PREVENTION AND TREATMENT OF HYPERTENSION STUDY (PATHS)

VETERANS AFFAIRS COOPERATIVE STUDY #996

A Collaborative Program of the NHLBI, NIAAA, and the VA Cooperative Studies Program

OPERATIONS MANUAL

JULY, 1991

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FIGURES/TABLES

I. PURPOSE OF THE OPERATIONS MANUAL

This Operations Manual describes the detail of personnel responsibilities, study procedures and instructions for completing data forms for the VA Cooperative Study #996, "Prevention and Treatment of Hypertension Study (PATHS)." As a complement to the original study proposal, the Operations Manual emphasizes those day to day activities required of personnel in order to complete a successful study. The Operations Manual should be used by the study personnel at each site as a reference covering most routine aspects of the study and problems that are likely to occur. However, should questions arise, the Chairman's Office should be contacted for clarification and assistance.

Lastly, use of the Manual should insure that procedures will be done as uniformly as possible in all participating sites. **Therefore, all study personnel should carefully read and understand the contents of both the original study proposal and this Operations Manual.**

II. STUDY OVERVIEW

Alcohol consumption of three or more drinks per day has been recognized as an important correlate of blood pressure in many epidemiologic studies, but few interventional studies have been conducted to examine the effect of a reduction in alcohol intake on blood pressure, and these have been of insufficient size or duration to allow definitive conclusions. Therefore, in collaboration with the National Heart, Lung and Blood Institute (NHLBI) and the National Institute on Alcohol Abuse and Alcoholism (NIAAA) we are conducting a prospective randomized controlled VA cooperative study to determine whether blood pressure is lowered over six months of alcohol moderation in nondependent heavy drinkers (three or more drinks per day average) with above average normal (80-89 mm Hg) and mildly hypertensive (90-99 mm Hg) levels of diastolic blood pressure, and to determine whether a reduction in alcohol intake can be maintained for two years. During the first 1.5 years, the study will be conducted (Phase I) at four VA medical centers (Baltimore, Jackson, New York and Phoenix) in order to assess recruitment and alcohol intake reduction success: 116 male veterans meeting the entry criteria will be randomized to either an alcohol reduction intervention group or a control observation group. If recruitment and the intervention technique are judged to be successful, then up to three additional centers (St. Louis, West Haven and Minneapolis) will be added in order to randomize 464 additional participants in the seven centers, and complete the study in 3.5 additional years (Phase II), for a total of 580 participants and five years duration. Alcohol intake will be monitored by self-reports using a retrospective diary (Chronological Drinking Record) and by various biochemical markers, such as apolipoproteins, HDL cholesterol, and carbohydrate deficient transferrin, which will be analyzed at a central laboratory. The alcohol intervention technique has been developed and will be overseen by the NIAAA. Echocardiograms will be performed to assess the effects of blood pressure and alcohol intake changes on left ventricular mass, and will be monitored and analyzed in a central laboratory.

III. OBJECTIVES OF THE STUDY

A. Primary Objectives

1. To determine whether systolic and diastolic blood pressure are lowered after six months of alcohol moderation compared to no intervention in nondependent moderate to heavy drinkers with diastolic blood pressure between 80 and 99 mm Hg.

2. To determine whether systolic and diastolic blood pressure are lowered independently in the mildly hypertensive stratum (90-99 mm Hg diastolic, or 80-89 mm Hg if on antihypertensive medication when initially screened) over six months.

3. To determine whether a reduction in alcohol intake can be achieved at six months and can be maintained for two years.

B. Secondary Objectives

1. To determine whether a dose response relationship exists between blood pressure change and changes in self-reported alcohol intake and/or biochemical markers of alcohol intake, controlling for weight, heart rate, exercise, urinary sodium and potassium, and dietary intake of calcium and other nutrients, in each treatment group and in both groups combined.

2. To determine whether there is a difference between the treatment and control groups in terms of echocardiographic left ventricular mass changes at six months compared to baseline, and to determine whether a dose response relationship exists between changes in blood pressure, self-reported alcohol intake and/or biochemical markers of alcohol intake and changes in left ventricular mass.

3. To determine if drug treatment for hypertension is required at a lower rate in the intervention group compared to the control group over two years.

4. To determine the relationship between changes in self-reported alcohol intake (by retrospective diary) and changes in the following biochemical markers: apolipoprotein A_1 and A_2, HDL (and HDL_2 and HDL_3) cholesterol, gamma glutamyltransferase (GGT) and carbohydrate-deficient transferrin (CDT).

IV. ORGANIZATION AND ADMINISTRATION

The successful completion of this cooperative study will depend on the coordinated support of a variety of research components including: several participating medical centers, the Study Chairman's office, the NHLBI and NIAAA project offices, the coordinating center and several central laboratories. This section will review the organizational structure (Figure 1) for this study and the responsibilities of these various components. Appendix A is a directory identifying individuals with major responsibilities in each of these components.

A. Office of the Study Chairman

Overall leadership will be provided by the Study Chairman who will be located at the Memphis, Tennessee VA Medical Center. This office will include a full-time Study Coordinator and a full-time study secretary. The primary responsibilities of this office are as follows:

1. To maintain surveillance over the study program so as to guarantee implementation of the scientific and procedure requirements of the study protocol by the participating centers; and to monitor in a general way that all study activities are in compliance with CSP policies as set forth in the Guidelines for VA Cooperative Studies.

2. To maintain current records and to review completed study forms for all study patients.

3. To organize and plan for regularly scheduled study meetings. This will involve the selection of dates and the development of an agenda.

4. To assist the Study Biostatistician in developing and monitoring study center performance.

5. To insure that all study personnel are adequately trained in study operating procedures and that the required levels of standardization across centers are being adequately met.

6. To develop and coordinate with the study committees those policies by which publication of study results will be undertaken.

7. To provide for dissemination of news regarding ongoing study progress through a periodic newsletter.

B. Cooperative Studies Program Coordinating Center (CSPCC)

The coordinating center (CSPCC) for this cooperative study is located at the VA Medical Center, Perry Point, Maryland. The CSPCC is organized into sections and staffed with specialists in administration, biostatistics, statistical computing, and data processing. A study team comprised of individuals from each of the sections has been involved in the study from the initiation of planning. The primary responsibilities of the CSPCC are as follows:

1. To coordinate all administrative activities of the study.

2. To provide for all data processing needs of the study including: keyentering and keyverifying study data; maintaining files of patient records; developing computerized editing systems to insure data quality; and developing a data base management system for monitoring data flow, for error reporting and for data retrieval.

3. To develop statistical computing software for study randomization, all study interim reports, and final statistical analysis.

4. To collaborate with the study investigators in the biostatistical interpretation of study results including preparation of manuscripts for publication.

5. To provide budget guidelines; to coordinate budget requests; and to review special funding requests.

6. To print and disseminate study data collection forms.

C. Participating Medical Centers

There are seven participating medical centers in this cooperative study. Overall leadership at each center will be provided by the Participating Investigator (PI). The study team will include a Data Collector, an Interventionist and a Secretary. Both the Data Collector and Interventionist will be actively involved in screening individuals for entry into the study. The Data Collector who will be blinded with regard to participants' treatment groups will be solely responsible for collecting follow-up data. The Interventionist will be solely responsible for administering the alcohol intake reduction program to participants who are assigned to the intervention group. The primary responsibilities of each participating center are as follows:

1. To provide office space and other facilities required for screening visits, for follow-up visits, and for intervention visits.

