1yr/2yr/3yr/4yr Graduate or professional: _____ Refuses to answer: _____

Framingham

Not applicable

New York Cardiovascular Center

1. Education: (last year completed) 6 7 8 9 10 11 12 13 14 15 16 18
(or less) High School College PG

Tucson

7. How many years of formal education or schooling have you had? (For example, completion of high school = 12) _____

ARIC (continued)

*

New York Cardiovascular Center (continued)

*

Comparability Study FAMILY HISTORY OF CVD

ARIC

- 3. a. Is your natural mother living? Y/N/U
- b. Approximately how old was she when she died?
- c. What was the cause of your natural mother's death?
Cancer/Heart Attack/Stroke/Other/(Specify) _____/Unknown
- 5. (same question re natural father)

(continued on following page)

CHS

- 24. In the table below, please write the first names of all your brothers, then all your sisters, including those who have died or with whom you have lost touch, in the column labeled FIRST NAME. Circle the appropriate gender for each (M-male, F-female).
- 25. Next, in the column labeled YEAR OF BIRTH, please write the year when each of your brothers or sisters was born.
- 26. Please record whether they are still alive by circling the appropriate answer in the STILL ALIVE column (Y=yes, N=no, D=don't know). If they are no longer alive, please write their age at death in the AGE column.
- 27. Please record whether any of your brothers or sisters have ever had a heart attack by circling the appropriate answer in the HEART ATTACK column (Y=yes, N=no, D=don't know). If they had a heart attack, please write their age at first heart attack in the AGE column.
- 28. Please record whether any of your brothers or sisters have ever had a stroke by circling the appropriate answer in the STROKE column (Y=yes, N=no, D=don't know). If they had a stroke, please write their age at first stroke in the AGE column.

First Name:	Male/Female	Year of Birth	Still alive? Y/N/DK Age at Death	Heart Attack? Y/N/DK Age	Stroke? Age
-------------	-------------	---------------	--	--------------------------------	----------------

Framingham

Not applicable

Y/N/DK

New York Cardiovascular Center

- 1. Have any of the following relatives been diagnosed with any of these conditions: (mark those that apply)

	Mother	Father	Siblings	Children
High blood pressure				
Stroke				
Coronary heart disease				
Angina				
(others listed)				

(continued on following page)

Tucson

54. Did your natural father ever have any of the following conditions? (If your father is living in the household **and** has answered this year's (Survey 12) questionnaire, check here [] and skip to question #56.
 f. Heart Disease? Y/N
 g. High Blood Pressure? Y/N
 h. Stroke? Y/N
55. Is your natural father still living? 1. Y, Current age _____. 2. No, Age at death _____. 3. Don't know
 (same question re natural mother)

ARIC (continued)

I would next like to ask a few questions about the health of your brothers and sisters. We are interested in your full brothers and sisters, who have the same mother and father that you do, including those who have died or with whom you have lost touch.

6. a. How many full brothers and sisters do you have?
 b. How many brothers?
 c. How many sisters?
7. What is the first name of your first full brother or sister?
8. Is (name) a brother or a sister?
9. What was (name's) year of birth?
10. Is (name) living? Y/N/U
11. How old was (name) when he/she died?
12. Did (name) ever have a heart attack? Y/N/U
13. How old was (name) when he/she had his/her FIRST heart attack?
14. Did (name) ever have a stroke? Y/N/U
15. How old was (name) when he/she had his/her FIRST stroke?

(Repeat from #7 for other siblings.)

New York Cardiovascular Center (continued)

2. Did any of the above relatives die before the age of 60 from one of the following conditions (mark those that apply)

	Mother			
High blood pressure				
Stroke				
Coronary heart disease		Father	Siblings	Children
(others listed)				

Comparability Study HISTORY OF DIABETES

ARIC

- 8. Has a doctor ever said you had any of the following?
 - k. Diabetes (sugar in the blood)? Y/N/Unknown

CHS

- 21. Has a doctor ever told you that you had any of the following conditions or diseases; and if so, when were you FIRST told that you had the condition?
 For each condition or disease listed below, please check the appropriate box as follows: If a doctor has never told you that you had the condition, please mark "Never told." If a doctor first told you DURING THE PAST YEAR that you had the condition, please mark "First told during the past year." If a doctor first told you MORE THAN ONE YEAR AGO that you had the condition, please mark "First told more than one year ago."
- | | | | |
|-------------|------------|------------------------------------|--------------------------------------|
| B. Diabetes | NEVER TOLD | FIRST TOLD DURING THE
PAST YEAR | FIRST TOLD MORE THAN
ONE YEAR AGO |
|-------------|------------|------------------------------------|--------------------------------------|

Framingham

Clinical Diagnostic Impression--Part III, Non Cardiovascular Diagnoses
 (0=No, 1=Yes, old, 2=Yes, new, 3=Yes, recurrent, 4=Maybe, 9=Unknown)
 Diabetes Mellitus

New York Cardiovascular Center

- 7. Have you been diagnosed with any of the following medical problems?
 Diabetes Y/N (If yes, when?) Year _____

Tucson

- 32. **SINCE YOUR LAST QUESTIONNAIRE**, have you had any of the following:
 - k. Diabetes?
 - 1. Yes
 - 2. No

Date: _____

Comparability Study HISTORY* OF HYPERTENSION (*History = Self-Report)

ARIC

- 8. a. Has a doctor ever said you had high blood pressure or hypertension (high blood)? Y/N/U
- b. Has there ever been a time when you didn't get treatment for your high blood pressure when you needed it? Y/N/Treatment not needed
- c. What was the main reason you were unable to get blood pressure treatment?
 Could not pay for it and didn't have enough insurance.
 Didn't have a doctor or clinic to get medical care.
 Wasn't able to get to the doctor or drug store.
 Didn't have time or had more important things to take care of.
 Other
- d. When did you last see a doctor about your high blood pressure? ___/___ (month/year)

CHS

- 21. Has a doctor ever told you that you had any of the following conditions or diseases; and if so, when were you FIRST told that you had the condition?
 For each condition or disease listed below, please check the appropriate box as follows: If a doctor has never told you that you had the condition, please mark "Never told." If a doctor first told you DURING THE PAST YEAR that you had the condition, please mark "First told during the past year." If a doctor first told you MORE THAN ONE YEAR AGO that you had the condition, please mark "First told more than one year ago."

B. High blood pressure	NEVER TOLD	FIRST TOLD DURING THE TOLD MORE THAN	FIRST TOLD MORE THAN
	PAST YEAR	ONE YEAR AGO	

Framingham

Currently receiving medication for the treatment of hypertension? (0=No, 1=Yes, 9=Unknown).

New York Cardiovascular Center

- 1. Have you ever been told that your blood pressure was high? Y/N If yes, when _____ (specify year)
- 2. Has a doctor ever told you that you had hypertension and told you to take medications for your blood pressure? Y/N
 If yes, when _____ (specify year)
- 3. a. Are you presently taking medication for your BP? Y/N
- b. If yes, when started? _____ (specify year)
- 4. What medication(s) are you currently taking for your BP? Drug Class: diuretic
 ACE Inhib.
 calcium blocker
 beta blocker
- 5. a. If you are not currently taking medication for you BP, have you ever taken medication for this purpose? Y/N
- b. If yes, when? _____ -thru- _____ (Years taken)

vasodilator
 other

Tucson

32. SINCE YOUR LAST QUESTIONNAIRE, have you had any of the following:
- h. High blood pressure?
 - 1. Yes, I saw a doctor
 - 2. Yes, I did not see a doctor
 - 3. No

Comparability Study INCOME

ARIC				
60.	Please look at this card. Which of these income groups represents your <u>total combined family income for the past 12 months</u> ? Include income from all sources such as wages, salaries, social security or retirement benefits, help from relatives, rent from property, and so forth. (HAND CARD 3 TO RESPONDENT.) Please tell me the letter only.			
	Under \$5,000 A	\$25,000 - \$34,999 F
	\$5,000 - \$7,999 B	\$35,000 - \$49,999 G
	\$8,000 - \$11,999 C	\$50,000 - \$74,999 H
	\$12,000 - \$15,999 D	\$75,000 - \$99,999 I
	\$16,000 - \$24,999 E	\$100,000 and over J
CHS				
8.	Which of the income groups on this card represents your total combined family income, before taxes, for the past 12 months? Include income from all sources such as wages, salaries, social security or retirement benefits, help from relatives, rent from property and so forth. Please tell me the letter only. (Card 4)			
	Under \$5,000 A	\$25,000 - \$34,999 F
	\$5,000 - \$7,999 B	\$35,000 - \$49,999 G
	\$8,000 - \$11,999 C	over \$50,000 H
	\$12,000 - \$15,999 D	Refuses to answer 9
	\$16,000 - \$24,999 E		
Framingham				
Not applicable				
New York Cardiovascular Center				
14.	Personal income (Past 12 months) **			
	0	5,000-9,999	30,000-34,999	10 60,000-69,999
	1	10,000-14,999	35,000-39,999	11 70,000-79,999
	2	15,000-19,999	40,000-44,999	12 80,000-89,999
	3	20,000-24,999	45,000-49,999	13 90,000-99,999
	4	25,000-29,999	50,000-59,999	14 100,000 +
		7		
15.	Family income (Past 12 months) **			
	0	5,000-9,999	30,000-34,999	10 60,000-69,999
	1	10,000-14,999	35,000-39,999	11 70,000-79,999
	2	15,000-19,999	40,000-44,999	12 80,000-89,999
	3	20,000-24,999	45,000-49,999	13 90,000-99,999
	4	25,000-29,999	50,000-59,999	14 100,000 +
**(Include all sources of income, i.e., salary, rent collected, gifts, social security, help from relatives, etc.)				
Tucson				
Not applicable				

Comparability Study OCCUPATION

ARIC

- 53. Since your last ARIC visit, have you changed your occupation, stopped working, or retired? Y/N
- 54. I would like you to look at this card while I read it to you. Please tell me the letter of the one which best describes your CURRENT occupation.
 - Homemaking, not working outside the homeA
 - Employed at a job for pay, either full or part-time...B
 - Employed, but temporarily away from my regular workC
 - Unemployed, looking for work.....D
 - Unemployed, not looking for work.....E
 - Retired from my usual occupation and not workingF
 - Retired from my usual occupation but working for payG

(continued on next page)

CHS

- 6. Please look at the card and tell me which one best describes the kind of work you have done most of your life: (Card 2)
 - professional/technical/managerial/administrative - 1
 - sales/clerical service - 2
 - craftsman/machine operator/laborer - 3
 - farming/forestry - 4
 - housewife - 5
 - other (specify) _____- 6
 - refuses to answer - 7

(continued on next page)

Framingham

Functional Performance

Are you working now: (0=No, 1=Yes, Full time, 2=Yes, Part time, 9=Unknown)

New York Cardiovascular Center

- 11. What is your workshift? Day 0 Evening 1 Night 2
- 12. Present job title:
 - A. How long have you had this title? _____ Years _____ Months
 - B. Briefly describe your main duties for this job title:
- 13. How long have you been with your employer? _____ Years _____ Months

Tucson

If you retired **permanently** before this date, **check here []**, and skip to question 55.

- 50. **SINCE YOUR LAST QUESTIONNAIRE**, did you
 - a. begin your first job? 1. Yes, full-time / 2. Yes, part-time / 3. No
 - b. start working again? 1. Yes, full-time / 2. Yes, part-time / 3. No
 - c. change jobs? 1. Yes, full-time / 2. Yes, part-time / 3. No
 - d. stop working? 1. Yes, full-time / 2. Yes, part-time / 3. No

(continued on next page)

Comparability Study OCCUPATION (cont'd)

ARIC (continued)

- 55. Did you retire because of health reasons? Y/N
- 56. (ASK ITEM 1 FROM OCCUPATION WORKSHEET) Are(were) you self-employed for this occupation? Y/N
(ASK ITEM 2 FROM OCCUPATION WORKSHEET)
- 57. Since your last ARIC visit, have(did) you change(d) the company for which you work(ed)? Y/N
- 58. Please give me the name and address of your company. It will help us categorize your (former) occupation.
 - a. COMPANY NAME
 - b. STREET ADDRESS
 - c. CITY
 - d. STATE
 - e. ZIP CODE
 (ASK ITEM 3 FROM OCCUPATION WORKSHEET)
- 59. Occupation code from worksheet: ____|____|____

CHS (continued)

- 7. Please look at this card while I read it all to you. Then tell me which one best describes your current occupation:
 - employed at a job for pay, either full- or part-time - 1
 - homemaking, not working outside the home - 2
 - employed, but temporarily away from my regular job - 3
 - retired from my usual occupation and not working - 4
 - retired from my usual occupation but working for pay - 5
 - retired from my usual occupation, but volunteering - 6
 - unemployed, looking for work - 7
 - unemployed, not looking for work - 8
 - other (specify) _____ - 9

Tucson (continued)

- 51. a. **SINCE THE LAST QUESTIONNAIRE**, have you worked in any dusty jobs? 1. Y / 2. N
IF YES TO 51a:
 - b. Please specify the jobs and industries involved: **Jobs:** _____ **Industries:** _____
 - c. For how many total years have you worked in these jobs/industries? _____ (total years)
 - d. How intense was the exposure? 1. Mild / 2. Moderate / 3. Severe
- a. **SINCE THE LAST QUESTIONNAIRE**, have you been exposed to gases or fumes in your work? 1. Y / 2. N
IF YES TO 52a:
 - b. Please specify the jobs and industries involved: **Jobs:** _____ **Industries:** _____
 - c. For how many total years have you worked in these jobs/industries? _____ (total years)
 - d. How intense was the exposure? 1. Mild / 2. Moderate / 3. Severe

Comparability Study PREVALENT CVD**ARIC**

(Health History Form)

A. AFU CHEST PAIN CONFIRMATION

1. Did the participant report positive rose angina in the annual follow-up call preceding this visit?
2. In the ARIC telephone call you mentioned having some pain or discomfort in your chest in the past year. Could you tell me where it was?
Y / P - No-pain recalled / L - No-location not recalled (locations not to be read)
3. In the past two months has your chest discomfort either occurred more often, lasted longer when it occurs, or come on at rest? Y/N

(Annual Follow-up Questionnaire)

E. POSSIBLE INFARCTION

17. Since our last contact have you had a severe pain across the front of your chest lasting for half an hour or more? Y/N
18. Did you see a doctor because of this pain? Y/N
19. What did he say it was? H - Heart Attack / O - Other Disorder

F. INTERMITTENT CLAUDICATION

20. Since we last contacted you, have you had pain in either leg on walking? Y/N
21. Does this pain ever begin when you are standing still or sitting? Y/N
22. In what part of your leg do you feel it? (If calves not mentioned, ask: Anywhere else?)
Pain includes calf/calves - C / Pain does not include calf/calves - N
23. Do you get it if you walk uphill or hurry? Y/N/H [Never hurries or walks uphill]
24. Do you get it if you walk at an ordinary pace on the level? Y/N
25. Does the pain ever disappear while you are walking? Y/N
26. What do you do if you get it when you are walking? S - Stop or slow down / C - Carry on
27. What happens to it if you stand still? R - Relieved / N - Not relieved
28. How soon? L - 10 minutes or less / M - More than 10 minutes

G. STROKE/TIA

29. Since our last contact have you been told by a physician that you had a stroke, slight stroke, transient ischemic attack, or TIA? Y/N
(If "Yes," ensure that this event is included in the "HOSPITALIZATIONS" section, if appropriate.)

(Personal History Form)

"Has a doctor ever said you had any of the following?" j. Heart failure or congestive heart failure? Y/N/U

B. CONGESTIVE HEART FAILURE

9. Since your last ARIC visit, have you had to sleep on 2 or more pillows to help you breathe? Y/N
10. Since your last ARIC visit, have you been awakened at night by trouble breathing? Y/N
11. Since your last ARIC visit, have you had swelling of your feet or ankles (excluding during pregnancy)?
12. Did it tend to come on during the day and go down overnight? Y/N

(Also TIA/Stroke Form)

CHS

Bonnie to supply this portion.

Comparability Study PREVALENT CVD (cont'd)**Framingham**

(Medical History--Cerebrovascular)

Cerebrovascular episodes since last exam (0=No, 1=Yes, 2=Maybe, 9=Unknown)

 Sudden muscular weakness (If more than one event specify in comments on bottom of screen) Sudden speech difficulty Sudden visual defect Double vision Loss of vision in one eye Unconsciousness Numbness, tingling Numbness and tingling is positional CT scan (head) since last exam (date/place _____) Seen by neurologist since last exam (write in who & when below)* Date (mo/yr,99/99=Unkn) Observed by Onset time (1=Active, 2=During sleep, 3=While arising, 9=Unknown)* Exact/approximate time (use 24-hour military time, 99.99=Unknown)** Duration (use format days/hours/mins, 99/99/99=Unknown) Hospitalized or saw M.D. (0=No, 1=Hosp, 2=Saw M.D., 9=Unknown) Number of days stayed at

1st Examiner Opinions

 Cerebrovascular Disease (0=No, 1=Yes, 2=Maybe, 9=Unknown) Stroke in Interim Transient Ischemic Attack in Interim (TIA)

Neurology Comments

(Medical History--Peripheral Arterial and Venous)

 Do you have lower limb discomfort while walking (0=No, 1=Yes, 9=Unknown)

If yes, fill in below

Left Right Vascular symptoms (0=No, 1=Yes, 9=Unkn)

Discomfort in calf while walking

Discomfort in lower extremity (not calf) while walking

Occurs with first steps

After walking a while

Related to rapidity of walking or steepness

Forces to stop walking

Time for discomfort to be relieved by stopping (minutes) (00=No relief with stopping, 88=Not Applicable)

Number of days/month of lower limb discomfort (00=No, 88=N/A, 99=Unknown)

(continued on next page)

Comparability Study PREVALENT CVD (cont'd)**Framingham (continued)**

Is one foot colder than the other? (0=No, 1=Yes, 9=Unknown)

(leaving out Venous Disease questions)

1st Examiner Opinions: (0=No, 1=Yes, 2=Maybe, 9=Unknown)

Intermittent Claudication

(Clinical Diagnostic Impression)

Coronary Heart Disease

Angina Pectoris (0=No, 1=Yes-Old, 2=Yes-Recurrent, 4=Maybe, 9=Unknown)

Coronary Insufficiency

Myocardial Infarct

Other Heart Diagnoses in Interim

Rheumatic Heart Disease (0=No, 1=Yes, 2=Maybe, 9=Unknown)

Aortic Valve Disease

Mitral Valve Disease

Other Heart Disease (includes congenital)

Congestive Heart Failure

Arrhythmia

Functional Class (0=None; NYHA Classif 1,2,3,4) (Class 1=Ordinary physical activity, does not cause symptoms)

(Class 2=Ordinary physical activity, results in symptoms)

(Class 3=Less than ordinary physical activity results in symptoms)

(Class 4=Any physical activity results in symptoms)

Comments CDI Heart

Peripheral Vascular Disease in Interim

Intermittent Claudication (0=No, 1=Yes, old, 2=Yes, new, 3=Yes, recurrent, 4=Maybe, 9=Unknown)

Cerebrovascular Disease (0=No, 1=Yes, old, 2=Yes, new, 3=Yes-Recurrent, 4=Maybe, 9=Unknown)

Stroke

Transient Ischemic Attack (TIA)

(Second Examiner Opinions in Interim)

Congestive Heart Failure

Cardiac Syncope

Angina Pectoris

Coronary Insufficiency

Myocardial Infarction

Comments about chest and heart disease

Intermittent Claudication

Comments about peripheral vascular disease

Stroke

TIA

Comments about possible Cerebrovascular Disease

Comparability Study PREVALENT CVD (cont'd)

New York Cardiovascular Center

(History and Physical Examination)

7. Have you been diagnosed with any of the following medical problems?
- | | |
|----------------------------------|----------------|
| Heart Attack Y/N (If yes, when?) | Year: 8-9, 0-9 |
| Angina Y/N (If yes, when?) | Year: 8-9, 0-9 |
| Stroke Y/N (If yes, when?) | Year: 8-9, 0-9 |
| Claudication Y/N (If yes, when?) | Year: 8-9, 0-9 |

Tucson

14. e. Did a doctor ever tell you that this [attacks of shortness of breath with wheezing] was due to heart trouble? Y/N
15. a. Do you ever have attacks/episodes of chest tightness? Y/N

IF YES to 15a:

- b. How often are you bothered by such attacks/episodes? 1 (Rarely) 2 3 4 5 (Very often) Circle appropriate number
- c. How old were you when you had your first such attack/episode? _____age
- d. Have you ever had wheeze with your chest tightness?
- e. Do you have chest tightness with exertion? Y/N
- f. Do you ever have chest tightness apart from exertion? Y/N
- g. Did a doctor ever tell you that this was due to heart trouble (such as angina)? Y/N

SINCE YOUR LAST QUESTIONNAIRE, have you had any of the following:

- i. Stroke? 1. Yes, I saw a doctor / 2. Yes, I did not see a doctor / 3. No
- j. Any kind of heart problem? 1. Yes, I saw a doctor / 2. Yes, I did not see a doctor / 3. No
- Please specify

Comparability Study RACE

<p>ARIC</p> <p>Interviewer chooses -- only asks participant if doubts.</p> <p>23. Race: White W Black - B American Indian or Alaskan Indian I Asian or Pacific Islander A</p>						
<p>CHS</p> <p>2. a. Please look at this card and tell me which best describes your race. (Card 1)</p> <table border="0" style="width: 100%;"> <tr> <td style="text-align: center;">White - 1</td> <td style="text-align: center;">American Indian/Alaskan native - 3</td> <td style="text-align: center;">other: specify - 5</td> </tr> <tr> <td style="text-align: center;">Black - 2</td> <td style="text-align: center;">Asian/Pacific Islander - 4</td> <td></td> </tr> </table> <p>b. Do you consider yourself of Hispanic origin? Y/N</p>	White - 1	American Indian/Alaskan native - 3	other: specify - 5	Black - 2	Asian/Pacific Islander - 4	
White - 1	American Indian/Alaskan native - 3	other: specify - 5				
Black - 2	Asian/Pacific Islander - 4					
<p>Framingham</p> <p>Will be using the 1990 US Census classifications (5 race categories: white, black, Asian or Pacific Islander, American Indian or Native Alaskan, other; 2 Hispanic categories: Hispanic or non-Hispanic)</p>						
<p>New York Cardiovascular Center</p> <p>Self-administered</p> <p>2. Race: Asian Hispanic Black White Other</p> <p style="padding-left: 40px;">0 1 2 3 4</p> <p>4. Ethnic Identification: (can include nationality, ancestry)</p>						
<p>Tucson</p> <p>Not applicable</p>						

Comparability Study SMOKING

ARIC

- 25. Have you ever smoked cigarettes? (Code "NO" if less than 400 cigarettes in a lifetime.) Y/N
- 26. Did a doctor or other health professional ever advise you to stop smoking? Y/N
- 27. Do you now smoke cigarettes? Y/N
- 28. When did you smoke your last cigarette?
Less than 2 months ago - A / At least 2 months, but less than 12 months - B / At least 12 months, but less than 24 months / At least 24 months, but less than 36 months - D / 36 or more months ago - E
- 29. Prior to quitting, how many cigarettes did you usually smoke per day? ___|___ cigarettes per day
- 30. How many cigarettes do you smoke per day now? ___|___ cigarettes ___|___ cigarettes per day

(continued on next page)

CHS

- 64. Which of the following best describes your current smoking status?
Never Smoked - 1 / Former Smoker, Quit More Than 1 Year Ago - 2 / Former Smoker, Quit Less Than 1 Year Ago - 3 / Current Smoker - 4 / Don't Know - 9
- 65. Does anyone living with you smoke cigarettes regularly? (This includes any other member of your household.) Y/N/DK
- 66. Do you ever use snuff or smokeless tobacco? Y/N/DK

Framingham

- Smoked cigarettes regularly in the last year? (0=No, 1=Yes, 9=Unknown)
- How many cigarettes do/did you smoke a day? (01=one or less, 99=unknown)
- Do you inhale? (0=No, 1=Yes, 9=Unknown)

Cigarette Brand

Code the first 8 letters	Code	Code	Code	Code
	1=Normal	1=Regular	1=Nonfilter	1=Regular
Strength	2=Lite	Type 2=Menthol	2=Filter	2=King
	3=Ultralite			3=100 mm
	8=N/A			4=120 mm
	9=Unknown	Filter	Length	8=N/A

(continued on next page)

9=Unknown

New York Cardiovascular Center

- 26. Do you smoke cigarettes? Y/N 8=N/A
- 27. If yes, for how many years have you smoked? 0-5, 09=Unknown
- 28. How many cigarettes do you currently smoke on an average work day? (Include all cigarettes smoked for the day) 0-9, 0-9
- 29. For how many years have you smoked this amount? 0-5, 0-9
- 30. Has there ever been a time when you smoked more or less than you do now? Y/N

(continued on next page)

Comparability Study SMOKING (cont'd)

Tucson

46a. Have you ever smoked cigarettes regularly? 1. Yes, and I still smoke. 2. Yes, but I no longer smoke. 3. No, I never smoked (skip to question #47).

If you have not smoked cigarettes **at all** since 1972, **check here [] and go to question #47.**

If YES to 46a:

- a. How old were you when you began to smoke cigarettes? ____ (age started)
- b. **ON THE AVERAGE** of the entire time you have smoked, how many cigarettes did you smoke per day? ____ (cigarettes per day) (If less than one, write in 0.)
- c. Do/did you inhale the cigarette smoke? 1. Deeply / 2. Moderately / 3. Slightly / 4. Not at all
- d. **Usually**, how much of the tobacco in your cigarette do/did you actually smoke? 1. Almost all / 2. About 3/4 / 3. About 1/2 / 4. Less than 1/2

(continued on next page)

ARIC (continued)

- 31. Do(Did) you inhale the cigarette smoke?
Not at all - N / Slightly - S / Moderately - M / Deeply - D
- 32. Please tell me if you are currently using or have ever used a pipe, cigars, cigarillos, chewing tobacco, snuff, or nicotine gum or patch prescribed by a doctor; for example, Nicorette, Nicoderm, Habitrol?
 - a. Pipe/cigars/cigarillos Currently/Never/Past Use
 - b. Chewing tobacco Currently/Never/Past Use
 - c. Snuff Currently/Never/Past Use
 - d. Nicotine gum or patch Currently/Never/Past Use
- 33. During the past year, about how many hours per week, on the average, were you in close contact with people when they were smoking? For example, in your home, in a car, at work or other close quarters. ____|____|____ hours
- 34. Does anyone living with you now smoke cigarettes? Y/N/Unknown
- 35. Have you ever lived for at least one year with someone (including a parent or spouse) who smoked cigarettes regularly in your home? Y/N/Unknown
- 36. For how many years in total have you lived with someone who smoked cigarettes regularly in your home? ____|____ years
- 37. Does anyone working with you now smoke cigarettes regularly in your work area? Y/N/Does not work/Unknown
- 38. Have you ever worked for at least one year with someone who smoked cigarettes regularly in your work area? Y/N/Unknown
- 39. For how many years in total have you worked with someone who smoked cigarettes regularly in your work area? ____|____ years

Framingham (continued)

- || How many hours since last cigarette? (01=1 hour or less, 24=24 or more hours, 88=currently non-smoker, 99=Unknown)
- Do you now smoke cigars? 0=No / 1=Yes, inhale / 2=Yes, no inhale / 9=Unknown
- Do you now smoke pipes? 0=No / 1=Yes, inhale / 2=Yes, no inhale / 9=Unknown
- Passive Smoking**
- Does your spouse smoke now? (0=No, 1=Yes, 2=Not Married, 9=Unknown)
- If yes, how much does he/she smoke a day?

	Pipes/day	Cigars/day
Total	_ _	_ _
At Home	_ _	_ _
- ||| Excluding you and your spouse, how many other smokers live in your household?
(Cigarette, cigar or pipe smokers) (0=None, 98=Nursing home resident, 99=Unknown)

New York Cardiovascular Center (continued)

- 31. If yes, how many cigarettes were you smoking per day? 0-9, 0-9 Is this: more or less than your present amount.
- 32. How many years did you smoke this amount? 0-5, 0-9

Comparability Study SMOKING (cont'd)

Tucson (continued)

e. We know it is difficult to remember, but please try to estimate how long you have smoked the various types of cigarettes listed and how many of each you usually smoked per day.

	Years Smoked	No. of Cigarettes Per Day
a. Filtered very low tar and nicotine.	_____	_____
b. Filtered low/medium tar and nicotine.	_____	_____
c. Filtered regular tar and nicotine.	_____	_____
d. Unfiltered.		

f. How many cigarettes do you smoke per day **now**? _____(cigarettes per day) (0=none) **OR**, check here if no longer smoke []

g. What type of cigarettes do you usually smoke? (Please check below.) **OR**, check here if no longer smoke []

Size:	Kind:	Type:
Regular [<input type="checkbox"/>]	Regular [<input type="checkbox"/>]_____	Non-Menthol [<input type="checkbox"/>]
Long [<input type="checkbox"/>]	Light [<input type="checkbox"/>]_____	Menthol [<input type="checkbox"/>]
Extra Long [<input type="checkbox"/>]	Ultra Light [<input type="checkbox"/>]	
Brand Name: _____		

h. If you no longer smoke cigarettes, how old were you when you stopped? _____(age stopped permanently) **OR**, check here if still smoking []

i. If you no longer smoke cigarettes, why did you stop?

1. I had respiratory problems. / 2. I had other health problems. / 3. Other reasons **OR**, check here if still smoking []

47a. Have you **ever** smoked pipes or cigars regularly? Y/N

If you have not smoked pipes/cigars **at all** since 1972, **check here** [] **and skip to question #48.**

IF YES TO 47a:

b. How many pipes or cigars per day are you smoking now? _____(number per day) (If less than one, write in 0.)

c. On the average over the entire time you smoked a pipe or cigars, how many pipes or cigars did you smoke each day? _____(number per day)
(If less than one, write in 0.)

d. How old were you when you began to smoke a pipe or cigars regularly? _____(age)

e. If you no longer smoke a pipe or cigars, how old were you when you stopped? _____(age stopped) **OR**, check here if still smoking []

f. Do/did you usually inhale when you smoke either pipes or cigars? 1. Deeply / 2. Moderately / 3. Slightly / 4. Not at all.

48a. Have you **ever** smoked non-tobacco cigarettes regularly? Y/N

IF YES TO 48a:

b. How many non-tobacco cigarettes per week do you smoke now? _____(number per week) (If less than one, write in 0.)

c. On the average over the entire time you smoked non-tobacco cigarettes, how many did you smoke each week? _____(number per week)
(If less than one, write in 0.)

d. How old were you when you began to smoke non-tobacco cigarettes?

e. If you no longer smoke non-tobacco cigarettes, how old were you when you stopped? _____(age stopped) **OR**, check here if still smoking []

f. Do/did you usually inhale when you smoked non-tobacco cigarettes? 1. Deeply / 2. Moderately / 3. Slightly / 4. Not at all.