2. To implement operational procedures using guidelines in this operations manual.

3. To apply strategies that will insure that eligible participants are located and enrolled in the study so that sample size requirements are met.

4. To assure that study participants are seen for required follow-up visits and that all study forms are completed accurately.

5. To assure that all study participant records are kept current and accurate and that all study forms are mailed to the Study Chairman's office and the CSPCC according to the data handling guidelines presented in this operations manual (see Section XVI.).

6. To obtain specimens for central laboratory analyses and echocardiograms for central reading and to submit these materials using procedures specified by the central labs.

7. To maintain regular contact with the Study Chairman's office in order to provide current status reports of ongoing study operations.

D. NHLBI and NIAAA Project Offices

The project offices will review the progress of the study for their institutes and will provide leadership within the study. They will also facilitate the transfer of study funds to the Department of Veterans Affairs.

E. Cooperative Studies Program Central Office

The Cooperative Studies Program Central Office will distribute study funds to the participating medical centers. It will also periodically review the progress of the study and will coordinate the review of the results of the feasibility phase by the Cooperative Studies Evaluation Committee.

F. Central Echocardiogram Laboratory

The Central Echocardiogram Laboratory is located at Georgetown University and will provide training for echocardiography technicians who will be obtaining echocardiogram recordings for study participants. It will provide for central reading of study echocardiograms and will provide results to the CSPCC.

G. Central Lipid Laboratory

The Central Lipid Laboratory is located at the Washington VA Medical Center. Its primary responsibilities will be to analyze specimens from study participants for levels of various alcohol markers and to send these results to the CSPCC.

H. Study Committees

1. Executive Committee

The Executive Committee is the major decision-making body with a primary responsibility for study management. The membership of this committee will include the study chairman, the study biostatistician, the directors of the central laboratories, the PI from each of the participating medical centers and the project officers from NHLBI and NIAAA. The committee directs the operational aspects of the study, decides on all proposed changes in the protocol and on any subprotocols that gain

interest, as well as deciding on all uses of study data. The committee will make all decisions regarding publication policies. In a monitoring role, the committee will exercise the responsibility of dealing with under-performing centers, problems associated with data quality and failure to comply with protocol requirements. At the end of the feasibility phase, it will be responsible for selecting additional centers.

2. Data and Safety Monitoring Board

The Data and Safety Monitoring Board will be responsible for reviewing the progress of the study and making recommendations about any significant changes such as early termination. It will review the data collected during the initial feasibility phase of the study and will be particularly concerned at that time with the effect of the alcohol intervention and with recruitment of participants. If it decides to recommend that the study should continue, it will then review the Executive Committee's decision about adding additional centers. The Data and Safety Monitoring Board will include a biostatistician, a cardiovascular epidemiologist, experts in clinical hypertension, alcohol research and nutrition, a behavioral scientist and ex-officio, nonvoting representatives of the supporting agencies.

3. Human Rights Committee

The Human Rights Committee will be responsible for reviewing this study at least once a year to ensure that participants' rights and safety are protected in this study. They are independent of, but will meet with, the Data and Safety Monitoring Board.

4. Cooperative Studies Evaluation Committee

The Cooperative Studies Evaluation Committee (CSEC) will exercise an important responsibility in monitoring this study. This committee is responsible for reviewing all proposed VA cooperative studies. Its approval was required before initiating this study. In addition, CSEC will review the recommendations of the Data and Safety Monitoring Board at the conclusion of the feasibility phase. A positive recommendation from CSEC and the concurrence of the Directors of the NHLBI, NIAAA and the Veterans Health Services and Research Administration will be required before proceeding to the full-scale trial.

V. BIOSTATISTICAL CONSIDERATIONS

A. Outcome Variables

The primary outcome measurements are changes in systolic blood pressure and in diastolic blood pressure from baseline to the six-month visit. Analysis of covariance adjusting for baseline values will be used to determine statistically significant differences between the two treatment groups. The analysis will be performed using the intention-to-treat principle; all randomized participants with any follow-up data will be included. The final treatment blood pressure will be as defined in Section VIII.A.4. For individuals who are put on antihypertensive medication during the study, their final blood pressure will be calculated using the BP measurements prior to medication. A secondary analysis using the six-month visit data for all participants, regardless of protocol status, will also be performed. Differences in six-month blood pressure will also be tested in the mildly hypertensive stratum alone. Furthermore, the treatment differences in the two strata (a strata by treatment interaction) will be tested.

Evaluation of differences in blood pressure at two years will be difficult because there may be a substantial difference between groups with regard to initiation of antihypertensive medication. However, we will be able to compare the proportions and determine if the difference is statistically significant. Survival analysis techniques will also be used to evaluate this data.

The alcohol intervention will be evaluated using self-report. Individuals will be asked to quantify their alcohol use at baseline, at six months, and at two years. Those participants who have at least a 50% reduction in alcohol consumption between baseline and evaluation will be labelled "successes," those with less than a 50% reduction will be labelled as "failures." Participants with missing data will be labelled as "failures." Tests comparing the proportion of successes in the two groups will be conducted for both the six-month and two-year evaluations. Techniques of regression analysis will be useful in exploring the dose-response relationship between change in blood pressure and change in alcohol intake. Partial correlations will be used to examine the strength of this relationship after adjusting for other changes (such as weight) that may also occur.

In addition, a series of biochemical markers of alcohol use will be measured at baseline, at six months, and at two years. The following measurements will be taken: apolipoprotein A_2, apolipoprotein A_1, gamma GT, CD transferrin, and HDL. Analysis of covariance will be used to evaluate

differences in these measurements between the two groups. The primary biochemical marker of interest will be apolipoprotein A_2. In addition, relationships among the alcohol intake indices will be explored.

Analysis of covariance will be used to evaluate differences in left ventricular mass between the two groups. Participants who are not "echoable" at baseline will be excluded from analysis. The dose-response relationship between changes in blood pressure and alcohol intake and changes in left ventricular mass will be examined.

Participants who go on antihypertensive medication will continue to be followed in the study. For both the alcohol and echocardiogram variables, they will be treated the same as the other participants. However, for evaluation of blood pressure, measurements obtained after the start of antihypertensive medication will not be used.

Since some subgroups may respond more than others, subgroup analyses will be performed to tentatively identify some of them. Such analyses are exploratory and not confirmatory and will be reported as such. One interesting subgroup would be those participants who are at least 55 years old.

B. Sample Size

All sample sizes are calculated to provide 90% power for two-sided tests at the alpha = .05 level.

1. Blood Pressure

The main end point is the change in blood pressure from baseline to the six-month visit. Blood pressure will be measured two times at each visit. Using estimates of variance components we can expect a standard deviation (s) in diastolic blood pressure change of about 7 mm Hg. The corresponding standard deviation for systolic blood pressure is about 11 mm Hg. We are interested in detecting differences (δ) of two mm Hg in DBP and of three mm Hg in SBP for the entire sample. We also require good power for detecting differences of 3 and 4.5 mm Hg for DBP and SBP respectively for those participants in the upper stratum (baseline DBP 90-99 mm Hg). Total sample size requirements can be calculated using the formula,

$$N = 4\left[\frac{(z_{.025} + z_{.1})}{\delta}\right]^2,$$

where $z_{.025}$ and $z_{.1}$ are obtained from the standard normal distribution. Requirements would be 516 for DBP and 566 for SBP for the entire sample and 230 for DBP and 252 for SBP for the upper stratum.