Comparability Study ROSE ANGINA (OR OTHER ANGINA INFORMATION)

ARIC

- 7. Since we last contacted you, have you had any pain or discomfort in your chest? Y/N
- 8. Do you get it when you walk uphill or hurry? Y/N/H [Never hurries or walks uphill]
- 9. Do you get it when you walk at an ordinary pace on the level? Y/N
- 10. What do you do if you get it while you are walking? S - Stop or slow down / C - Carry on {Record "Stop or slow down" if subject carries on after taking nitroglycerin}
- 11. If you stand still, what happens to it? R - Relieved / N - Not relieved
- 12. How soon? L - 10 minutes or less / M - More than 10 minutes
- 13. Will you tell me where it was? (Record answer verbatim in space below. Then, circle Y or N for all areas.)
 - a. Sternum (upper or middle) Y/N / b. Sternum (lower) Y/N / c. Left anterior chest Y/N / d. Left arm Y/N / e. Other Y/N
 - f. Specify:
- 14. Do you feel it anywhere else? Y/N (If "Yes," record above)
- 15. Did you see a doctor because of this pain or discomfort? Y/N
- 16. What did he say it was? A - Angina / H - Heart Attack / D - Other Heart Disease / O - Other

CHS

- 25. Have you ever had any pain or discomfort in your chest? Y/N
 - A. Do you feel the pain when you walk uphill or hurry? Y/N
 - B. Do you feel the pain when you walk at an ordinary pace on the level? Y/N
 - C. What do you do if you feel it while you are walking?
 - 1 - Stop or slow down, or continue at same pace after taking nitroglycerin
 - 2 - Continue at same pace

(continued on next page)

Framingham

- Any chest discomfort since last exam (0=No) (1=Yes) (2=Maybe) (9=Unknown)
- Chest discomfort with exertion or excitement (0=No) (1=Yes) (2=Maybe) (9=Unknown)
- Chest discomfort when quiet or resting (0=No) (1=Yes) (2=Maybe) (9=Unknown)
- Chest Discomfort Characteristics (must have checked first box above)
 - * Date of onset (mo/yr, 99/99=Unknown)
 - Usual duration (minutes, 999=Unknown)
 - Longest duration (minutes: 1=1 min. or less, 900=15 hrs. or more, 999=Unknown)
 - Location (0=No, 1=Central sternum and upper chest, 2=L Up Quadrant, 3=L Lower ribcage, 4=R Chest, 5=Other, 6=Combination, 9=Unknown)
 - Radiation (0=No, 1=Left shoulder or L arm, 2=Neck, 3=R shoulder or arm, 4=Back, 5=Abdomen, 6=Other, 7=Combination, 9=Unknown)

(continued on next page)

New York Cardiovascular Center

- 7. Have you been diagnosed with any of the following medical problems?
 - Angina Y/N (If yes, when?)
 - Year _____

Tucson

Not applicable

Comparability Study ROSE ANGINA (OR OTHER ANGINA INFORMATION) (cont'd)

CHS (continued)

- D. If you stand still, what happens to the pain?
1 - Relieved in 10 minutes or less / 2 - Takes longer than 10 minutes to be relieved / 3 - Not relieved / 9 - Don't know
- E. Where do you get this pain or discomfort? *Mark the place or places with an "X" on the body diagram at right.*
- F. Have you had this pain in the past two weeks? Y/N
If yes, how many times in the past two weeks have you had this pain? _____ times
- G. Has there been an increase in the frequency or severity in the past two weeks? Y/N
- H. Have you seen a doctor about this pain? Y/N
- I. Have you ever had a severe pain across the front of your chest lasting for half an hour or more? Y/N
- J. Did you see a doctor because of this pain? Y/N
- K. If you saw a doctor, what did your doctor say it was? 1 - Angina / 2 - Heart Attack / 3 - Other (specify: _____)

Framingham (continued)

Chest Discomfort relief. (0=No, 1=Yes, 8=Not tried, 9=Unknown)

- Nitroglycerine in <15 minutes
- Rest in <15 minutes
- Spontaneously in <15 minutes
- Other cause in <15 minutes

- 1st Examiner believes angina pectoris in interim (0=No) (1=Yes) (2=Maybe) (9=Unknown)
- 1st Examiner believes coronary insufficiency in interim (0=No) (1=Yes) (2=Maybe) (9=Unknown)
- 1st Examiner believes myocardial infarct in interim (0=No) (1=Yes) (2=Maybe) (9=Unknown)

Comments:

A.2 Example Documents for Recruitment and Retention

This section contains examples of documents that cohorts may wish to use, or adapt to their needs, for the recruitment and retention processes.

A.2.1 Initial Letter to Accompany the Sleep Habits Questionnaire

Dear (your name) Study Participant John Jones,

The attached questionnaire has been designed to explore your sleep and other related health habits. This is part of a new research effort (The SLEEP HEART HEALTH STUDY) which is being offered to members of the (your cohort name) study as well as to members of four other major studies throughout the country.

Recent research findings have suggested that there may be links among high blood pressure, heart disease and breathing disorders during sleep. There are many important questions about the ways in which these health problems could affect us. For instance, we do not yet know whether sleep problems are risk factors for heart disease in the same way that high cholesterol might be. A better understanding of this will help us determine how to prevent heart disease and improve overall health.

Your name was selected, because you have been a valuable member of (name). We hope you will decide to help us and take a few minutes to complete the questionnaire. Your participation in this new research effort will help us learn how frequently sleep problems occur and why some people are at greater risk of developing breathing difficulties during sleep and heart disease.

If you agree to complete the questionnaire, you also will become a member of the SLEEP HEART HEALTH STUDY. Your answers are completely confidential. Only your (ID, study number) will appear on study documents.

Completing this questionnaire does not commit you to any other involvement. However, some participants will be invited to participate in a sleep study to be completed in their home. If you are selected, additional information regarding that study will be sent to you.

Please remember that completing this questionnaire in no way obligates you to additional participation. However, it is very important to have as many completed questionnaires as possible. We are interested in your answers even if you have no sleep problems.

Studies like the SHHS and (parent study name) have helped us make significant progress toward reducing heart disease. We appreciate your cooperation and look forward to hearing from you if questions arise.

Sincerely,

PI and telephone contact person with number

A.2.2 SHHS Brochure

This brochure is modeled after the University of Wisconsin Study's three-fold, double-sided brochure. Outer side shows SHHS name and logo along with parent study name and investigators names and telephone numbers.

Inner informational side (example follows):

What is the purpose of the Sleep Heart Health Study?

The Sleep Heart Health Study (called SHHS) will obtain information on the sleep and health habits of people across the country to determine how sleep and other health habits may affect heart disease. To do this most effectively, we have chosen to work with 6 centers already examining heart and lung disease and your health. The (...) study is fortunate to be one of those chosen.

Why is the SHHS important?

Recent research findings have suggested a link between breathing disorders during sleep and heart disease. There are times during sleep in which breathing may stop for brief seconds. Persons who have a high number of these may be given the diagnosis of "sleep apnea." We believe that this disorder and a milder form called "sleep disordered breathing" may be more common than previously thought and may therefore be an important link to heart disease. The only way to truly know how common these sleep problems are and how they may be related to heart disease is to study the occurrence in a large group of people. The (name of your cohort) is such a group for whom we already have important related information.

What will the findings show?

We expect to learn just how common breathing disorders are during sleep. Additionally, we expect to see what type of person is most likely to have the problem. Furthermore, we expect to learn whether sleep problems in general lead to other health problems during the day, such as extreme sleepiness or heart disease.

How will I benefit?

A sleep study is very interesting. Experts will evaluate your sleep, determining how much time you slept, the type of sleep you had and how your heart and breathing respond during sleep. This is important information which can form a normal baseline for you or may reveal a sleep problem in very early stages which could be easily corrected. You will receive a report of your sleep study. If any abnormality is found, we will share that with you and any doctor you choose. Additionally, you will learn a great deal about your sleep habits and the best way to improve them.

THERE IS NO COST FOR THIS STUDY, even though this type of test could cost \$500-\$1500 if taken privately. For the many people who need this test, the waiting time is usually several months.

Beyond any personal benefit, your help is important to understand how sleep may affect heart disease. Our findings may improve your health or the health of someone you love.

What is an overnight study like?

If you agree to participate in the home sleep study, a specially trained team of technicians will come to your home on a convenient evening between 8 and 10pm. Then, sensors will be painlessly applied to your skin and scalp. Two sensors will be attached to your head with water soluble paste. Four others will be attached to your face to monitor eye movements and chin muscle tone. Two will be attached to your chest, much like a cardiogram. These will measure heart rate and breathing. A thin plastic tube will be taped under your nose to monitor breathing. Finally, a sensor will be taped to your finger to measure the oxygen in your blood.

The signals recorded by the sensors can be “read” by a sleep specialist. Information from the signals tell us about the type of sleep and breathing you are having. Please note:

NO ELECTRICITY OR ENERGY IS GIVEN TO YOU!

THE TEST IS COMPLETELY PAINLESS

(We have included a picture of one of our staff wearing the sleep monitoring equipment so you can have an idea of how you will look!)

Despite all these attachments, most everyone sleeps comfortably. You are able to move around comfortably. The technician will show you how to separate from the recorder if you need to get up during the night. Your night can continue in the usual manner. The equipment will be picked up at a pre-arranged time in the morning.

What else will be done during the study?

Prior to attaching the sensors, the technicians will take your blood pressure and help you complete several brief questionnaires. There will be one questionnaire which will be left with you in the event you wish to tell us something privately.

Additionally, there may be other small studies which you may be invited to join. These may involve tests of memory, MRI or x-ray studies of head size. As always you are under no obligation to join these studies.

How do I schedule a study?

[This is site specific.]

If you wish to participate please call (...at ...).

A convenient time will be chosen for your study. Since we only need to test you during your normal sleep hours, the study should not interfere with your work schedule.

You will be called several days prior to the study to review the plans and see whether there have been any major changes in your health. As you can imagine, to accommodate the large group of participants, our schedules are important. We appreciate any notice you can give us regarding necessary changes in your appointment once it is scheduled.

What happens afterward?

On the morning following the sleep test, a technician will pick up the equipment at your home. You will be sent a report of your study following its review. If problems arise, we will contact you within one week.

<p>What is the purpose of the Sleep Heart Health Study?</p> <p>The Sleep Heart Health Study (called SHHS) will obtain information on the sleep and health habits of people across the country to determine how sleep and other health habits affect heart disease. To do this most effectively, we have chosen to work with 6 centers already examining heart and lung disease and <u>your</u> health. The (...) study is fortunate to be one of those chosen.</p> <p>Why is the SHHS important?</p> <p>Recent research findings have suggested a link between breathing disorders during sleep and heart disease. There are times during sleep in which breathing may stop for brief seconds. Persons who have a high number of these may be given the diagnosis of "sleep apnea."¹ We believe that this disorder and a milder form called "sleep disordered breathing" may be more common than previously thought and may therefore be an important link to heart disease.</p> <p>The only way to truly know how common sleep problems are and how they may be related to heart disease is to study the occurrence in a large group of people. The (name of your cohort) is such a group for whom we already have important related information.</p> <p>What will the findings show?</p> <p>We expect to learn how common breathing disorders are during sleep. Additionally, we expect to see what type of person is most likely to have the problem. Furthermore, we expect to learn whether sleep problems in general lead to other health problems during the day, such as extreme sleepiness or heart disease.</p> <p>How will I benefit?</p> <p>A sleep study is very interesting. Experts will evaluate your sleep, determining how much time you slept, the type of sleep you had and how your heart and breathing respond during sleep. This is important information which can form a normal baseline for you or may reveal a sleep problem in very early stages which could be nicely corrected.</p>	<p>If any abnormality is found we will share with you and any doctor you choose. Additionally, you will learn a great deal about your sleep habits and the best way to improve them.</p> <p>THERE IS NO COST FOR THIS STUDY, even though this type of test could cost \$500-\$1500 if taken privately. For the many people who need this test, the waiting time is usually several months.</p> <p>Beyond any personal benefit, your help is important to understand how sleep may affect heart disease. Our findings may improve your health or the health of someone you love.</p> <p>What is an overnight study like?</p> <p>If you agree to participate in the home sleep study, a specially trained team of technicians will come to your home on a convenient evening between 8 and 10 pm. Then, sensors will be painlessly applied to your skin and scalp. Two sensors will be attached to your head with water soluble paste. Four others will attach to your face to monitor eye movements and chin muscle tone. Two will be attached to your chest, much like a cardigan. These will measure heart rate and breathing. A thin plastic tube will be taped under your nose to monitor breathing. Finally, a sensor will be taped to your finger to measure the oxygen in your blood.</p> <p>The signals recorded by the sensors are "read" by a sleep specialist. Information from the signals tells us about the type of sleep and breathing you are having. Please note:</p> <p>NO ELECTRICITY OR ENERGY IS GIVEN TO YOU!</p> <p>THE TEST IS COMPLETELY PAINLESS.</p> <p>(We have included a picture of one of our staff wearing the sleep monitoring equipment so you can have an idea of how you will look!)</p>	<p>Despite all these attachments, most everyone sleeps comfortably. You are able to move around comfortably. The technician will show you how to separate from the recorder if you need to get up during the night and then leave your home. The equipment will be picked up at a pre-arranged time in the morning.</p> <p>What else will be done during the study?</p> <p>Prior to attaching the sensors, the technicians will take your blood pressure and help you complete several brief questionnaires. There will be one questionnaire which will be left with you in the event you wish to tell us something privately.</p> <p>Additionally, there may be other small studies which you may be invited to join. These may include tests of memory, MRI or X-ray studies of head size. As always, you are under no obligation to join these studies.</p> <p>How do I schedule a study? [This has to be site specific.]</p> <p>If you agree to participate, please call (... at ...).</p> <p>A convenient time will be chosen for your study. Since we only need to test you during your normal sleep hours, the study should not interfere with your work schedule.</p> <p>You will be called several days prior to the study to review the plans and see whether there have been any major changes in your health. As you can imagine, to accommodate the large group of participants, our schedules are important. We appreciate any notice you can give us regarding necessary changes in your appointment once it is scheduled.</p> <p>What happens afterward?</p> <p>On the morning following the sleep test a technician will pick up the equipment at your home. You will be sent a report of your study following its review. If problems arise, we will contact you within one week.</p>
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A.2.3 Letter to Invite Individual to Participate in Home Sleep Study

Dear

Thank you for your participation in the SHHS. Information from the sleep habits questionnaire is being studied now. We will send you results of that part of the study as soon as they are available.

Now, we would like to invite you to participate in the home sleep study. If you recall, we will be studying 6000 people across 6 centers to examine sleep and breathing across the night.

We expect that results of this landmark study will be presented and referred to throughout the world. This is a major effort and YOU are a very important part. Without people like you, we would still know very little about sleep and breathing.

Please consider participating in the next phase of our study. I have enclosed a pamphlet to answer questions regarding the study. Feel free to give (name...) a call if additional questions occur.

Sincerely,

Study PI and Coordinator

A.2.4 Tidbits for Entry into a Newsletter “Did You Know” Series

SNORING

Did you know that about half the adult population snores during sleep?

Snoring is the result of air passing through a restricted or blocked area. Snoring, then, is much like the sound one gets from a wind instrument when different reeds are applied.

In some cases the blockage in the air passage is due to something in the way such as enlarged tonsils or adenoids.

In other cases, normal throat tissue may lose tone as we age or when we sleep and sag into the air passage. This is particularly true when we lie down on our backs. Sometimes even turning on one's side clears this tissue out of the air passage and snoring stops.

APNEA (May not be appropriate until the end of the study.)

Did you know that 5-10 % of people may have a complete blockage of the air passages during sleep? The blockage is usually cleared with a loud snort or gasp which is intermittent during the night. If the blockage of air is complete, we call that apnea.

Apnea stands for the cessation or stoppage of the flow of air. The stoppage may only last seconds but may reoccur every sleeping minute. To end each one of these episodes, the brain wakes up for seconds and breathing returns. Once sleep reoccurs, the blockage returns. This cycle can go on every night and all night long!