2. Self-Report of Alcohol Intake

In order to assess the effectiveness of the intervention in reducing alcohol intake, participants will be asked about their changes in drinking behavior. If 20% of the control group participants and 60% of the intervention group participants report a 50% decrease in alcohol consumption after six months, we would need 78 participants in both groups combined to detect this difference with 90% power. A difference of this magnitude would be detected during the feasibility phase of the study. A smaller difference would be expected after two years of follow-up. If half of these participants (10% vs. 30%) maintain this reduction after two years, then 202 participants would be required.

3. Biochemical Marker of Alcohol Intake: Apolipoprotein A_2

We estimate that the correlation (r) between change in alcohol intake and change in apolipoprotein A_2 is .61, the standard deviation of change in apolipoprotein is about 5 mg %, and the standard deviation of change in alcohol intake is about 18 g/day. Since the slope (b) of a linear regression equation relating two variables, x and y, can be calculated using the formula,

$$b = r_{XY} \frac{s_X}{s_Y},$$

then we can also calculate that a change of 30 g/day in alcohol intake would imply a change in apolipoprotein A_2 of 5.1 mg %. In order to detect a difference of 5.1 mg % with a standard deviation of 5 mg %, a total sample size requirement of 42 can be obtained from the formula in Section V.B.1.

4. Conclusions

It appears from these sample size calculations that a total sample size of about 580 will be sufficient to test blood pressure changes. Since all randomized participants with any follow-up data will be included in this analysis, the dropout rate is expected to be very low (<2%) and to have little effect on power. Therefore, no adjustment for dropouts is necessary. Furthermore, if the mildly hypertensive (upper) stratum includes at least 260 participants, there will be good power for detecting the desired difference within this stratum. It also appears that the alcohol intervention can be assessed with ample power after the first 80 participants have completed the six-month study. Generalizability of the study results will be limited if there are few participants in the lower stratum. To obtain adequate power in the upper stratum and to support generalizability with regard to the lower stratum, recruitment will be monitored so that at least 200 participants will be in the lower stratum and at least 260 in the upper stratum.

VI. STUDY DESIGN

A. Participant Progress Through the Study

This study is divided into three phases:

1. Prerandomization screening phase
2. Initial treatment phase
3. Maintenance Phase

Each phase is described in Sections IX-XI individually and summarized in this section (see Figure 2 and Table 1).

B. Design Summary

This is a prospective, randomized, parallel study comparing the effects on blood pressure and other end points of an intervention to produce alcohol moderation versus nonintervention in nondependent moderate to heavy drinkers ($\geq$21 drinks/week) with upper normal (80-89 mm Hg) and mildly hypertensive (90-99 mm Hg) levels of diastolic blood pressure off antihypertensive medications (Figure 2). The screening process is summarized in Figure 3 and is described in detail in Section IX.C. Ambulatory male and female veterans who are considered potential participants, primarily based on a brief self-administered prescreening questionnaire, will be invited to attend three screening visits. If they are on antihypertensive medications prior to entry into the study, these medications will be discontinued before beginning the screening phase (see Section IX.B). Baseline evaluations during this phase will include: medical history; blood pressure, weight and heart rate determinations; physical examination; local and central laboratory studies; psychosocial and health habits assessment; dietary and physical activity assessments; assessment of alcohol intake and alcohol dependence; and echocardiogram. If a participant meets the inclusion criteria, he will be randomized either to an intervention to reduce alcohol intake (to no more than 14 drinks per week and at least 50 percent less than his baseline level) or to a control condition. All participants will be followed for two years. If blood pressure exceeds certain safety criteria, open treatment of hypertension will be initiated, but the participant will remain in the study.

Due to the behavioral nature of the alcohol intervention, an open design is required. Those participants randomized to the control group will be scheduled for data collection visits only. Because of this design feature, particular care will be taken to maintain blindness to intervention assignments among clinic personnel involved in collecting the primary study data common to both groups.

To avoid differences in response to the BP measurement environment, data collection will take place in the same location for both randomization groups, and participants in the alcohol intervention group will be seen in a different location for the intervention sessions. Data collection visits will be at monthly intervals for the first six months and quarterly for the remaining 18 months. Data collection at each visit is indicated in Table 1.

A self-reported retrospective diary approach will be used to assess alcohol intake. In addition to alcohol intake history and locally determined laboratory measurements, biochemical markers will be determined in a Central Lipid Laboratory for GGT, HDL cholesterol with HDL_2 and HDL_3 subfractions, apolipoproteins A_1 and A_2, and CDT in order to validate changes in alcohol intake. These markers are more sensitive in combination and are more effective in detecting drinkers who report less or no drinking than are collateral reports. In addition, total cholesterol, LDL cholesterol and triglycerides will be measured and a urine drug screen will be performed. Alcohol history and central laboratory tests will be obtained during the baseline assessments and at the 3-, 6-, 12-, 18- and 24-month visits.

Echocardiograms will be performed during the baseline period and six months after randomization in order to assess the relationship between changes in alcohol intake and blood pressure and indices of left ventricular (LV) mass and function which have been shown to have predictive power for cardiovascular events and to be directly affected by heavy drinking.

FIGURE 1

Organizational Structure of PATHS

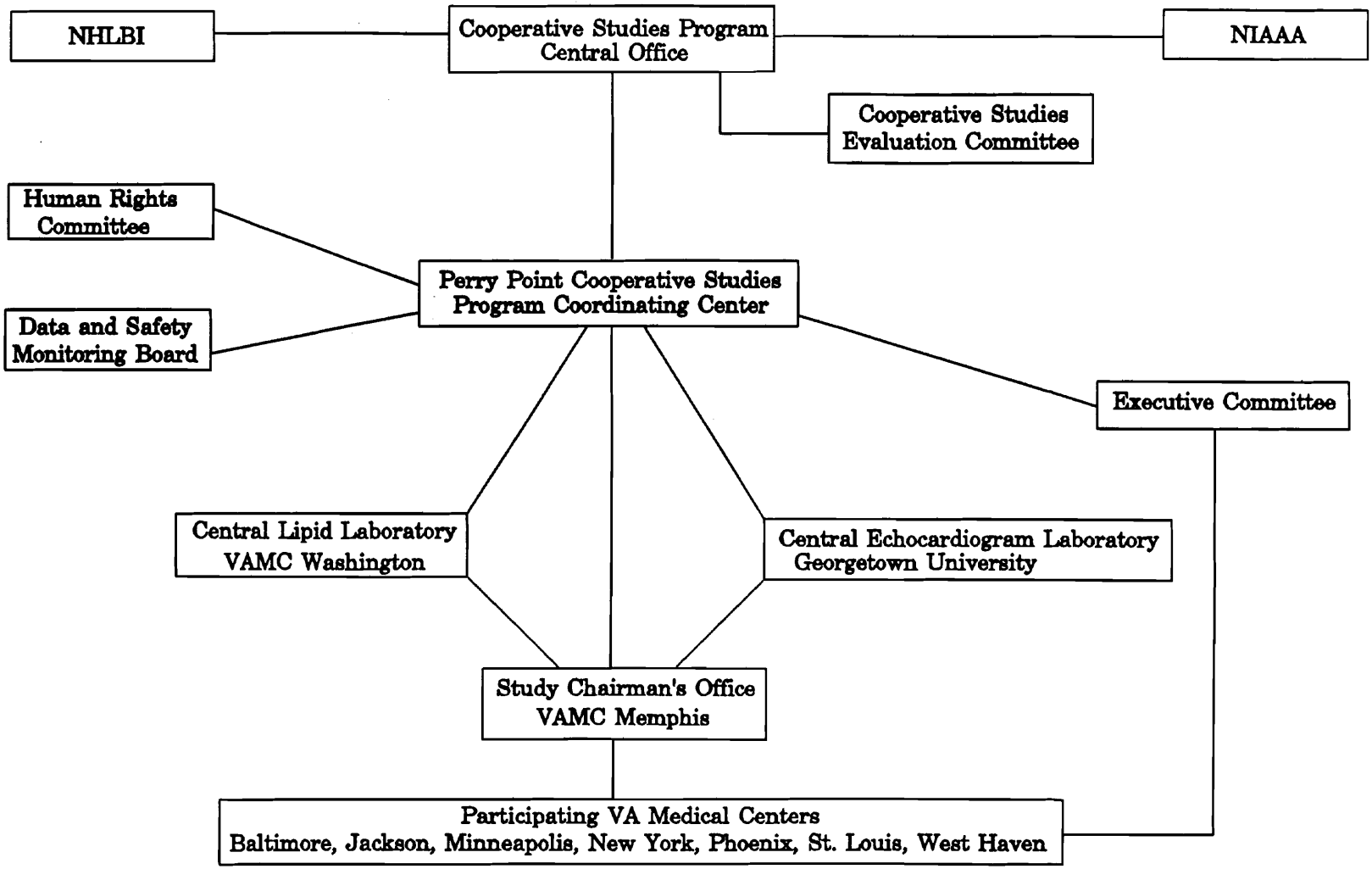


FIGURE 2

PATHS Schema

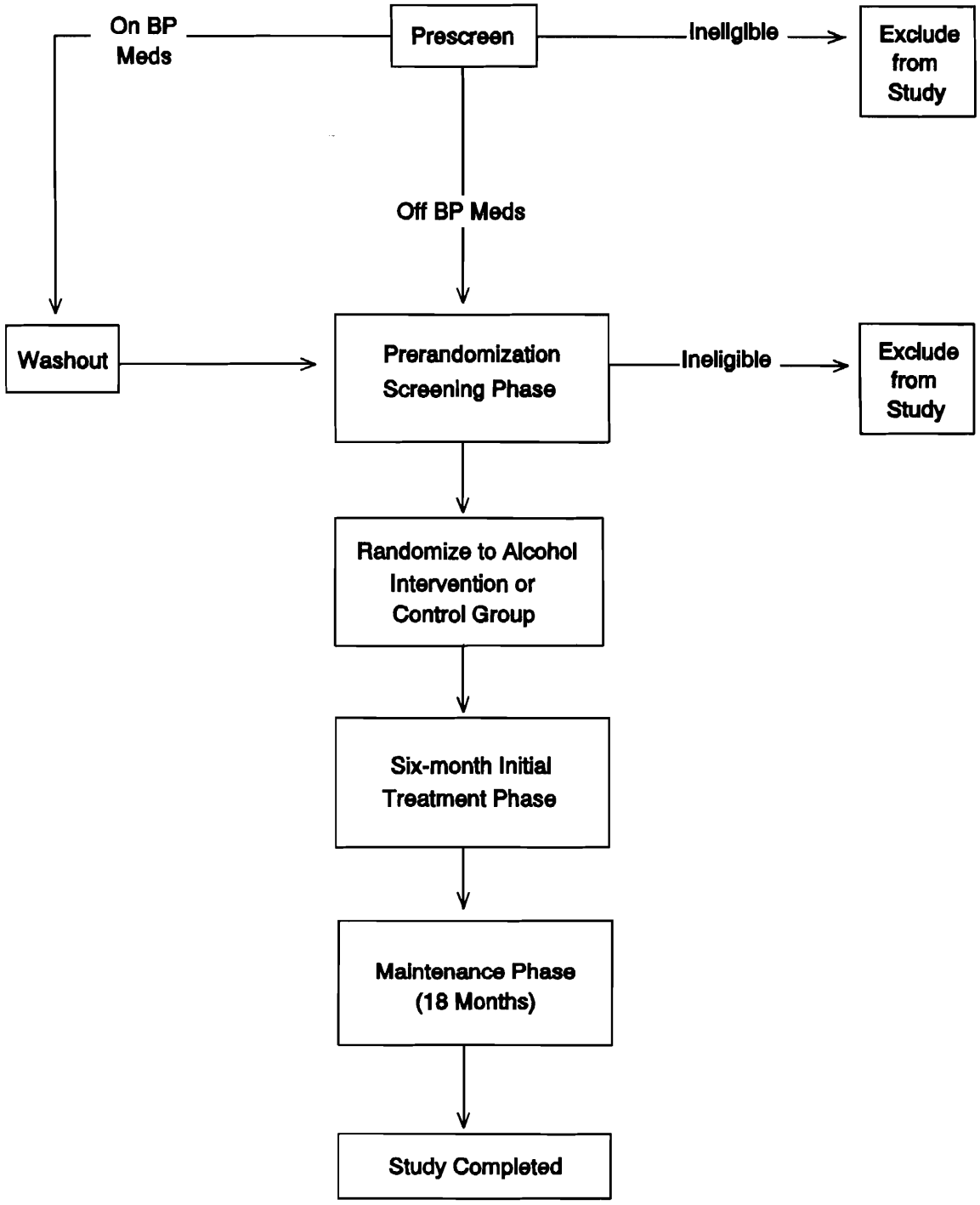


Table 1

Data Collection Schedule

		Screening Phase				Initial Treatment Phase						Maintenance Phase					
		VISIT															
		S1[1]	S2	S3		F1[2]	F2	F3	F4	F5	F6	F7	F8	F9	F10	F11	F12
	TIME[3]	0	2	4	R	1	2	3	4	5	6	9	12	15	18	21	24
ITEM	Form #				A												
Screening Consent	87	X			N												
Heart Rate, Blood					D												
Pressure, and					O												
Weight	2	X	X	X	M	X	X	X	X	X	X	X	X	X	X	X	X
Demographic Charac-					I												
teristics	3	X			Z												
Alcohol Use (ADS)	4	X			A												
Medical History	5	X			T												
Lifetime Drinking					I												
History	6		X		O												
Physical Activity	7		X		N						X		X		X		X
Psychosocial and																	
Health Habits	8		X								X		X		X		X
Beck Inventory	9		X								X		X		X		X
Local Lab	10		X								X		X		X		X
Drug Screen	10		X								X		X		X		X
ECG	10		X								X		X				X
Physical Exam	11			X													
Study Consent	88			X													
Diet Questionnaire	12			X				X			X		X		X		X
Chronological																	
Drinking Record	13			X				X			X		X		X		X
Central Lab	14			X				X			X		X		X		X
Overnight Urine	10			X							X		X		X		X
Echocardiogram	15				X						X						