Patients with this disorder are very sleepy during the day, probably because their sleep is so disrupted. Also with each apnea, oxygen levels dip, sometimes quite a bit. In this case the person may also suffer from a lack of adequate oxygen.

Some of the effects are daytime sleepiness, loss of memory, loss of the ability to concentrate, feelings of depression and irritability.

SLEEP HYGIENE

Did you know that there are simple behavioral changes that you can make to improve your sleep?

1. Wake up at the same time every day. This will help reinforce/reset your biological clock.
2. Settle problems and concerns earlier in the day. Finding a quiet time in the late afternoon when you can focus on solutions for your problems will help reduce the stress related to them. Once stress is reduced, the sleep system can respond.
3. Avoid alcohol, nicotine and caffeine late in the day. Alcohol tends to disrupt the natural flow of sleep across the night. Nicotine and caffeine are stimulating and may not allow the sleep system to respond properly.

4. Make your sleep area as safe and secure from noise and interruption as possible. Even though we don't believe it, radio and TV or conversation noises tend to disrupt rather than lull sleep.
5. Develop some late afternoon exercise time. Even low impact aerobics such as walking or swimming is helpful. Along with reducing stress, the activity increases body heat which tends to deepen sleep.

SLEEP DEPRIVATION

Did you know that a large segment of our society is sleep deprived. Sleep loss is accumulative. Even though we attempt to make it up over the weekend, by midweek we are once again dangerously sleepy. Sleepy people suffer a number of symptoms, such as, slowed reaction time, loss of attention, actual short microsleeps (even behind the wheel of a car). They tend to get stuck on simple ideas and have problems problem-solving and making proper decisions.

The best way to test how much sleep you need is to allow yourself to sleep as long as possible on vacation. After a few days of make-up time, your normal sleep need will emerge. The likelihood is that you need between 7-9 hours of sleep each day to feel fully rested.

DREAM SLEEP

Did you know that sleep is an important part of our 24-hour day? Sleep can be a very active time for our brains. During sleep, we cycle in and out of dream sleep, called rapid-eye-movement or REM sleep at least 4 times. These cycles begin after about 90 minutes and occur every 90 minutes thereafter. During this time our brains appear to be as active as they are in wake. We know from our own experience and others reports, that our thoughts may be very confused and our experiences very vivid. We think this is so because, during this state, random areas in the brain are activated and the thinking part of our brain tries to make a sensible story from these random thoughts.

Fortunately, our bodies are almost completely paralyzed and unable to respond during this time. We can't, for instance, charge off on a big white horse or act out other aspects of our dreams.

Researchers do not know why we dream but many believe it is a way that the brain sorts out information and settles new memories into place. Sleep is a fascinating journey.

ANY OTHERS?

There have been suggestions of other rewards/incentives such as coffee mugs, refrigerator magnets, wallet-sized business cards, etc., all bearing the study logo and local telephone numbers. This could become a meaningful budget problem.

A.2.5 Follow-up Questionnaire for Home Study

Dear

Thank you for participating in this phase of the SHHS study. We realize that allowing someone into your home in the evening may be inconvenient. For that reason, we want to be sure that our service met with your expectations.

(name of coordinator) will call you over the next few days to thank you for your participation and check if there were any problems. However, we wanted to give you an opportunity to confidentially let us know if any serious problems arose during your testing.

Will you read over this survey? If you wish to respond to any of the items, please seal the completed survey in the self addressed envelop and return it to us. In this way, your privacy is protected and we will be able to work toward improving our service.

Answer format Yes/No

1. Were we helpful in scheduling you?
2. Did we answer your questions completely?
3. Was our schedule convenient for you?
4. Did our technicians arrive on schedule?
5. Were they polite and comfortable to be near?
6. Was the equipment clean?
7. Did you find the equipment difficult to use?
8. How comfortable was the equipment to wear?

Please add any other comments which you think may be helpful to us.

Thank you again.

(Study coordinator's name)

A.3 Equipment Evaluation

The process of choosing sleep monitoring equipment involved: (1) defining the procedures and signals needed to most appropriately address the SHHS hypotheses; (2) evaluating the feasibility and trade-offs of alternative approaches for collecting these data (including a feasibility study); and (3) soliciting input from industry, including participation in local (Cleveland) and central (Steering Committee) demonstrations of equipment.

1. Defining the needs

The Polysomnography (PSG) Committee, composed of William Bonekat (Sacramento), Paul Enright (Tucson), Daniel Gottlieb (Framingham), Conrad Iber (Minnesota), Mark Sanders (Pittsburgh), Philip Smith (Baltimore) and Susan Redline (Chair, Reading Center), met regularly by conference call and at Steering Committee meetings. (PSG member David Rapoport, New York, was not involved in these deliberations.) Based on data from the literature and personal experience, the following measurements were identified as needed for collection of the *minimally necessary* data for assessment of sleep disordered breathing and its relationship to cardiovascular morbidity:

[a] Oximetry (finger pulse): To gauge hypoxic stress, needed for event identification.

Heart Rate (ECG): To identify autonomic variability, bradycardia (i.e., cardiac outcomes).

Chest wall and abdomen movement (piezoelectric or inductance bands): To distinguish central from obstructive events.

Nasal/oral airflow (thermistery and/or pressure-flow): essential for the identification of respiratory events.

Body position (mercury gauge): To identify positional apnea.

A more complete montage, that would permit precise measurement of sleep time, allow sleep staging, and permit arousal detection, would additionally require measurements of:

[b] EEG (2 central; one for redundancy in case of failure/loss)

EOG (bilateral); chin EMG (identified after pilot work indicated the difficulties in identifying REM-specific arousals without these data.)

These additional measurements would improve the classification of apneic activity by providing an accurate determination of how much of the monitoring time was spent asleep; by gauging the impact of sleep apnea on sleep continuity (fragmentation); and by collecting data on physiological responses thought important in the pathogenesis of apnea-associated heart disease. These measurements were determined to be needed in at least a sample of subjects studied with the "minimal" montage, to establish the validity and/or define the limits of the non-EEG studies, and, possibly, to resolve ambiguous non-EEG studies.

Other measurements, often considered part of full sleep studies, which were not recommended for collection were: snoring (poorly standardized collection and analysis

procedures); and leg movements (cumbersome in free living subjects, not directly relevant to the SHHS hypotheses).

Either the “minimal” ([a], above) or the more complete montage, would require data collection with systems that were comparable across clinical sites and were capable of storing data electronically in a format compatible with a single software analysis system. The home was determined to be the optimal setting for the majority of studies because of participant acceptability, cost, and (possibly) for minimization of a “first-night” effect. The sleep laboratory was identified as a potential setting for the EEG-based studies. However, a survey of the participating sleep laboratories revealed the lack of common computer-based sleep data acquisition units. Thus, all studies (including those with EEG) would require the purchase of equipment with EEG capacity specifically for use in the SHHS.

2. Trade-offs and feasibility

The advantages/disadvantages of collecting all data with a single home visit with EEG-based equipment (Approach 1) was compared to home collection of (a) above, with EEG data collection in a only a sample (with either a second home or in-laboratory study) (Approach 2).

Approach 1 (collect the full montage in the entire cohort using in home, EEG capable systems.

Advantages:

Use of a widely-accepted montage, producing study results that likely would have good credibility in the larger scientific community.

Would minimize misclassification of apneic activity due to either: overestimation of sleep time (very relevant in older populations who often have fragmented sleep), or underestimation of respiratory events which cause arousals without desaturation (possibly common in the general population, and also associated with the newly recognized “upper airway resistance syndrome” []).

Would allow assessment of stage-specific respiratory events (i.e., to pursue hypotheses about REM-specific apnea).

Would minimize the number of contacts/participant (compared to a 2-stage sampling strategy), possibly saving costs and reducing subject burden.

Would provide a large amount of data useful for defining the abilities of different types of sleep measures to predict morbidity, thus, contributing to a much needed literature on criteria for sleep study procedures.

Disadvantages:

Few precedents for collection of these data in a large scale study (little known about feasibility and acceptability).

Longer time needed for hook-ups.

Immense data storage requirements.

Larger data processing costs.

Increased subject burden, associated with longer hook-ups and use of more cumbersome equipment.

Approach 2Advantages:

Previous experience in research settings.

Simpler hook-ups, potentially higher technical success rates, and less hook-up time.

Disadvantages:

Less data and potentially more misclassification (poorer ability to estimate sleep time, and limited arousal and sleep data).

Potentially more complicated sampling frames, and more subject contacts (for secondary EEG studies).

PSG Feasibility Pilot Study: Assessment of Multichannel Testing in the SHHS Cohort

A pilot study was undertaken to evaluate the use of two different in-home PSG machines, the MiniSomno (Approach 1) and the Edentec (Approach 2), to gauge whether the subject burden would be minimal enough to justify the increased information obtainable with the MiniSomno. In addition, the recruitment process and the sleep habits questionnaire were piloted.

The pilot study was planned in February, 1995, with sleep studies to be scheduled in March, 1995.

Objectives

The objects of the evaluation of the in-home machines were to determine:

1. subject acceptability of multichannel in-home sleep and respiratory recording in the SHHS cohorts,
2. an EEG system alters subject acceptability,
3. time requirements for hook-up and downloading of each system,
4. any gross differences in subject acceptability and technical failure rates according to age, gender, site and cohort effects, and

5. the willingness of participants to participate in a second assessment, in the eventuality of a poor initial technical study.

Other issues that were identified for exploratory analyses:

1. technical failure rates, and
2. time/technician costs

Subjects

Participants were recruited from the following sites: Sacramento, Pittsburgh, Minnesota, Baltimore, Washington County -ARIC and Hagerstown, South Dakota, and Tucson. A target of 10 participants per site was set. Subjects were to be randomly assigned to one of the two machines, resulting in approximately 35 evaluated on each machine. However, for logistical reasons some subjects were not randomly assigned, some used volunteers instead of parent study subjects, and one site only piloted the Edentec. Technicians were trained on equipment use and on the protocol at the Reading Center in Cleveland, OH.

Data Collected

A “contact form” was developed for the recruitment process of this pilot study. This form provided the demographic characteristics of those contacted and their interest in participation. However, different sites used different methods for recruiting their subjects. Some sites completed contact forms for only those who agreed to do a PSG study, some sites returned all recruitment contacts attempted, and one site did not use the contact form for recruitment.

Before and after the PSG study, the technicians completed “worksheets” to collect data on hook up and pickup times and made notes on problems encountered while doing the PSG study. In addition, an “assessment” survey was completed by the participant regarding their experiences with the sleep study equipment and components, and how the equipment may have impacted their usual waking and sleeping activities.

A “sleep habits” questionnaire was also administered to participants. This questionnaire inquired about typical sleeping habits (e.g., sleep time, problems sleeping, problems with daytime sleepiness, etc). This data was collected on all those who consented to a PSG study. In addition, some sites used this questionnaire as a recruitment form, thus including additional data on nonparticipants as well.

Results

Overview

The total number of subjects contributing data to the study was 138. Of these, 78 agreed to do an in-home sleep study (32 using MiniSomno and 46 using the Edentec). Of these 78, five studies could not be evaluated due to data errors/equipment failures. Two of the study participants actually had physical disabilities which precluded them from completing a PSG study. Thus, there were 71 PSG studies to evaluate.

Initial contact and recruitment (Table 1)

Contact forms were completed and returned for 128 individuals. This group was comprised of 59% females and an average age of 69 years. The contact forms yielded 68 participants for home sleep studies. Of the remaining subjects, 30 refused, 24 were unlocateable, and 4 were unable to participate due to illness. Most of those unlocateable were a result of the telephone recruitment strategy and most occurred in the Tucson cohort.

Technician worksheet results (Table 2)

Those participating in the home sleep studies were an average of 68 years of age and 52% were females. Each site contributed anywhere from 10 to 15 participants per site. There were 46 Edentec studies done and 32 MiniSomno studies scheduled. Two of these 78 sleep studies could not be done due to physical limitations of the participants. The required hook up time for the Edentec was an average of 37 minutes, 8 minutes less than the average of 45 minutes for the MiniSomno. The average pick up time the next morning were similar for both machines, about 18 to 22 minutes.

Sleep Habits Survey (Table 3)

This survey was administered to more subjects (18 more) than those who consented to do a sleep study. Most people did not have difficulty completing the survey. There were only a few missing values, except on the snoring and stopped breathing questions.

There was a very wide range in habits in terms of when people go to sleep at night and when they wake up in the morning. Most people (80%) fell asleep within 20 minutes of going to bed and average about 7 hours of sleep per night. About two-thirds of the sample took naps with an average of 4 naps per week. About 10 to 20% of the participants reported troubles with falling asleep or falling back to sleep. Less than 10% reported problems with feeling sleepy during the day or that they don't get enough sleep at night. Eight percent reported use of sleep medications.

Key questions of interest regarded snoring status and characteristics and problems of stopped breathing while sleeping. Seventy-eight percent of the sample answered yes to "have you ever snored." The remaining were split between "no" (12%) and "not sure" (11%). Many people indicated they were unsure as to "how often" they snored (21%), the "loudness" of their snoring (25%), the number of "years of snoring" (70%), and whether their snoring is increasing or decreasing over time (42%). Thirteen percent of the entire group (n=96) had indicated they had "stopped breathing" while sleeping. But, 38% were unsure as to whether this had ever happened to them. Only 3 subjects indicated they'd actually been told by a doctor that they had sleep apnea.

Twenty-six percent of the participants were often or almost always awakened from their sleep by pain in the joints, muscles, or back. Many (61%) were often or almost always awakened by the need to go to the bathroom.

Participants had moderate to high likelihood of dozing off while in the following situations: sitting and reading (45%), watching TV (47%), sitting in public place(18%), as a passenger in the car (24%), lying down to rest (63%), and after lunch (23%). Only a small percentage (1-3%) had

moderate to high chances of dozing off while sitting and talking to someone, stopped in traffic for a few minutes, at the dinner table, while driving, or during routine activities.

Comparison of Edentec to MiniSomno (Table 4)

There were 46 Edentec and 32 MiniSomno studies scheduled. The Edentec had slightly less problems associated with it than did the MiniSomno. In terms of the hook-up procedures, 87% of the MiniSomnos and 91% of the Edentec had very little or no difficulty with this. Both machines had very little or no discomfort reported for the attachment of lead wires, ECG pads, gluing sensors, taping of oxygen sensor on finger, and taping of eye sensors.

Eighty-nine percent of the Edentec wearers had little or no interference with normal evening activities compared to 81% of the MiniSomnos. Thirty-one percent of the MiniSomno users reported moderate to a great deal of difficulty in falling asleep while wearing the equipment (as compared to 15% for Edentec). Staying asleep was more difficult for the MiniSomno users (37% compared to 11% in Edentec) and were more likely to be awakened by the discomfort of the system, tossing and turning, and getting comfortable in bed. Participants, in general, worried about the equipment causing the participants to wake up.

In general, for either machine, the different parts of the system did not cause much discomfort. The only exception was the sensor over the lip, where 24% of the MiniSomno users reported moderate to a great deal of discomfort (compared to 8% of the Edentec users). Most participants had very little or no discomfort when the ECG pads or paste from hair were removed. When asked to compare this procedure to other procedures they had undergone, 20% of the Edentec versus 43% of the MiniSomno users said it was less comfortable than those other procedures. About seventy percent of the participants, for both types of equipment, said they would be willing to do the sleep test again.

On a more informal level, study coordinators and Investigators conducted unstructured interviews to gauge overall attitude toward the study. The majority of participants, in each equipment group, reported the experience to be positive, expressing interest in sleep information.

On the basis of this, it was concluded, that although subject burden is greater with use of more complicated equipment, the burden did not generate negativity about overall study participation. Approach 1 was chosen.

PSG Results (Table 5)

Of the 78 studies attempted, two were not doable due to physical disabilities of the subjects and five others were lost due to mechanical/data transfer errors (9%). In terms of overall quality of the remaining studies (n = 71), 51% yielded excellent results with all channels good. The results were OK with at least 1 channel problematic in 23% of the studies. Ten percent of the studies were OK but had more than 50% of the channels problematic. Five percent of the studies were uninterpretable.

The apnea-hypopnea index (AHI) ranged from 0.29 to 64.38. Twenty-three percent of the completed studies had AHI scores of five or less. Five subjects (8%) had AHI scores greater than 40 points. The mean AHI score was 16.5 (SD = 17.1) and the median score was 10.4.

The arousal index, only available from the MiniSomno studies, ranged from 0.14 to 21.79. The mean response was 8.6 (SD = 7.6) and the median response was 8.5. The correlation between the arousal index and the AHI score was not significantly different from zero ($r = 0.14$; p -value = 0.54).

Table 1

SHHS PSG PILOT STUDY: Results of Contact Form
(N=128)

1. Age of Participant	<u>Mean</u>	<u>SD</u>		
(years; 44% missing)	69.15	13.77		
2. Gender			<u>n</u>	<u>%</u>
	Female		73	59
	Male		51	41
	(Missing)		4	
	Total		128	100
3. Parent Study			<u>n</u>	<u>%</u>
	CHS**		69	54
	SHS		15	12
	Tucson		44	34
	Total		128	100

[** CHS: 10 ARIC, 27 Pittsburgh, 21 Sacramento, 11 Hagerstown]

4. Type by Result of Contact

Type of Contact

<u>Result of Contact</u>	<u>Missing</u>		<u>Telephone</u>		<u>In-person, at clinic</u>		<u>In-person, at home</u>	
	<u>n</u>	<u>%</u>	<u>n</u>	<u>%</u>	<u>n</u>	<u>%</u>	<u>n</u>	<u>%</u>
	Scheduled sleep study	6	86	27	44	25	51	10
Refused			12	20	17	35	1	9
Unable to participate due to illness			1	2	3	6		
Contact later, after Unable to locate								
All other (Missing)	1	14	21*	34	3	6		
Total	7	100	61	100	49	100	11	100

5. Result of Contact by Study

<u>Result of Contact</u>	<u>CHS</u>		<u>Parent Study</u>				<u>Total</u>	
	<u>n</u>	<u>%</u>	<u>SHS</u>		<u>Tucso</u>		<u>n</u>	<u>%</u>
	<u>n</u>	<u>%</u>	<u>n</u>	<u>%</u>	<u>n</u>	<u>%</u>	<u>n</u>	<u>%</u>
Scheduled sleep study	43	63	15	100	10	23	68	53
Refused	19	28			11	25	30	23
Unable to participate due to illness	3	4			1	2	4	3
Contact later, after Unable to locate	3	4			21*	48	24	19
All other (Missing)	1	1			1	2	2	2
Total	69	100	15	100	44	100	128	100

*The 21 correspond to 10 with “no answer/bad #/busy” and 11 “left message”

Table 2

SHHS PSG PILOT STUDY: Results from Technician Worksheet
(N=78 : 46 Edentec, 32 MiniSomno)

1. Age of Participant

	<u>Mean</u>	<u>SD</u>
(years; missing 15%)	66.76	13.23

2. Gender

	<u>n</u>	<u>%</u>
Female	37	50
Male	37	50
(Missing)	4	
Total	78	100

3. Parent Study

	<u>n</u>	<u>%</u>
ARIC - Minn.	10	13
CHS**	43	55
SHS	15	19
Tucson	10	13
Total	78	100

[** CHS : 10 ARIC, 10 Pittsburgh, 12 Sacramento, 11 Hagerstown]

4. Required hook up time
(minutes)

	<u>Mean</u>	<u>SD</u>	<u>n</u>
Edentec	37	29	40
Minisomno	45	32	28
Combined	40	30	68

5. Required pick up time
(minutes)

	<u>Mean</u>	<u>SD</u>	<u>n</u>
Edentec	22	18	29
Minisomno	18	10	17
Combined	21	16	46

Table 3

SHHS PILOT STUDY: Results of the Sleep Habits Survey
(N=96)

(NOTE: Results are numbered according to the question number on the survey.)

1. At what time do you fall asleep?

Range: 8:30 p.m. to 1:30 a.m. work days (n=94)
 8:00 p.m. to 2:00 a.m. weekends (n=92)
 Median = 11 p.m. on work days and weekends

2. How many minutes does it take to fall asleep at bedtime?

Minutes	<u>n</u>	<u>%</u>
1 to 5	29	33
6 to 10	17	19
11 to 15	15	17
16 to 20	10	11
21 to 25		
26 to 30	11	13
31 to 35		
36 to 40	1	1
More than 40	5	6
Missing	8	
Total	96	100

3. At what time do you wake up?

Range: 3 a.m. to 9:00 a.m. on work days (n=93)
 Range: 3 a.m. to Noon on week ends (n=91)
 Median = 6:15 a.m. on work days
 Median = 7:00 a.m. on weekends

4. Hours of sleep?

Mean = 7.1 hours, SD = 1.2 (n=92)
 Median = 7 hours; Range: 4 to 9 hours

5. Take naps?

	<u>n</u>	<u>%</u>	
NO	35	37	
YES	60	63	If YES, Mean=4 naps Median = 3 ; SD =2.7
Missing	1		
Total	96	100	

□

(Continuation - Results of the Sleep Habits Survey)

6. How often do you have each of the following?

		Never (0)	Rarely (1/mo)	Sometimes (2-4/mo)	Often (5-15/mo)	Almost Always (16-30/mo)
a. Trouble falling asleep	n	12	39	31	10	4
	%	13	41	32	10	4
b. Wake up at night, hard time getting back to sleep	n	16	34	30	10	6
	%	17	35	31	10	6
c. Wake up early, cannot get back to sleep	n	20	42	23	10	0
	%	21	44	24	11	0
d. Don't feel rested during day, even with lots of sleep	n	18	38	32	6	2
	%	19	40	33	6	2
e. Feelings of too much sleepiness during the day	n	20	45	27	4	0
	%	21	47	28	4	0
f. Not getting enough sleep	n	17	50	21	6	2
	%	18	52	22	6	2
g. Take sleeping pills/ other meds. to help sleep	n	72	6	10	2	6
	%	75	6	10	2	6

7. Have you ever snored?

	n	%
NO	11	12
YES	73	78
Not sure	10	10
Missing	2	
Total	96	100

Questions 8 - 11 are FOR THOSE WHO HAVE or MIGHT SNORE

8. How often do you snore?

	n	%
Don't snore anymore	4	5
Rarely (< 1 night / week)	14	19
Sometimes (1-2 nights / week)	17	23
Frequently (3-5 nights / week)	11	15
Always/almost always (6-7 nights / week)	12	16
Unsure	15	21
Missing	12	
Total	85	99

(Continuation - Results of the Sleep Habits Survey)

9. How loud is your snoring?

	<u>n</u>	<u>%</u>
Only slightly louder than heavy breathing	20	28
About as loud as mumbling or talking	22	31
Louder than talking	7	10
Extremely loud - can be heard through door	4	6
Unsure	18	25
Missing	10	
Total	81	100

10. How many years have you snored?

	<u>n</u>	<u>%</u>	
Years	21	30	Range: 2 to 50 years
			Median = 10 years
Unsure	49	70	
Missing	11		
Total	81	100	

11. Is your snoring?

	<u>n</u>	<u>%</u>
Increasing over time	6	9
Decreasing over time	7	10
Staying about the same	27	39
Unsure	29	42
Missing	12	
Total	81	100

12. Have you ever stopped breathing while sleeping?

	<u>n</u>	<u>%</u>
NO	47	49
YES	12	13
Unsure	36	38
Missing	1	
Total	96	100

13. How often do you stop breathing? FOR THOSE WHO HAVE STOPPED & UNSURE

	<u>n</u>	<u>%</u>
Rarely (< 1 night / week)	3	6
Sometimes (1-2 nights / week)	2	4
Frequently (3-5 nights / week)	2	4
Always/almost always (6-7 nights / week)	1	2
Unsure	40	83
Missing	1	
Total	49	99

(Continuation - Results of the Sleep Habits Survey)

14. Have you ever been told by a doctor that you have sleep apnea?

	<u>n</u>	<u>%</u>	
NO	89	96	
YES	3	3	These 3 YESes <u>do not</u> sleep with a CPAP or mouthpiece
Unsure	1	1	
Missing	3		
Total	96	100	

15. How often have you been awakened by?

		Never (0)	Rarely (1/mo)	Sometimes (2-4/mo)	Often (5-15/mo)	Almost Always (16-30/mo)
a. Coughing or wheezing	n	36	43	11	2	0
	%	39	47	12	2	0
b. Chest pain or tightness	n	76	12	5	0	0
	%	82	13	5	0	0
c. Shortness of breath	n	67	16	4	1	3
	%	74	18	4	1	3
d. Sweats or hot flashes	n	63	16	10	3	0
	%	68	17	11	3	0
e. Noise in your surroundings	n	34	39	10	4	5
	%	37	42	11	4	5
f. Pain in joints muscles, back	n	28	23	17	12	12
	%	30	25	19	13	13
g. Heartburn or indigestion	n	45	35	9	3	1
	%	48	38	10	3	1
h. Leg cramps or leg jerks	n	22	42	16	9	4
	%	24	45	17	10	4
i. Need to go to the bathroom	n	5	11	21	20	38
	%	5	12	22	21	40

16. Anybody sleep near you?

	<u>n</u>	<u>%</u>
Never	18	19
Sometimes	13	14
Usually	63	67
Missing	2	
Total	96	100

(Continuation - Results of the Sleep Habits Survey)

17. How likely are you to doze off or fall asleep in the following situations?

		Never	Slight	Moderate	High	Doesn't Apply
a. Sitting & reading	n	16	36	34	9	0
	%	17	38	36	9	0
b. Watching TV	n	12	38	32	13	0
	%	13	40	34	13	0
c. Sitting, inactive in a public place	n	50	25	15	2	3
	%	53	26	16	2	3
d. As a passenger in a car for 1 hr.	n	39	32	15	8	1
	%	41	34	16	8	1
e. Lying down to rest in afternoon	n	15	20	35	25	0
	%	16	21	37	26	0
f. Sitting & talking to someone	n	77	14	2	1	0
	%	82	15	2	1	0
g. Sitting quietly after lunch	n	52	20	17	5	1
	%	55	21	18	5	1
h. In a car, stopped in traffic for a few minutes	n	80	11	2	0	2
	%	84	12	2	0	2
i. At dinner table	n	89	4	1	0	1
	%	94	4	1	0	1
j. While driving	n	74	14	0	1	6
	%	78	15	0	1	6
k. During routine activities	n	81	11	2	1	0
	%	85	12	2	1	0

Table 4**SHHS PSG PILOT STUDY : Comparison of Edentec to MiniSomno**

Edentec (N=46) and the MiniSomno (N=32)

1. How much difficulty did you have, if any, with the hook-up procedure?

	<u>None</u>	<u>Very Little</u>	<u>Moderate</u>	<u>A Great Deal</u>
Edentec (n)	27	13	4	0
(%)	61	30	9	0
MiniSomno (n)	21	6	3	1
(%)	68	19	10	3

2. After the monitor was attached, how much difficulty did you have, if any, with your normal evening activities?

	<u>None</u>	<u>Very Little</u>	<u>Moderate</u>	<u>A Great Deal</u>
Edentec (n)	28	12	3	2
(%)	62	27	7	4
MiniSomno (n)	18	8	5	1
(%)	56	25	16	3

3. How much discomfort, if any, did the following aspects of the hook-up cause you?**a. Rubbing my head prior to attaching the lead wires**

	<u>None</u>	<u>Very Little</u>	<u>Moderate</u>	<u>A Great Deal</u>
MiniSomno (n)	25	5	2	0
(%)	78	16	6	0

b. Rubbing my chest prior to attaching the ECG pads

	<u>None</u>	<u>Very Little</u>	<u>Moderate</u>	<u>A Great Deal</u>
Edentec (n)	39	5	0	0
(%)	89	11	0	0
MiniSomno (n)	25	5	1	0
(%)	81	16	3	0

c. Gluing the sensors to my hair

	<u>None</u>	<u>Very Little</u>	<u>Moderate</u>	<u>A Great Deal</u>
MiniSomno (n)	22	8	2	0
(%)	69	25	6	0

d. Taping the oxygen sensor to my finger

	<u>None</u>	<u>Very Little</u>	<u>Moderate</u>	<u>A Great Deal</u>
Edentec (n)	38	5	1	0
(%)	86	11	2	0
MiniSomno (n)	27	3	2	0
(%)	84	9	6	0

e. Taping the eye sensors to my face

	<u>None</u>	<u>Very Little</u>	<u>Moderate</u>	<u>A Great Deal</u>
MiniSomno (n)	27	4	1	0
(%)	84	13	3	0

4. How much difficulty did you have, if any, falling asleep while wearing the equipment?

	<u>None</u>	<u>Very Little</u>	<u>Moderate</u>	<u>A Great Deal</u>
Edentec (n)	22	16	6	1
(%)	49	36	13	2
MiniSomno (n)	12	10	7	3
(%)	38	31	22	9

5. Once asleep, did you have more difficulty than usual in staying asleep?

	<u>None</u>	<u>Very Little</u>	<u>Moderate</u>	<u>A Great Deal</u>
Edentec (n)	26	13	4	1
(%)	59	30	9	2
MiniSomno (n)	12	8	8	4
(%)	38	25	25	12

6. Once asleep, did any of the following cause you to wake up?

	<u>Edentec</u>		<u>MiniSomno</u>	
	<u>No</u>	<u>Yes</u>	<u>No</u>	<u>Yes</u>
a) Discomfort from the sensors or vest	42	1	26	5
b) Tossing and turning	39	4	20	12
c) Worrying about the equipment	33	11	23	8
d) Problems getting comfortable in bed	40	3	23	9

7. How much discomfort, if any, did the following equipment cause you?**a. Wires on the head**

	<u>None</u>	<u>Very Little</u>	<u>Moderate</u>	<u>A Great Deal</u>
MiniSomno (n)	26	5	1	0
(%)	81	16	3	0

b. Sensor over the lip

	<u>None</u>	<u>Very Little</u>	<u>Moderate</u>	<u>A Great Deal</u>
Edentec (n)	26	14	2	2
(%)	59	32	4	4
MiniSomno (n)	11	12	5	2
(%)	37	40	17	7

c. Vest or belt

	<u>None</u>	<u>Very Little</u>	<u>Moderate</u>	<u>A Great Deal</u>
Edentec (n)	38	6	1	0
(%)	84	13	2	0
MiniSomno (n)	21	6	2	2
(%)	68	19	6	6

d. ECG pads on chest

	<u>None</u>	<u>Very Little</u>	<u>Moderate</u>	<u>A Great Deal</u>
Edentec (n)	41	4	0	0
(%)	91	9	0	0
MiniSomno (n)	23	6	0	1
(%)	77	20	0	3

e. Finger sensor

	<u>None</u>	<u>Very Little</u>	<u>Moderate</u>	<u>A Great Deal</u>
Edentec (n)	29	13	2	1
(%)	64	29	4	2
MiniSomno (n)	24	5	2	0
(%)	77	16	7	0

f. Straps around chest and stomach

	<u>None</u>	<u>Very Little</u>	<u>Moderate</u>	<u>A Great Deal</u>
MiniSomno (n)	24	4	1	2
(%)	77	13	3	7