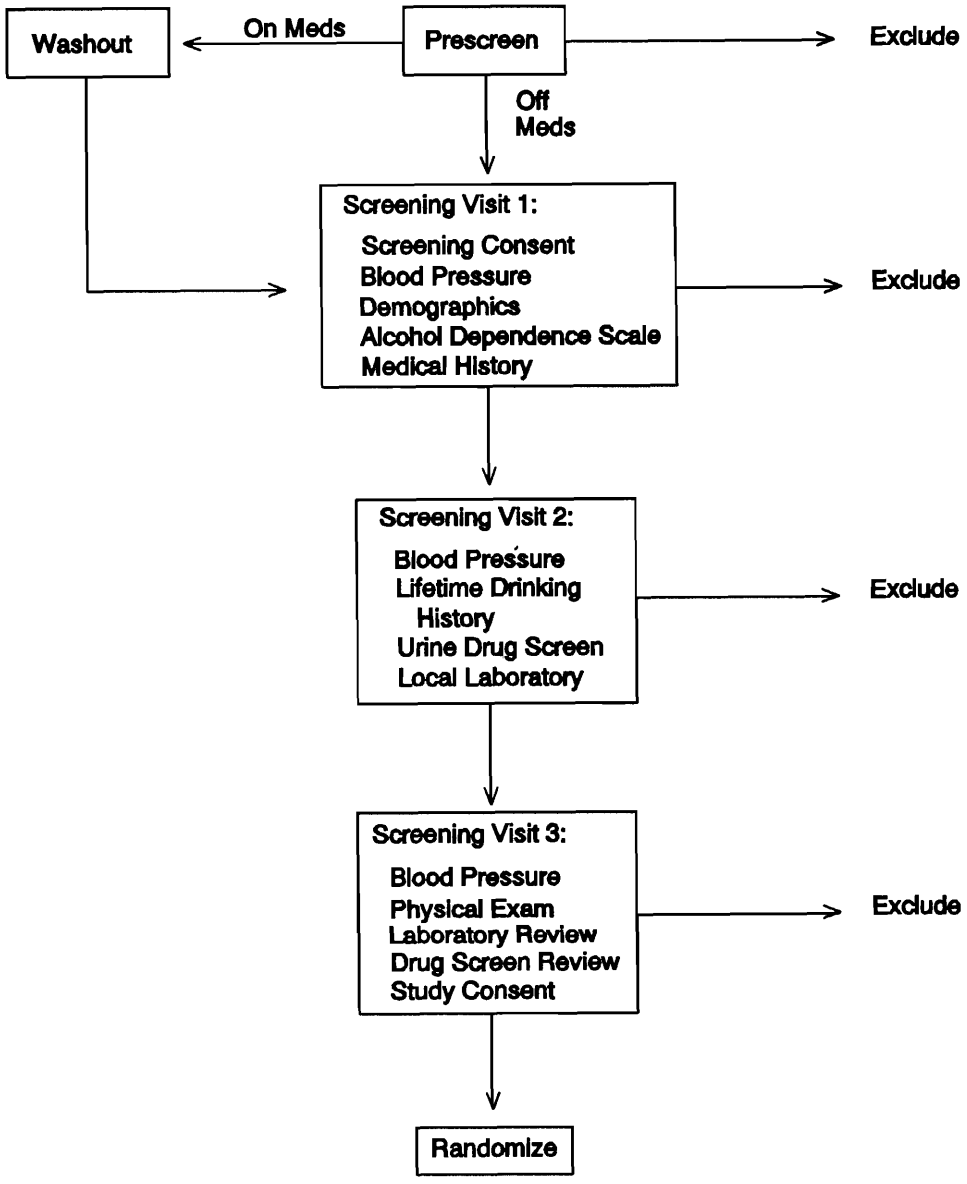
[1] S indicates a screening visit.

[2] F indicates a follow-up visit.

[3] Time of visit is weeks after first screening visit for screening visits and months after randomization for follow-up visits.

FIGURE 3

Flow Diagram for Screening
(Inclusion/Exclusion Procedures)



VII. INCLUSION AND EXCLUSION CRITERIA

A. Inclusion Criteria:

1. Male and Female Veterans: If a site encounters any difficulty about the administrative eligibility of some veterans for the study, reference should be made to VA Circular 10-89-58 (June 13, 1989). This circular states that any veteran, including Category A, B or C, is administratively eligible for participation in PATHS. Participants are not to be counted in the discretionary totals for categories B and C. See Appendix C for a complete copy of the circular.

2. Age: 25-79 Years

3. Moderate to Heavy Drinkers: To qualify for randomization, the consumption of alcohol must average at least 3 drinks per day (21 drinks [294 grams] per week) over the previous six months as documented by the Lifetime Drinking History (LDH) questionnaire at screening visit 2.

4. Blood Pressure: Average untreated blood pressure over three visits must be between 80 and 99 mm Hg, inclusive, diastolic and $\leq$179 mm Hg systolic.

5. Informed Consent: Appropriate informed consent must be obtained.

B. Exclusion Criteria

Individuals must be excluded for factors or conditions that would interfere with the objectives of the study or which could produce significant morbidity during the course of the study. Table 2 summarizes these items and also provides a reference to those forms and items within forms that would be used to document exclusions. Table 3 indicates which forms and which items within forms contain information that might be used to exclude individuals. The Exclusion section of Form 20 must be completed for all screened individuals who are excluded, except for those who are excluded on the basis of information reported on Form 1. Codes to be used on Form 20 are included in Table 2.

1. Alcohol Dependence: Meets criteria for alcohol dependence using the Alcohol Dependence Scale (ADS). Individuals meeting the criteria for alcohol dependence (score $\geq$5) will be

referred for further evaluation and treatment of their alcohol dependence.

2. Psychoactive Substance Dependence: Diagnosed psychoactive substance dependence, at any time during the year prior to recruitment. Participants who test positive on a urine drug screen will be further examined and, if dependence is indicated, excluded.

3. Direct Alcohol-Attributed Medical Conditions

   a. Acute or chronic liver disease, including biopsy-proven cirrhosis or alcoholic hepatitis. Specific, single exclusionary findings include jaundice (bilirubin >2.5 mg%), hypoalbuminemia (<3.0 g%), hypoprothrombinemia (PT>3 seconds over control), ascites, encephalopathy or varices.

   b. Pancreatitis, acute or chronic: An acute attack within the previous three years or documented chronic pancreatitis.

   c. Peripheral neuropathy.

   d. Cerebellar dysfunction.

   e. Significant cognitive deficits secondary to alcohol excess: Wernicke's or Korsakoff's syndrome or other alcohol-induced organic brain syndrome.

   f. Current megaloblastic (or megalocytic) anemia, with both hematocrit <37% and the MCV >102 cu microns.

   g. Alcohol related upper gastrointestinal bleeding in the past year.

4. Diagnosed Psychiatric Conditions (current or history of [by participant or in prior medical record])

   a. Major psychotic disorder, requiring medication for control.

   b. Major affective disorder, requiring medication for control.

c. Major personality disorder, expected to impair reliable participation in the study.

d. Severe anxiety disorder.