8. How much discomfort, if any, did the following aspects of the study cause you?

a. Removing the ECG pads

	<u>None</u>	<u>Very Little</u>	<u>Moderate</u>	<u>A Great Deal</u>
Edentec (n)	28	12	3	2
(%)	62	27	7	4
MiniSomno (n)	18	11	1	1
(%)	58	36	3	3

b. Removing the paste from your hair

	<u>None</u>	<u>Very Little</u>	<u>Moderate</u>	<u>A Great Deal</u>
MiniSomno (n)	22	6	1	2
(%)	71	19	3	7

9. Would you be willing to do this sleep test again?

	<u>Yes</u>	<u>No</u>	<u>Unsure</u>
Edentec (n)	32	6	8
(%)	70	13	17
MiniSomno (n)	22	3	7
(%)	69	9	22

10. Compared to other procedures you have undergone in this study (e.g., _____), how would you describe the sleep study?

	Edentec		MiniSomno	
	n	%	n	%
1) Much more comfortable	11	31	3	10
2) Slightly more comfortable	6	17	2	7
3) About the same	11	31	12	40
4) Slightly less comfortable	6	17	9	30
5) Much less comfortable	1	3	4	13

Table 5**SHHS PILOT STUDY: Results of the PSG studies**

(n = 78)

1. Overall Study Quality

	<u>MiniSomno</u>		<u>Edentec</u>	
	<u>Frequency</u>	<u>Percent</u>	<u>Frequency</u>	<u>Percent</u>
Uninterpretable	5	16	0	0
OK, but > 50% channels with problems	3	9	5	11
OK, but at least 1 channel with problems	14	44	4	9
Excellent, all channels good	8	25	32	70
Not completed:				
Subject disability	0	0	2	4
Mechanical/data failure	<u>2</u>	<u>6</u>	<u>3</u>	<u>6</u>
	32	100	46	100

2. Apnea-Hypopnea Index (AHI)

Value label	<u>Value</u>	<u>Freq.</u>	<u>Percent</u>	<u>Valid Percent</u>	<u>Cum. Percent</u>
LE 5	1	15	19.2	23.1	23.1
GT 5-LE 10	2	15	19.2	23.1	46.2
GT 10-LE 20	3	19	24.4	29.2	75.4
GT 20-LE 30	4	6	7.7	9.2	84.6
GT 30-LE 40	5	5	6.4	7.7	92.3
GT 40	6	5	6.4	7.7	100.0
Missing	.	13	16.7	Missing	
Total		78	100.0	100.0	

3. Arousal Index

<u>Value</u>	<u>Freq.</u>	<u>Percent</u>	<u>Valid Percent</u>	<u>Cum. Percent</u>
0.14	1	1.3	4.2	4.2
0.15	1	1.3	4.2	8.3
0.16	1	1.3	4.2	12.5
0.20	1	1.3	4.2	16.7
0.23	1	1.3	4.2	20.8
0.28	1	1.3	4.2	25.0
0.51	1	1.3	4.2	29.2
0.57	1	1.3	4.2	33.3
1.14	1	1.3	4.2	37.5
6.64	1	1.3	4.2	41.7
6.65	1	1.3	4.2	45.8
7.87	1	1.3	4.2	50.0
9.18	1	1.3	4.2	54.2
10.44	1	1.3	4.2	58.3
10.64	1	1.3	4.2	62.5
11.00	1	1.3	4.2	66.7
14.77	1	1.3	4.2	70.8
14.78	1	1.3	4.2	75.0
16.26	1	1.3	4.2	79.2
16.86	1	1.3	4.2	83.3
17.11	1	1.3	4.2	87.5
19.49	1	1.3	4.2	91.7
19.55	1	1.3	4.2	95.8
21.79	1	1.3	4.2	100.0
Missing	54	69.3	Missing	
	-----	-----	-----	
Total	78	100.0	100.0	

A.4 Choice of Equipment

The interest of the SHHS investigators in purchasing equipment for this study was advertised in a commercial publication. The system requirements (both for Approach 1 and 2) were summarized and distributed to 22 equipment manufacturers (all known major suppliers of sleep equipment and any others who contacted us). Fifteen companies contacted the Sleep Reading Center by writing or telephone. An evaluation process was developed which included assessment of: commercial specifications (size, computer requirements, sampling and storage rates, storage medium, electrical supply), channel characteristics (amplifiers, filters, etc.), construction (sturdiness, bulk), sensor descriptions, and software. A decision was made to exclude equipment that required a bedside stand-alone computer (because of bulk, electrical requirements, and the complexity of presenting such a system in the home). Eight companies, producers of equipment that appeared to most closely meet study requirements, made equipment demonstrations (to the Steering Committee and/or to members of the PSG committee). Five different devices were also evaluated (with hands-on testing) at the Sleep Reading Center or one of the participating clinical sites. Finally, three companies were identified as making equipment that met minimal study requirements for Approach 1. Of these, one was excluded because of AC electrical requirements and inflexibility in adjusting sampling rates. The final choice of the CompuMedics SleepWatch PS was based on the following considerations:

1. Most robust and flexible hardware, with up to 24 channels for data acquisition (compared to 9 for the alternative system);
2. Fully developed software (in contrast to incompletely developed software for the alternative, necessitating a separate software agreement with another company);
3. Ability to do in-home set-up procedures without a separate laptop computer;
4. Attractive pricing;
5. A high level of enthusiasm by the company in participating in the study, customizing hardware and software, and providing technical support.

A.5 IRB-Approved Informed Consent Forms

Following are current Informed Consent Forms for each site.

Framingham Informed Consent

PATIENT INFORMATION AND CONSENT FORM

TITLE: Sleep Heart Health Study

INVESTIGATOR: George O'Connor, M.D.
Boston University
Pulmonary Center, K603
80 E. Concord Street
Boston, MA 02118

PURPOSE OF THE STUDY

You are being asked to participate in a research study. The purpose of this study is to find out if disturbances in breathing during sleep lead to increased risk of heart disease, stroke, and diseases of the blood vessels.

STUDY DESIGN

Volunteers in this study will undergo monitoring of their breathing during sleep in an overnight study in their own homes. On two occasions approximately three and one-half years apart, volunteers will undergo a complete evaluation for any evidence of cardiovascular disease during visits to the Framingham Study clinic. In addition, a home visit will be performed approximately two years after the overnight sleep study to measure the blood pressure. The data collected will be analyzed to see if abnormal breathing during sleep is a risk factor for cardiovascular disease or high blood pressure.

PROCEDURES

A visit to your home will be scheduled. During this visit you will be weighed and have your blood pressure measured. An overnight study will be performed using a portable monitoring system which will be brought to your own home. While you sleep, this system will monitor your breathing pattern, blood oxygen level, brain waves (electroencephalogram), eye movements, and heart rhythm. This monitoring will be done by means of sensors which will be attached to the surface of your skin with adhesives. The research technician visiting your home will attach these sensors to your skin in the early evening. You will be given the name and phone number of someone you may call at any time during the study night if you have questions or if any problems arise with the sleep monitor. You will be shown how to disconnect the wires and remove the sensors in the morning when you get up. The technician will visit your home the day after the sleep monitoring is done to retrieve the monitor.

POTENTIAL RISKS

You may have difficulty sleeping because of discomfort due to the sensors attached to your skin or due to anxiety caused by the presence of the sleep monitor in your bedroom. A small percentage of patients (less than one in 100) experience mild skin irritation at the site of the sensors.

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POSSIBLE BENEFITS

It is possible that a previously unrecognized problem with breathing during sleep (sleep apnea) may be discovered and, if you wish, reported to your physician. Early recognition and treatment of such a problem can prevent serious health problems.

CONFIDENTIALITY

The records of this research study will be kept confidential. Results will be reported in scientific publications only for groups of volunteers without any information which could be used to identify individuals.

WHOM TO CONTACT WITH QUESTIONS

If you have any questions about this research study, about your rights as a research subject, or if you feel you have suffered a research-related problem, you should contact the study investigator, George O'Connor, MD at (617) 638-4860.

If you have questions about your rights as a research subject, you may also contact the IRB Coordinator, Boston University Medical Center Institutional Review Board, 88 E. Newton Street, Boston, MA, IRB coordinator at (617) 638-7207.

VOLUNTARY PARTICIPATION/WITHDRAWAL FROM THE STUDY

You are free to refuse to participate in the study and you may withdraw from the study at any time.

STATEMENT OF INFORMED CONSENT

I have read the above description of this research study, and I understand it. I have been informed of the risks and benefits involved, and all of my questions have been answered to my satisfaction. Furthermore, I have been assured that any future questions I may have will also be answered by a member of the research team. I understand that I will receive a copy of this form.

I understand that I am free to withdraw this consent and discontinue participation in this research at any time without prejudice.

I voluntarily consent to my participation in the described research study.

Signatures:

Subject's Date

Investigator Date

Revised July 25, 1995

VALID FOR USE THROUGH 8/13/95
IRB LLF 8/13/95

Johns Hopkins Informed Consent

COMMITTEE ON HUMAN RESEARCH CONSENT FORM

**The Johns Hopkins University
School of Hygiene and Public Health**

Title of Research Project:

CHR# H.34.94.05.23.A

SLEEP HEART HEALTH STUDY

Explanation of Research Project:

The purpose of the Sleep Heart Health Study (SHHS) is to learn about how snoring and breathing disturbances during sleep affect a person's risk of developing heart disease and stroke. The SHHS is a research program sponsored by the National Heart, Lung and Blood Institute, which is being conducted in six communities in the United States. The JOHNS HOPKINS UNIVERSITY is conducting the study in WASHINGTON COUNTY, MARYLAND, by recruiting participants from the Atherosclerosis Risk in Communities (ARIC) Study and the Cardiovascular Health Study (CHS).

If you agree to participate in the study, you will undergo a home sleep study and complete additional brief questionnaires. The home sleep study involves being connected to a special battery-operated monitoring device by several wires and sensors. Technicians will visit you at home on the evening of the home sleep study. They will ask you to fill out a brief questionnaire, measure your blood pressure, and then connect you to the sleep monitoring device. Using washable paste, wires will be connected to the surface of your scalp, on the sides of your forehead and under your chin, in order to record how well you are sleeping. Wires will be connected over the front of your chest using removable adhesive disks to monitor your heart rhythm. Light-weight belts will be fitted around your chest and abdomen and a sensor will be taped under your nose to assess your breathing. An additional sensor will be taped on one of your fingers to measure the oxygen level in your blood during the night. All of these wires and sensors will be connected to the sleep monitor which will be located by your bedside. The technicians will leave your home after they have finished connecting you to the sleep monitor. They will leave with you a brief questionnaire to complete after you awake in the morning.

You will attempt to sleep in your usual manner. You will be able to get up and move about during the night. Furthermore, if absolutely necessary, you will be able to disconnect yourself from the device before the night is over. After you awake in the morning, you will disconnect yourself from the device. That morning, the technician will return to your home to collect the device and the questionnaire at a time that is convenient for you.

After completion of the home sleep study, you will be periodically contacted over the next several years to inquire about your health.

RISKS AND BENEFITS:

The examination procedures used in this program are considered safe. For this study, we are using a Compumedics monitor. We are not going to make any diagnosis with the information collected with this monitor, which is only to be used for research purposes.

Some people report a moderate degree of difficulty sleeping during the night of the monitoring. There could be some discomfort at the site of electrode leads which will be placed on your chest and head. Adhesive disks and tape are used to attached sensors and wires to the skin. These adhesives can be washed from your hair and skin with warm soapy water or shampoo. When removed, however, they may cause some temporary pain, may remove some hair, and may leave a small area of red skin which is painless and resolves within a few days.

The benefits to you are that a review of your sleep patterns including any irregular heart rhythms which may be detrimental to your health will be identified at no cost to you. These results will be available to both you and your physician, if you choose to have your physician receive them. The study does not provide diagnostic or medical care for you and is not intended to interfere with your relationship with your doctor.

By participating in this important study, you will be contributing to the advancement of medical knowledge so that doctors may obtain more information about sleep patterns, their relation to heart disease, and factors which could be important in treating people in the future.

COST AND PAYMENTS:

There is NO CHARGE for any of the tests or sleep clinic visit.

CONFIDENTIALITY:

The information that we gather from you will be confidential. All the data collected will be identified by number only and will be available only to scientists in the aggregate. Only the selected personnel who install the unit and who manage the data will have access to names of study participants. If you request it, the results of you study will be sent to your physician.

RIGHT TO WITHDRAW:

You are free to refuse to participate in this study or to withdrawn at any time. Your decision to do so will not adversely affect your medical care at this institution or cause a loss of benefits to which you might be otherwise entitled.

COMPENSATION FOR ILLNESS OR INJURY:

In the event of physical injury or illness resulting from the research procedures, no monetary compensation will be made but any immediate emergency medical treatment will be provided if necessary.

CONSENT FORM

Sleep Heart Health Study

Any question you may have concerning your rights as a research subject may be directed to any staff personnel or one of the following:

Joel G. Hill, M.S.
Study Coordinator
301-791-1847

F. Javier Nieto, M.D.
Principal Investigator
410-955-4380

Moyses Szklo, M.D.
Co-Investigator
410-955-3462

A copy of this consent form will be given to you. Your signature below means that you have freely agreed to participate in this research study.


Subject's signature

Witness to Consent Procedures

Signature of Investigator

Date

NOT VALID WITHOUT THE
COMMITTEE OR IRB STAMP
OF CERTIFICATION



Void One Year From Above Date
CHR No. _____

Minnesota Informed Consent
UNIVERSITY OF MINNESOTA

Twin Cities Campus

*Division of Epidemiology
School of Public Health*

*Suite 300
1300 South Second Street
Minneapolis, MN 55454-1015
612-624-1818
Fax: 612-624-0315*

July 12, 1995

Ms. Ellen Stewart
Executive Assistant
IRB: Human Subjects Committee
1300 South Second Street, Suite 10
Minneapolis, MN 55454

RE: "Cardiovascular Consequences of Sleep Apnea"
IRB Code Number: 9406M8378 (approval date, August 18, 1994)

Request for a Change in the Protocol

Dear Ms. Stewart:

As was indicated in our original application, the referenced study is a multi-center epidemiological study involving six field centers, a data coordinating center, and a reading center. Over the past few months we participated in a pilot study for which we obtained IRB approval (see our request for a change in the protocol dated March 5, 1995 and your approval dated May 1, 1995). A common, final protocol has been developed which is somewhat different from the approved application. The changes, which are not substantial and pose no risk to the participants, are summarized below.

1. Change of the Sleep Monitor:

The study's primary measurement is a non-invasive recording of sleep physiology at the subject's home. Following the pilot study experience, the Steering Committee decided to use a sleep monitor that includes electroencephalographic (EEG) sensors. The monitor we used in the pilot was called MINISOMNO (manufactured by Puritan Bennett company), but price and company-related issues precluded its use in the full scale study. The full scale study will be done with a monitor called Compumedics SLEEPWATCH Systems. Like the MINISOMNO, this battery-operated monitor is a new device which is not yet FDA approved. However, the arguments that I presented in my letter (March 5) to justify exemption of the MINISOMNO from the requirement to obtain IDE number, apply to Compumedics SLEEPWATCH as well. For the record, I reiterate the criteria of section 812.2 (c)(3), the section specifying criteria for exemption from obtaining IDE number.

§812.2 (c): Exempt investigations. This part does not apply to investigations of the following categories of devices:

§ 812 (c) (3) A diagnostic device, if the sponsor complies with applicable

requirements in §809.10(c) and if testing:

- (i) **Is noninvasive.** (Sleep monitoring is a non-invasive procedure.)
- (ii) **Does not require an invasive sampling procedure that presents significant risk.** (No invasive sampling procedures are involved in our study.)
- (iii) **Does not by design or intention introduce energy into a subject,** (None introduced in our study.)

and (iv) Is not used as a diagnostic procedure without confirmation of the diagnosis by another, medically established diagnostic product or procedure. (Our study is not intended to establish clinical diagnoses. As was specified in our protocol, should abnormalities be detected, participants will be referred to their primary care physicians for diagnostic and medical work-up.)