5. Cardiovascular Diseases

a. Unable to withdraw contraindicated medications (see Section XVIII).

b. Hypertensive retinopathy greater than K-W group II, current or history of.

c. Cerebral or subarachnoid hemorrhage, history of.

d. Atherothrombotic stroke or myocardial infarction, within the six-month period prior to recruitment.

e. Symptomatic ischemic heart disease.

f. Current atrial fibrillation or other significant dysrhythmia that would preclude accurate blood pressure measurement or is indicative of serious underlying heart disease.

g. Current congestive heart failure (CHF), as evidenced by at least two of the following:
   1) recent dyspnea or orthopnea not of pulmonary origin;
   2) ventricular diastolic gallop (S_3);
   3) basal pulmonary rales;
   4) evidence of congestive heart failure on chest x-ray.

If signs are controlled with digoxin, patient may be included. However, if a diuretic and/or an angiotensin converting enzyme inhibitor is required or indicated for CHF, the patient must be excluded (since these are also antihypertensive medications).

h. Surgically curable or other secondary forms of hypertension.

6. Other

a. Malignancies or other diseases that are likely to be fatal or disabling during follow-up.

b. Seizure disorder.

c. Coagulopathies, bleeding diatheses or any condition being treated with anticoagulants.

d. Blood pressure outside of screening range.

e. Unable or unwilling to participate.

f. Anticipates moving/relocating out of area within six months.

g. Current pregnancy.

Table 2

ITEM	EXCLUSION CODE*	FORM (ITEM)
1. Alcohol Dependence	100	4
2. Psychoactive substance dependence (within previous year).	200	5(12), 8(22,26,28,29,31, 33,34), 10(35-37), 11(1)
3. Direct alcohol-attributed medical conditions:		
a. Acute or chronic liver disease:	310	
1) Biopsy-proven cirrhosis or alcoholic hepatitis.	311	5(3,4)
2) Jaundice (bilirubin >2.5 mg%).	312	10(24)
3) Hypoalbuminemia (<3.0 g%).	313	10(23)
4) Hypoprothrombinemia (PT>3 seconds over control).	314	10(25)
5) Ascites.	315	11(6)
6) Encephalopathy.	316	5(6,7)
7) Varices.	317	5(10), 11(12)
b. Pancreatitis, acute or chronic: acute attack within previous 3 years or documented chronic pancreatitis.	320	5(5)
c. Peripheral neuropathy.	330	5(8)
d. Cerebellar dysfunction.	340	5(9)
e. Significant cognitive deficits secondary to alcohol excess: Wernicke's or Korsakoff's syndrome or other alcohol-induced OBS.	350	5(11)
f. Current megaloblastic anemia: Hct<37% and MCV>102 cmu.	360	10(2,5)
g. Alcohol related upper gastrointestinal bleeding in past year.	370	5(6)
4. Diagnosed psychiatric conditions (current or history):		
a. Major psychotic disorder (requiring medication for control).	410	5(13)
b. Major affective disorder (requiring medication for control).	420	5(14)
c. Major personality disorder (expected to impair reliable participation).	430	5(16)
d. Sever anxiety disorder.	440	5(15)
5. Cardiovascular Diseases:		
a. Unable to withdraw contraindicated medications (Section XVIII).	510	2(11-16), 5(30-37)
b. Hypertensive retinopathy (>K-W group II, current or history).	520	5((26), 11(2)
c. Cerebral or subarachnoid hemorrhage, history.	530	5(21)
d. Atherothrombotic stroke or myocardial infarction (within previous six months).	540	5(20,22), 10(42), 11(10)
e. Symptomatic ischemic heart disease.	550	5(23)
f. Current atrial fibrillation or other significant dysrhythmia.	560	5(25), 10(40), 11(5a)
g. Current CHF, uncontrolled by digoxin alone.	570	5(24), 11(4,5c,13)
h. Surgically curable or other secondary forms of hypertension.	580	5(27)
6. Other:		
a. Malignancies or other diseases likely to be fatal or disabling.	610	5(17)
b. Seizure disorder.	620	5(18)
c. Coagulopathies, bleeding diatheses or any condition being treated with anticoagulants.	630	5(19)
d. Blood pressure outside of screening range.	640	2(8)
e. Diastolic blood pressure ≥115 mm Hg at a single visit.	650	2(7)
f. Systolic blood pressure ≥220 mm Hg at a single visit.	660	2(7)
g. Unable or unwilling to participate.		
1. Anticipates moving/relocating out of area within six months.	671	3(17)
2. Unable to participate	672	
3. Can't be located for first screening visit	673	
4. Fails to keep appointments for first screening visit	674	2(1)
5. Failure to return to clinic within 30 days of previous visit.	675	2(1)
6. Refuses to consent.	676	5(1), 11(15)
h. Consumes less than three drinks per day on LDH for past six months.	680	6
i. Currently pregnant	690	

*Call Study Chairman's Office about any exclusion not explicitly listed.

Table 3

Forms (and Item#s) with Exclusion Potential

Form 2: 1, 7-8, 11-16

Form 3: 17

Form 4:

Form 5: 1, 3-27, 30-37

Form 6:

Form 8: 22, 26, 28-29, 31, 33-34

Form 10: 2, 5, 23-25, 35-37, 40, 42

Form 11: 1-2, 4, 5a, 5c, 6, 10, 12-13, 15-16

VIII. BLOOD PRESSURE DEFINITIONS AND SAFETY MONITORING

A. Blood Pressure Definitions

1. A Visit Blood Pressure is defined as the average of two seated systolic and diastolic readings at that visit determined by a random zero sphygmomanometer.

2. The Inclusion Blood Pressure is an untreated blood pressure of 75-109 mm Hg, inclusive, diastolic, with a systolic blood pressure less than 200 mm Hg at the first screening visit and for the average of the four readings at the first two screening visits, and 80-99 mm Hg diastolic with a systolic BP less than or equal to 179 mm Hg for the average of the six readings of the three screening visits.

3. The Baseline Blood Pressure is the average of the six blood pressure readings during the three screening visits for randomized participants.

4. The Treatment Blood Pressure is the average of the blood pressures at the last two visits in the six-month postrandomization period except as follows:

   a. Use only the last if the next to last is more than two months before the last.

   b. If the participant has been placed on open drug treatment for hypertension, use only visits prior to initiation of the open treatment.

   c. Use only the last if there are no visits (off antihypertensive medications) beyond month three.

B. Safety Monitoring: Blood Pressure Escape

Standard treatment for hypertension will be initiated for participants in the trial, depending on length of follow-up and level of follow-up blood pressure. The criteria are as follows:

1. A diastolic blood pressure (DBP) of 115 mm Hg or greater (mean of 2 readings) or systolic of 220 mm Hg or greater at a single visit will require initiation of treatment for hypertension. If

the participant is still in the Screening Phase, this, of course, will also require exclusion from the study.

2. At any time after randomization, visit BP measurements $\geq$105 mm Hg diastolic or $\geq$180 mm Hg systolic at two consecutive visits approximately 1 week apart will require initiation of antihypertensive treatment.

3. At or after the six-month visit, a systolic blood pressure of $\geq$160 mm Hg, or a diastolic BP of $\geq$95 mm Hg averaged over three consecutive visits (six readings) will require initiation of treatment for hypertension. Completion of the three consecutive visits without exceeding these limits is required in order to continue without initiation of antihypertensive drug treatment.

4. Once a participant requires continuous antihypertensive drug treatment, interim visits will no longer be indicated. If visits are needed to adjust medication and/or monitor BP only, forms do not need to be filled out.

5. If a participant is begun on antihypertensive medication apart from the above guidelines, the PI should be notified immediately.

IX. PROCEDURES FOR PRESCREENING AND SCREENING PHASES

A. Recruitment of Participants

1. Overview

During the first 1.5 years, the study will be initiated (Phase I) at four VA medical centers in order to assess recruitment and alcohol intake reduction success: 116 male veterans meeting the entry criteria will be randomized to either an alcohol reduction intervention group or a control observation group. If recruitment and the intervention technique are judged to be successful, then up to three additional centers will be added to randomize 464 additional participants in the seven centers, and complete the study in 3.5 additional years (Phase II), for a total of 580 participants and five years duration. Randomization requirements for each participating center will be 29 participants per year or 2.4 per month during Phase I and will be increased to 58 per year or 3.8 per month during Phase II.

To achieve these goals, centers should be prepared to log at least 300 Brief Screening Instruments (BSI) per month (70 per week) during the full-scale trial. Since 27% of mailed out BSIs are returned, this would require mailing out 1100 BSIs per month (260 per week). At least six SV1s should be completed each week by each site for a total of over 40 completed SV1s per week study-wide. To help accomplish this goal, 12-15 SV1s a week average should be scheduled. While scheduling does take time, there should be enough time to schedule and conduct these important screening visits each week. The Secretaries can help facilitate recruiting and scheduling visits for the participants.

In Phase I, the average SV1 took about 30-35 minutes to complete. The SV2s and SV3s are more labor intensive taking an average of 2.5-3.5 hours to complete.

If the Phase I recruiting experience holds up, at least one randomization per week will be generated with the completion of six SV1s each week. A review of the SV1 exclusions during Phase I reveals that 45% of the participants were excluded at this visit and 70% of those excluded were excluded because of blood pressure out of range.

Specific strategies have been developed to help the centers with recruitment. Using these recommendations will help standardize procedures as much as possible and will result in obtaining the maximum amount of comparable information to locate eligible veterans. Table 4 illustrates the variety of sources that will be used for locating eligible participants.

TABLE 4

Participant Recruitment Sources

VA Hypertension Clinics
Other VA Medical Clinics
VA Dermatology Clinics
VA Surgery and Surgical Subspecialty Clinics
VA Dental Clinics
VA Admissions
VA Discharges
Veterans Service Organizations
Mailing Lists of Veterans
VET Centers
Advertising
Churches

Initial screening may be conducted in hypertension clinics and other ambulatory care areas including medical and nonmedical clinics, admitting/triage/emergency areas, lobbies or waiting rooms, and may involve patients discharged from the participating VA medical centers with conditions not excluded in the protocol. The latter will require follow-up screening visits after usual alcohol intake and blood pressure levels are re-established. Further recruitment may involve contact with local veterans organizations, the use of mailings to veterans living reasonably close to the medical center and the use of newspaper, television, radio and other types of advertising. Oncology and cardiology clinics and alcohol and other substance abuse units would be unlikely sources for participants.

Based on data from veterans entering cooperative hypertension studies or attending general medical clinics, as well as data from community surveys and participants in hypertension prevention or treatment trials, it is estimated that 5-14% of veterans screened will meet the alcohol entry criteria and the majority of these will meet the blood pressure criteria. It is estimated that 2-4% of the population screened for this study will be eligible and give consent.

A self-administered prescreening questionnaire (Brief Screening Instrument) that includes several "usual" alcohol intake items will be used to quickly eliminate a large number of ineligible individuals. If individuals report having at least 10 drinks/week (e.g., at least 2 drinks/day on at least 5

days/ week), they will be kept in the pool of individuals for additional screening. These participants will qualify for the first screening visit. The first screening visit may be conducted immediately or scheduled.

Study personnel will distribute copies of this instrument in areas where groups of veterans gather, such as VAMC waiting areas and VFW and American Legion posts. This instrument can also be administered to individual veterans and could also be included in mailings to groups of veterans. Completed questionnaires will not be sent to the Coordinating Center. However, answers to key questions must be recorded on the Brief Screening Instrument Log (Form 1). This form will be sent to the Coordinating Center for processing. The Executive Committee will monitor recruitment performance at least monthly during the feasibility phase and frequently thereafter. The Data and Safety Monitoring Board will also monitor recruitment.

2. Recruitment Strategies

a. The Participating Investigator (PI) is encouraged to inform and elicit cooperation about screening from the ACOS/Ambulatory Care, the Chief of Staff, and Service Chiefs. Brief presentations might be helpful and press releases should be provided to the medical center publication editor. A set of slides for presentation can be obtained from the Study Chairman.

b. The PI and Interventionist should provide a "press packet" for the public information officer. This packet should contain: a press release (see Figure 4), a public service announcement (see Figure 5), and a study overview, if needed. Request assistance and advice on publicizing study through the local print and broadcast media. If the public information officer cannot mail out the information, request a list of local media sources. Mail out and follow-up with a phone call. Thank the media for their time and help.

c. One of the most effective recruitment strategies utilized in Phase I was mass mailings to veterans. The PI needs to write or call the Chief for Information Resources Management (IRM) to request mailing labels of veterans in the hospital service area. Request veterans' addresses in counties closest to the hospital service area. During Phase I, three out of the four sites relied extensively on mass mailings as their main recruitment strategy. These sites sent out an average of 12,000 letters with 27% responding back to the sites. Of these, about 5% were eligible to be screened for an SV1. Mass mailings should probably be organized as the first recruitment strategy. Please review Appendix B for examples of letters prepared by the four sites in Phase I.

d. The PI and Data Collector should also get a list of local veteran service organizations and contact person(s). Make efforts to schedule brief presentations and announcements at service organization meetings. Provide copies of the Brief Screening Instrument with return envelope and stay to answer any questions or inquiries about the study. If possible, socialize with the contact person(s) and others at the service organizations. Thank them for their help. Follow-up weekly or as deemed necessary. Send thank you letter(s).

e. Request medical media to prepare posters and flyers (following graphic guidelines established at center, see Figure 6) about the study. Get permission to advertise at Vet Centers, VA Clinics, universities, etc. using the flyers and posters. Have the posters designed to include a place for the BSIs and return envelopes. This strategy worked well in the hospital clinics during Phase I.

f. If desired, contact local churches and get contact person(s) e.g. ministers in charge of outreach and lay persons. Churches may also publicize the study using press releases and public service announcements. Send thank you's.

g. The American Association of Retired Persons Organization and other senior organizations (Area Agency on Aging) will also advertise the study. Local nutrition programs usually have retired veterans attending their sites. Once permission is received from the nutrition site director(s), the Interventionist or Data Collector should go to the sites. Follow same procedure as in d.

h. If possible, establish a phone number with an answering phone to take messages. Also, decide who the study contact person will be for the press--PI or Interventionist. Answer inquiries quickly to help with press deadlines.

i. Document sources used for recruitment. Include number of presentations made and number of veterans screened. Keep track of the number of the letters sent through mass mailings, the number returned and the number eligible for SV1. Also, note problem areas with recommendations to overcome problems.