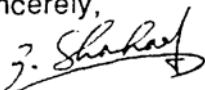
2. Additional study procedures:

A few risk-free procedures have been added to the encounter at the participant home (in addition to the sleep monitor hook-up). These include blood pressure measurement, measurement of the neck girth with a measuring tape, a brief health interview, and recording of the medications the participant may have taken that day.

The aforementioned changes required some revision of the consent form to be in line with the hook-up features of the Compumedics SLEEPWATCH monitor. I have also added a description of the new study procedures that were mentioned above. Since our pilot study experience indicated that some people report difficulty staying asleep while connected to a sleep monitor, I added that statement to the Risk and Benefits section. I have also improved the format of the consent form (larger font).

Thank you for taking the time to consider our request for a change in the protocol. The Steering Committee wants us to start the full scale study in late August so I hope this request for a change in the protocol can be reviewed by that time.

Sincerely,



Eyal Shahaar, M.D., M.P.H.
Principal Investigator

Enclosures:

1. Informational material on Compumedics SLEEPWATCH.
2. Revised consent form

Revised July 95

Consent Form

ARIC Home Sleep Study

Background Information:

This study is being conducted to learn more about how certain sleep characteristics may affect an individual's risk of developing heart disease or stroke. The study is a collaboration between researchers at the University of Minnesota (Drs. Eyal Shahar and Aaron Folsom) and at Hennepin County Medical Center (Drs. Conrad Iber and Mark Mahowald). You were selected for the Home Sleep Study from among participants in the Atherosclerosis Risk in Communities (ARIC) Study based on the Sleep Habits Questionnaire that you filled out. About 1,000 ARIC participants in Minnesota will take part in this study. We would like you to read the following information and ask any questions you may have before agreeing to participate.

Procedures:

If you agree to take part in the Home Sleep Study, our technicians will start by asking you a few questions about your health. They will record the medications you have taken today and measure your blood pressure. They will also measure your neck girth with a measuring tape. Next, they will connect you to a sleep monitoring device. This involves attaching several sensors (wires) to your skin using adhesive disks, similar to electrocardiographic (EKG) recording. The wires will be connected to a device that will record your heart function, breathing, eye movements, oxygen level, and brain activity. One sensor will be taped below your nose to record your breathing while you sleep. Another small sensor, taped to one of your fingertips, will measure your oxygen level throughout the night. In order for this sensor to function properly, you will need to remove any fingernail polish you may be wearing on that finger. To record your brain function as you sleep, the technician will attach two small disks to your scalp and several small disks to your forehead and chin. All of the wires will be tucked into pockets on a vest that you will wear until you go to bed, and in bed, while sleeping. When you go to bed you will attach a cable from that vest to a small recording box that will be placed next to your bed. Should the need

arise, you will be able to move about carrying the device with you, or disconnect yourself completely from all wires. Before leaving, the technicians will give you two short questionnaires to fill out: one at bedtime and another in the morning, when you wake up. When you wake up, you will disconnect yourself from the device and its wires. The technicians will return in the morning at a scheduled time to collect the device and the two questionnaires. Information about your sleep and a check for \$20 will be mailed to you 4-6 weeks after the study.

Risks and Benefits of Participation:

This home sleep study is considered safe. There may be some slight skin discomfort when the wires are attached or removed from your skin, but there are no other foreseeable risks. Although the majority of people who undergo this type of sleep study report that it does not interfere with their sleep, some individuals report difficulty staying asleep. The benefits of taking part in this study include receiving \$20, as well as obtaining information regarding your sleep. Additionally, if the sleep study reveals an unrecognized sleep disorder you will be informed. This Home Sleep Study and its results will be provided free of charge.

Compensation:

In the unlikely event that this research activity results in an injury, medical treatment will be available, including first aid, emergency treatment, and follow-up care as needed. Payment for any such treatment must be provided by you and/or your third party payer, if any, (such as health insurance or Medicare).

Confidentiality:

All information collected during the sleep study will be kept private. It will be used only by the investigators for scientific purposes and your name will not be used in any report that might be published.

Voluntary Nature of the Study:

Your participation in this study is completely voluntary and you may withdraw your consent at anytime. Refusal to participate will not adversely affect your

future relationship with the University of Minnesota, Hennepin County Medical Center, or the ARIC Study Investigators. We expect that the information obtained will be valuable in the national effort to discover more about the development and causes of heart disease and stroke. Your participation will be greatly appreciated.

Contacts and Questions:

At this point, our technicians will be happy to answer any questions you might have about the procedure or the study in general. If you have any additional questions please feel free to contact any of the following persons:

- Dr. Eyal Shahar, Principal Investigator at 624-8231
- Dr. Conrad Iber, Co-Investigator at 347-2432
- Dr. Mark Mahowald, Co-Investigator at 347-6288

At your request, a copy of this consent form will be provided to you.

Statement of Consent:

I have read the above information and understand that my participation in this study is voluntary, and I am free to withdraw my consent at anytime. All procedures have been clearly articulated to me and I fully understand them. I have asked questions and received clear and complete answers. I hereby consent to participate in the Home Sleep Study.

Date Signature of Participant

Printed Name of Participant

Witness

DATE (MO., DY., YR.)	LOCATION	DEPT.
	New York Informed Consent	
USE	DEPT.	IF NO PLATE, PRINT NAME, AGE, AND HISTORY NO.



THE NEW YORK HOSPITAL-CORNELL MEDICAL CENTER
Consent Form for Clinical Investigation

Project Title: AMBULATORY BLOOD PRESSURE AND BEHAVIOR (SLEEP SUBSTUDY)
Subject: Research Project No.

As a participant in our federally-funded study of the psychosocial causes of hypertension, we would like to invite you to participate in a new sleep study. This study is being conducted in subjects who have already been evaluated for cardiovascular disease, which is why you are eligible. Physicians, faculty members and staff of New York University, the New York Hospital and Cornell Medical College hope to learn more about possible effects of sleep patterns on blood pressure and cardiovascular disease.

If you agree to participate, we will ask you (a) to have some additional testing at the time of your visit to New York Hospital, and (b) to have your sleep monitored for one night. At the clinic visit you will be asked to blow into a tube to measure your breathing capacity, and also to have the blood pressure measured in one arm and one ankle. This is done by wrapping a blood pressure cuff around the arm or leg, inflating it, and then recording the onset of blood flow with a probe placed on the skin over the artery. The procedure is noninvasive. We will also measure the diameter of your neck, waist, and hip. Finally, we will give you a questionnaire to fill out, which asks about your sleep habits, lifestyle, and medical history. The whole procedure lasts less than 30 minutes.

The sleep recording will be made in your own home. A technician will come to your house just before your normal bedtime, and attach 8 small sensors to your face and head, using water soluble adhesive and tape. There will also be two elastic bands around your chest and waist to measure chest and stomach movement, and a small light sensor placed on one finger to measure blood oxygen level. The technician will return the following morning to disconnect the apparatus at a time convenient to you.

Although we cannot guarantee that you will receive any benefits from the study, we hope that the information that we will obtain (a) may help us to understand the causes of high blood pressure, (b) may lead to new interventions to prevent the development of hypertension, (c) may provide information that will influence current treatment regimens for individuals with hypertension, and (d) may provide information about abnormalities of your breathing during sleep which may affect your daytime functioning. If these are detected, you will be informed and provided with an appropriate referral to a Sleep Disorders Center.

The long term goals of the study are to determine whether people with disordered sleep patterns are at increased risk of strokes and heart attacks, so we plan to maintain contact with people who have been in the study, in order to find out who develops these complications and who does not. This will be

done either by mail or telephone, and we may ask you to make one clinic visit. At the present time, however, our funding only allows us to do this for one to two years.

You will not be responsible for any of the costs associated with your participation in this study, but we cannot offer you any financial compensation for taking part.

All information obtained during this study is confidential. You will receive a copy of your sleep monitoring results, along with a letter summarizing them. Any test results or information identified with you may only be disclosed with your written permission. No one will have access to your files, without your written permission.

Your decision on participation in this sleep study will not prejudice your future relationship with the New York Hospital-Cornell Medical Center. If you do decide to participate, you are free to discontinue participation at any time.

In accordance with federal regulations, we are obliged to inform you of the Medical Center's policy in the event physical injury occurs. If, as a result of your participation, you experience physical injury from known or unknown risks of the research procedures described, immediate medical care and treatment, including hospitalization if necessary, will be available. No Monetary compensation, however, is available, and you will be responsible for the costs of such medical treatment, either directly or through your personal medical insurance and/or other forms of medical coverage. If you have any questions regarding your rights as a research subject or concerning a research related injury, please call (212) 746-6026.

If you have any questions related to this study, please ask us. If you have questions during the course of your participation with us, Dr Thomas Pickering is available at (212)746-2149, or by writing to the Cardiovascular Center, Starr Pavilion 4th floor, 520 East 70th Street, New York, NY 10021.

You will be offered a copy of this form to keep.

You are making a decision as to participate or not. Participation is completely voluntary. Your signature indicates that you have read the information provided above and have decided to participate. Should you choose to discontinue participation in this study after signing a form, you may withdraw your participation at any time without prejudice.

Signature

Date

Time AM
PM

Signature of witness

Signature of Investigator

DATE (MO., DY., YR.)	LOCATION	SERVICE
SEE		IF NO PLATE, PRINT NAME, SEX, AND HISTORY NO.



THE NEW YORK HOSPITAL-CORNELL MEDICAL CENTER
 Consent Form for Clinical Investigation

Project Title: SLEEP HEART AND HEALTH STUDY

Subject: _____ Research Project No. _____

We would like to invite you to participate in a new sleep study. This study is being conducted in subjects who have already been evaluated for cardiovascular disease, which is why you are eligible. Physicians, faculty members and staff of New York University, the New York Hospital and Cornell Medical College hope to learn more about possible effects of sleep patterns on blood pressure and cardiovascular disease.

If you agree to participate, we will ask you (a) to make one clinic visit, and (b) to have your sleep monitored for one night. At the clinic visit you will be asked to blow into a tube to measure your breathing capacity, and also to have the blood pressure measured in one arm and one ankle. This is done by wrapping a blood pressure cuff around the arm or leg, inflating it, and then recording the onset of blood flow with a probe placed on the skin over the artery. The procedure is noninvasive. We will also measure the diameter of your neck, waist, and hip. Finally, we will give you a questionnaire to fill out, which asks about your sleep habits, lifestyle, and medical history. The whole visit lasts less than 30 minutes.

The sleep recording will be made in your own home. A technician will come to your house just before your normal bedtime, and attach 8 small sensors to your face and head, using water soluble adhesive and tape. There will also be two elastic bands around your chest and waist to measure chest and stomach movement, and a small light sensor placed on one finger to measure blood oxygen level. The technician will return the following morning to disconnect the apparatus at a time convenient to you.

Although we cannot guarantee that you will receive any benefits from the study, we hope that the information that we will obtain (a) may help us to understand the causes of high blood pressure, (b) may lead to new interventions to prevent the development of hypertension, (c) may provide information that will influence current treatment regimens for individuals with hypertension, and (d) may provide information about abnormalities of your breathing during sleep which may affect your daytime functioning. If these are detected, you will be informed and provided with an appropriate referral to a Sleep Disorders Center.

The long term goals of the study are to determine whether people with disordered sleep patterns are at increased risk of strokes and heart attacks, so we plan to maintain contact with people who have been in the study, in order to find out who develops these complications and who does not. This will be done either by mail or telephone, and we may ask you to make one clinic visit. At the present time, however, our funding only allows us to do this for one to two years.

You will not be responsible for any of the costs associated with your participation in this study, but we cannot offer you any financial compensation for taking part.

All information obtained during this study is confidential. You will receive a copy of your sleep monitoring results, along with a letter summarizing them. Any test results or information identified with you may only be disclosed with your written permission. No one will have access to your files, without your written permission.

Your decision on participation in this sleep study will not prejudice your future relationship with the New York Hospital-Cornell Medical Center. If you do decide to participate, you are free to discontinue participation at any time.

In accordance with federal regulations, we are obliged to inform you of the Medical Center's policy in the event physical injury occurs. If, as a result of your participation, you experience physical injury from known or unknown risks of the research procedures described, immediate medical care and treatment, including hospitalization if necessary, will be available. No Monetary compensation, however, is available, and you will be responsible for the costs of such medical treatment, either directly or through your personal medical insurance and/or other forms of medical coverage. If you have any questions regarding your rights as a research subject or concerning a research related injury, please call (212) 746-6026.

If you have any questions related to this study, please ask us. If you have questions during the course of your participation with us, Dr Thomas Pickering is available at (212)746-2149, or by writing to the Cardiovascular Center, Starr Pavilion 4th floor, 520 East 70th Street, New York, NY 10021.

You will be offered a copy of this form to keep.

You are making a decision as to participate or not. Participation is completely voluntary. Your signature indicates that you have read the information provided above and have decided to participate. Should you choose to discontinue participation in this study after signing a form, you may withdraw your participation at any time without prejudice.

Signature

Date

Time AM
 PM

Signature of witness

Signature of Investigator



Pittsburgh Informed Consent

Cardiovascular Health Study

Forsyth Co.
North Carolina

Sacramento
California

Pittsburgh
Pennsylvania

Washington Co.
Maryland

**7-3-95 Approved
Biomedical IRB
University of Pittsburgh**

CONSENT FORM

TITLE: SLEEP HEART HEALTH STUDY (SHHS) IN THE CARDIOVASCULAR HEALTH STUDY

PRINCIPAL INVESTIGATOR:

Anne B. Newman, M.D., M.P.H.
Assistant Professor
Department of Epidemiology
University of Pittsburgh
(412) 624-4052

CO-INVESTIGATOR:

Mark H. Sanders, M.D.
Associate Professor of Medicine
and Anesthesiology
Department of Medicine
University of Pittsburgh
(412) 692-2880

CONSULTANT:

Lewis H. Kuller, M.D., Dr.P.H.
Chairperson and Professor
Department of Epidemiology
University of Pittsburgh
(412) 624-3054

SOURCE OF SUPPORT: National Heart, Lung and Blood Institute

Description: Little is known about the degree to which sleep related breathing disorders are risk factors for the development of cardiovascular and cerebrovascular disease. It is believed that this disorder is present in 25% or more of older persons.

Participants from 5-6 research studies nationwide are being asked to participate in a new study that will attempt to better understand the relationship between breathing disorders and these other diseases.

Because I am a participant in the Cardiovascular Health Study I am being asked to participate. A total of approximately 6,000 participants will be recruited. In Pittsburgh, approximately 500 CHS participants will be evaluated.

Participant's Initials

I will be asked about my willingness to participate in an overnight in-home study, to be scheduled, at my convenience in the following four weeks. If I agree, a visit will be scheduled between 6 p.m. and 11 p.m., according to my availability and preferences. Prior to an evening home visit, I will receive a confirmation letter containing written instructions on necessary preparations for the home visit (e.g., attire, bathing and shampooing beforehand, etc.)

A 2-person research team will visit my home. At the beginning of the visit, the technicians will introduce themselves, present University of Pittsburgh study identification, explain the purpose of the study, and answer any questions. One research technician will ask permission to set up the recording device system on a nearby table while the other technician will proceed in administering the consent forms. After I have given written consent, I will be asked to sit next to the recording device system, at which time the hook-up is reviewed. The technicians will then proceed to attach the ECG pads, chest and abdominal straps, vest (or belt), the finger pulse oximeter, and abdominal straps, vest (or belt), a clip on my finger to measure by blood oxygen oximeter, and the head and eye electrodes, which will be attached with adhesive. Using a hand-held mirror, I then will be shown how to attach the lip sensor for measuring the flow of air that I breathe, which should be attached immediately prior to bed. All signals will be tested to be sure that all monitors are in working orders. Cables to the computer or recording device then will be disconnected. I will be instructed on how to walk with the equipment, how to reconnect cables prior to bed, and how to remove sensors in the morning.

I will be given two questionnaires to be completed in the morning following the study. A morning time for equipment pick-up (and EEG removal) will be agreed upon.

I will receive a letter within six weeks of the study, describing the results. I understand that this is not a diagnostic test, although the information obtained may be useful to my physicians and can be sent to him/her from the CHS office.

RISKS AND BENEFITS:

My participation in this study may help to provide needed information about the connection between sleep disorders and cardiovascular and cerebrovascular diseases. I will also receive my own sleep pattern test results that can also be sent to my doctor.

My sleep for the one night that I would be attached to a monitor may be disrupted because of the use of unfamiliar equipment. I will also have to wash to remove the adhesive that is used.

COSTS AND PAYMENTS: Although the clinic will not be able to provide care for other conditions they will help find care for such conditions if possible. There are no charges for the participant for this testing. or transportation costs for the use of public transit will be reimbursed.

Participant's Initials

RIGHT TO WITHDRAW: I understand that I am free to refuse to participate in this study or to withdraw at any time and that my decision will not adversely affect my care at this institution or cause a loss of benefits to which I might be otherwise entitled. I also understand that the investigator(s) may ask that I withdraw from the study.

COMPENSATION FOR ILLNESS OR INJURY: I understand that in the event of a physical injury or illness resulting from the research procedure no monetary compensation will be made, but any immediate emergency medical treatment which may be necessary will be provided. I can call the investigator to obtain information about treatment if it is needed.

VOLUNTARY CONSENT: I certify that I have read the preceding or it has been read to me and that I understand its contents. Any questions I have pertaining to the research have been and will be answered by the clinic staff. Any questions I have concerning my rights as a research subject will be answered by the Office of the Senior Vice President, Health Sciences (412-624-2396). A copy of this consent form will be given to me. My signature below means that I have freely agreed to participate in this experimental study.

Date

Patient/Subject Signature

Witness

I certify that I have explained to the above individual the nature and purpose, the potential benefits, and possible risks associated with participating in this research study, have answered any questions that have been raised, and have witnessed the above signature.

Date

Investigator Signature or designee

CONSENT TO RELEASE INFORMATION TO MY HEALTH CARE PROVIDERS

I do ___ do not ___ authorize the Cardiovascular Health Study and the SHHS to release the findings from tests and examinations to my physician, clinic, hospital.

Signature of Participant

CONSENT TO OBTAIN MY MEDICAL RECORDS

I do ___ do not ___ authorize the release of my medical records and/or the complete record of my hospitalization to the Cardiovascular Health Study at the University of Pittsburgh, Department of Epidemiology, Graduate School of Public Health. I request that this authorization remain valid for the duration of the study (1989-2000) unless I revoke the authorization in writing. I authorize you to accept a photocopy of this document as my official consent to release my medical records.

Signature of Participant/Next of Kin

Witness

Date

If next of kin, relationship



University of Pittsburgh

Health Sciences

Institutional Review Board for Biomedical Research

218 Nese Barkan Building Annex
c/o WPMC, 3811 O'Hara Street
Pittsburgh, Pennsylvania 15213
412-647-7644

TO: Lewis H. Kuller, M.D, Dr. P.H.
FROM: Richard L. Cohen, M.D., Chairman *R.L. Cohen*
DATE: April 11, 1995
RE: IRB #9406129: Cardiovascular Health Study

The Biomedical Institutional Review Board has reviewed the recent modifications to your protocol and consent form(s) and find them acceptable for expedited review. These changes are noted in your memo of 4/2/95.

The approval date on your consent form(s) should remain the same 6/16/94. Therefore, the protocol and consent form(s) together with a brief progress report must be resubmitted within a year from that time for annual review as required by the General Assurance No. M1259 given to DHHS by the University of Pittsburgh.

If any untoward events occur, please report them at once to the Board. Please refer to the above IRB number on all correspondence or telephone inquiries.

Two copies of your protocol and consent form(s) will be filed in our office. If your protocol involves the CRC, it is your responsibility to immediately forward to them a copy of your IRB approval and a complete protocol/consent form(s) packet.

If your research proposal involves an investigational drug, it is necessary for you to forward a copy of this approval letter along with a copy of the Cover Sheet, protocol, consent form(s) and drug brochure to Anna Giordano, R.Ph., Coordinator, Investigational Drug Service, PUH Pharmacy.

RLC/daw

Sacramento Informed Consent

CONSENT TO PARTICIPATE IN A RESEARCH STUDY,
UNIVERSITY OF CALIFORNIA, DAVIS

TITLE OF STUDY: Sleep Heart Health Study (SHHS)

INVESTIGATORS' NAMES, DEPARTMENTS, PHONE NUMBERS:

John A. Robbins, M.D., Internal Medicine, 734-5562

PURPOSE:

You have already agreed to participate in the Cardiovascular Health Study. We are asking that you additionally consent to participate in this second research which looks at problems with sleeping and the effects of these problems on your cardiovascular system.

PROCEDURE:

If you decide to volunteer, a monitor will be placed in your home by a technician. This monitor is about the size of a transistor radio. It has wires that are taped to your skin which measure your heart rate, respiratory rate and body position. You may either bring the apparatus to the clinic in the morning or a technician will come to your home to pick it up.

If the monitor shows that you do have significant breathing trouble when you sleep we will contact you and your primary physician.

ALTERNATIVES:

You may refuse to participate in this sleep study and this will in no way affect your participation in the Cardiovascular Health Study.

RISKS:

There are minimal risks associated with this study. No tissue or blood samples are taken. You could get tangled in the wires, but those are the only risks.

BENEFITS:

Society will benefit from your participation. We will gain information about how problems with sleeping may affect heart disease, stroke and other vascular problems. Personally you may benefit if we discover that you have problems with your sleep which may affect your cardiovascular health. If this is the case we will refer you to your physician who may be able to help you with these problems. This could be very beneficial to your health.

Initials _____

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CONFIDENTIALITY:

In the report of this study your name will not be specifically mentioned. This research may also eventually be published in medical journals, and again, your name will not be furnished. Absolute confidentiality cannot be guaranteed since research documents are not protected from subpoena.

COSTS/COMPENSATION:

You will not be billed for any of the tests which we carry out. In the very unlikely event that you are physically injured as a result of the research procedures not done primarily for your own benefit, you will receive medical treatment at no cost. The University of California does not provide any other form of compensation for injury.

RIGHT TO REFUSE OR WITHDRAW:

You may refuse to participate and still receive the care you would receive if not in the study. You may change your mind about being in the study and quit after the study has started. Sudden withdrawal from this study will not constitute a health hazard.

QUESTIONS:

If you have any questions, please ask us. If you have additional questions later, Dr. John Robbins or one of his associates will be happy to answer them. Please telephone us at 734-5562. You will be given a signed and dated copy of this form to keep. You will also be given a copy of the Experimental Subject's Bill of Rights.

YOUR SIGNATURE BELOW WILL INDICATE THAT YOU HAVE DECIDED TO VOLUNTEER AS A RESEARCH SUBJECT AND THAT YOU HAVE READ AND UNDERSTOOD THE INFORMATION PROVIDED ABOVE, AND THE BILL OF RIGHTS.

Date Signature of participant or legal representative

Date Signature of investigator

Initials _____

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Tucson Informed Consent-- with monetary compensation

SUBJECT'S CONSENT FORM

STUDY TITLE: Sleep Heart Health Study

INVESTIGATORS:

Stuart Quan MD, Paul Enright MD, Michael Lebowitz PhD

SPONSORS: National Heart, Lung and Blood Institute and the National Sleep Center

I AM BEING ASKED TO READ THE FOLLOWING MATERIAL TO ENSURE THAT I AM INFORMED OF THE NATURE OF THIS RESEARCH STUDY AND OF HOW I WILL PARTICIPATE IN IT. IF I CONSENT TO DO SO, SIGNING THIS FORM WILL INDICATE THAT I HAVE BEEN SO INFORMED AND THAT I GIVE MY CONSENT. FEDERAL REGULATIONS REQUIRE WRITTEN INFORMED CONSENT PRIOR TO PARTICIPATION SO THAT I CAN KNOW THE NATURE AND THE RISKS AND CAN DECIDE TO PARTICIPATE OR NOT PARTICIPATE IN A FREE AND INFORMED MANNER.

PURPOSE

I am being asked to participate in the University of Arizona's Sleep Heart Health Study. The purpose of this project is to learn more about how breathing disturbances during sleep affect a person's risk of developing heart disease or stroke. The results of this study will allow the investigators to determine whether people with breathing disturbances during sleep are at greater risk for developing heart disease or stroke.

SELECTION CRITERIA

I am being asked to participate because I am currently enrolled as a subject in the Specialized Center Of Research (SCOR) Study in Airways Obstructive Disease. I am at least 40 years of age. Approximately 6000 subjects will be enrolled nationwide. Approximately 900 subjects will be enrolled at the University of Arizona.

PROCEDURE

If I agree to participate, I will be asked to agree to the following. I will undergo a home sleep study and complete additional brief questionnaires. I understand that a home sleep study involves being connected to a special battery-operated monitoring device by several wires and sensors. Technicians will visit my home on the evening of the home sleep study. They will ask me to fill out additional questionnaires and then connect me to the sleep monitoring device. Wires using washable paste will be connected to the surface of my scalp, on the sides of my forehead and underneath my chin in order to record how well I am sleeping. Wires will be connected over the front of my chest using easily removable adhesive disks to monitor my heart rhythm and rate. Light-weight belts will be fitted around my chest and abdomen and a sensor will be taped under my nose to assess my breathing efforts. An additional sensor will be taped on one of my fingers to measure the oxygen level

in my blood during the night. All of these wires and sensors will be connected to the sleep monitor which will be located at my bedside. The technicians will leave my home after they have finished connecting me to the sleep monitor. They will leave with me a brief questionnaire to complete after I awaken in the morning. I will attempt to sleep in my usual manner. I understand that I will be able to get up and move about during the night. Furthermore, if absolutely necessary, I will be able to disconnect myself completely from the device before the night is over. After I awaken in the morning, I will disconnect myself from the device. I understand that at a mutually agreeable time, a technician will return to my home to collect the device and the questionnaire.

After completion of the home sleep study, I will be periodically contacted over the next several years to inquire about my health.

It may be necessary for me to sign a release so that the investigators can obtain some of my medical records for review.

RISKS

I understand that there is no known medical risk to the home sleep study which currently is used to diagnose sleep disorders. Approximately 33% of subjects report a moderate degree of difficulty sleeping during the night of the monitoring. Adhesive disks and tape are used to attach sensors and wires to the skin; when removed, they may cause some very temporary pain, may remove some hair, and may leave a small area of red skin which is painless and resolves within a few days. The paste used to attach the wires to the scalp, adjacent to the eyelids and underneath the chin will require removal with simple soap and water.

BENEFITS

Information about my sleep will be mailed to me 4-6 weeks after the study is completed. In addition, this information will be provided to my physician if I so desire.

CONFIDENTIALITY

My participation in this study will be treated as confidential. Any records or results relating to the study will be used only by the investigators for scientific purposes and my name will not be used in any reports that might be published.

PARTICIPATION COSTS AND SUBJECT COMPENSATION

There are no costs to me for participating in this study. A check for \$25.00 will be mailed to me 4-6 weeks after the study is completed as compensation for my participation.

LIABILITY

I understand that side effects or harm are possible in any research program despite the use of high standards of care and could occur through no fault of mine or the investigator involved. Known side effects have been described in this consent form. However, unforeseeable harm may also occur and require care. I understand that money for research-related side effects or harm, or for wages or time lost, is not available. I do not give up any of my legal rights by signing this form. Necessary emergency medical care will be provided without cost. For further information or in the event of research related injury, I can contact Dr. Stuart Quan at 626-6115, Dr. Paul Enright at 626-6114 or Dr. Michael Lebowitz 626-6379. If I have questions concerning my rights as a research subject, I may call the Human Subjects Committee office at 626-6721.

If I should withdraw voluntarily from the study or am asked by the doctor to leave the study, I must return all equipment used by the study.

AUTHORIZATION

BEFORE GIVING MY CONSENT BY SIGNING THIS FORM, THE METHODS, INCONVENIENCES, RISKS AND BENEFITS HAVE BEEN EXPLAINED TO ME AND MY QUESTIONS HAVE BEEN ANSWERED. I UNDERSTAND THAT I MAY ASK QUESTIONS AT ANY TIME AND THAT I AM FREE TO WITHDRAW FROM THE PROJECT AT ANY TIME WITHOUT CAUSING BAD FEELINGS OR AFFECTING MY MEDICAL CARE. MY PARTICIPATION IN THIS PROJECT MAY BE ENDED BY THE INVESTIGATOR FOR REASONS THAT WOULD BE EXPLAINED. NEW INFORMATION DEVELOPED DURING THE COURSE OF THIS STUDY WHICH MAY AFFECT MY WILLINGNESS TO CONTINUE IN THIS RESEARCH PROJECT WILL BE GIVEN TO ME AS IT BECOMES AVAILABLE. I UNDERSTAND THAT THIS CONSENT FORM WILL BE FILED IN AN AREA DESIGNATED BY THE HUMAN SUBJECT'S COMMITTEE WITH ACCESS RESTRICTED TO THE INVESTIGATORS: DR. STUART QUAN, DR. PAUL ENRIGHT AND DR. MICHAEL LEBOWITZ OF THE RESPIRATORY SCIENCES CENTER. I UNDERSTAND THAT I DO NOT GIVE UP ANY OF MY LEGAL RIGHTS BY SIGNING THIS FORM. A COPY OF THIS SIGNED CONSENT FORM WILL BE GIVEN TO ME.

Subject's signature: _____

Signature of Witness: _____

Date: _____

INVESTIGATOR'S AFFIDAVIT

I have carefully explained to the subject the nature of the above project. I hereby certify that to the best of my knowledge the person who is signing this consent form understands clearly the nature, demands, benefits and risks involved in participation, and the signature is legally valid. A medical problem of language or educational barrier has not precluded this understanding.

Investigator: _____

Date: _____

Tucson Informed Consent -- no monetary compensation

SUBJECT'S CONSENT FORM

STUDY TITLE: Sleep Heart Health Study

INVESTIGATORS:

Stuart Quan MD, Paul Enright MD, Michael Lebowitz PhD

SPONSOR: National Heart, Lung and Blood Institute and the
Center

National Sleep

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BENEFITS

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CONFIDENTIALITY

My participation in this study will be treated as confidential. Any records or results relating to the study will be used only by the investigators for scientific purposes and my name will not be used in any reports that might be published.

PARTICIPATION COSTS AND SUBJECT COMPENSATION

There are no costs to me for participating in this study, nor will I be paid for my enrollment.

LIABILITY

I understand that side effects or harm are possible in any research program despite the use of high standards of care and could occur through no fault of mine or the investigator involved. Known side effects have been described in this consent form. However, unforeseeable harm may also occur and require care. I understand that money for research-related side effects or harm, or for wages or time lost, is not available. I do not give up any of my legal rights by signing this form. Necessary emergency medical care will be provided without cost. For further information or in the event of research related injury, I can contact Dr. Stuart Quan at 626-6115, Dr. Paul Enright at 626-6114 or Dr. Michael Lebowitz 626-6379. If I have questions concerning my rights as a research subject, I may call the Human Subjects Committee office at 626-6721.

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Investigator: _____

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