Some items that need to be remembered whenever presentations are made or veterans are interviewed about participating in the study would include:

1) Introduce yourself and the VAMC you work for.

2) Speak clearly and with confidence about the study. Keep presentation(s) brief and to the point.

3) Speak louder, slower and in a lower tone for hard of hearing veterans.

4) Dress appropriately.

5) Shake hands and keep good eye contact. Smile.

6) Explain mailing procedures (as approved).

7) Socialize, drink coffee with the veterans, etc.

8) Be comfortable and courteous.

9) Thank them for their time.

FIGURE 4

Press Release

For Immediate Release

_____(Name of VAMC Facility)

is conducting a study of risk factors for heart disease. Veterans will be screened for their general health, drinking practices and risk factors for heart disease, and, if appropriate, will be followed for up to two years. Participants will be provided funds ($10.00/visit) for attendance at specified clinic visits. The information learned from this study should be useful in treating people with problems such as high blood pressure, abnormal blood cholesterol levels, and enlarged hearts. {At all times, the veteran's medical records and identity will be kept confidential.} Please call _____ (provide contact name and telephone number with extension) for further details.

FIGURE 5

Example PSA (Kill after _____).

Concerned about blood pressure and other cardiovascular problems? The Department of Veterans Affairs is conducting a study of various risk factors for diseases of the heart. They are looking for veterans to screen for this study. If eligible, veterans will be reimbursed to defray expenses for clinic visits. Call _____ (give VAMC contact and phone number) for further information

FIGURE 6

Example Flyer

For use : Immediate

Contact:

The _____ (name of facility) is prescreening veterans for a study of risk factors for heart disease. Eligible veterans will be asked questions about general health, drinking practices and various risk factors for heart disease. If the eligibility criteria are met, veterans will be provided funds to defray expenses for clinic visits. Participants may be followed for up to two years.

Call _____(name) at _____(phone number) for more information.

B. Study Candidates on Antihypertensive Medications

1. If a veteran currently taking antihypertensive medication(s) appears to meet the eligibility criteria (other than blood pressure) and it is anticipated that his diastolic pressure will not rise above 99 mm Hg or his systolic above 179 mm Hg, medications will be discontinued or tapered, if medically indicated, after informed consent is obtained. If he is receiving active care for hypertension by a non-VA physician, permission should be obtained from the physician for drug withdrawal.

2. An individual will not be eligible for screening until he has been off antihypertensive medications for a minimum of two weeks. A longer minimum period of observation, such as 3-4 weeks, should be observed for those individuals who may be on guanethidine or reserpine. All candidates must be seen at least once within one week after medication has been withdrawn for a blood pressure check. If there is uncertainty about how high or how quickly the blood pressure might rise or if a candidate would benefit from reassurance, a blood pressure check in less than seven days may be appropriate. If blood pressure exceeds the entry criteria levels during washout, the individual will be excluded from the study and appropriate antihypertensive therapy will be initiated. As long as blood pressure remains below the entry levels, the candidate may be followed at appropriate intervals in order to monitor for "return" of blood pressure to entry levels: some individuals may have been started on antihypertensive medications previously without adequate documentation of hypertension, some may have altered a risk factor contributing to their hypertension, and some may require months or years for their blood pressure to rise to previous untreated levels.

3. Treated patients may be on minimally effective combinations or doses of antihypertensive medications or may be noncompliant, so the number of medications a patient has been prescribed may not be predictive of his untreated blood pressure. Individuals should be excluded, however, if the screening blood pressure on medication exceeds the entry criteria or the patient seems compliant and his treatment requires more than two appropriately combined antihypertensive medications, including a diuretic, at usual maximal doses. An example of this would be: hydrochlorothiazide 50 mg/day + atenolol 100 mg/day + any appropriate dose of a vasodilator antihypertensive agent (e.g., hydralazine, prazosin, terazosin, a calcium channel blocker, or minoxidil).

Note: Eligibility issues on use of contraindicated medications during screening

The following guidelines should be carefully followed if a participant is on contraindicated medication(s) during screening:

1. The Data Collector or Interventionist should inform the Principal Investigator as soon as possible. Inform the PI about the type and dosage of the medication(s) the participant is taking and screening visit level.

2. If the participant is on a **contraindicated medication at SV1, initiate wash-out, get the blood pressure checked and repeat SV1. Do not submit blood pressure measurements to Perry Point on a Data Collection Form (Form 2).** Record on a progress note in the participant's study file. Inform PI of blood pressure readings.

3. **Beyond SV1, the Principal Investigator should contact the Study Chairman immediately for a review.** With this review, a decision will reached about the current screening level and the inclusion or exclusion of the participant in the study. Call the Study Chairman's Office with questions.

C. Screening Phase (Prerandomization)

1. There will be three biweekly visits during the prerandomization screening phase. Participants will be randomized at the third visit unless they are excluded. Baseline alcohol intake, special (central) laboratory tests and the baseline echocardiogram will be performed only after the participant meets the randomization criteria in order to reduce the volume and expense of unnecessary tests.

2. Exclusions During Screening

In addition to the exclusion criteria described in Section VII.B., individuals will be excluded for failure to return to clinic within 30 days of previous visit.

3. Screening Rules for Randomization

a. Blood Pressure

The objective of the screening rule is to identify persons with DBP between 80 and 99 mm Hg on the basis of three visits, and to assign each participant to either the lower stratum (DBP

80-89 mm Hg) or the higher stratum (DBP 90-99 mm Hg). Since recruitment of individuals with the desired ranges of DBP and alcohol consumption may be difficult, a sensible screening rule should try to avoid excluding candidates on the basis of a single visit. Therefore, a relatively wide range of acceptable BPs will be used for the first two visits and the target DBP range (80-99 mm Hg) will be required for the average of the three screening visits. Two measurements will be taken at each visit. The screening process may be terminated if the DBP at the first screening visit is not between 75 and 109 mm Hg or if the DBP averaged over the first two screening visits is not between 75 and 109 mm Hg. An individual is eligible for randomization if the DBP averaged over the three screening visits is between 80-99 mm Hg. The interval between each of these visits must be at least six days and no more than 30 days.

Participants will be classified as either lower stratum (80-89 mm Hg) or higher stratum (90-99 mm Hg) on the basis of the average of the six measurements. **But if the participant was placed on wash-out for antihypertensive medications prior to screening, he enters the upper stratum regardless of the average of the six measurements. Therefore, be sure to document hypertension history carefully on the Medical History form (Form 5).** This average will also provide the baseline value.

b. Alcohol Consumption

The information required to initially screen individuals for participation in the study is based on a brief self-administered questionnaire (see Section IX.A.). The Alcohol Dependence Scale (ADS) (Form 4) will be administered at screening visit 1 and will be used to identify and exclude alcohol dependent individuals. The Lifetime Drinking History (LDH) (Form 6) questionnaire will be administered at screening visit 2 to obtain more detailed information on drinking patterns in terms of typical quantity, frequency, variability (binge drinking) and beverage consumed. It is designed to provide quantitative indices of an individual's alcohol consumption pattern from the onset of drinking to the present. To qualify for randomization, the consumption of alcohol must average at least 3 drinks per day (21 drinks per week) over the prior six months.

Note: The intent of the protocol and the Planning Committee is to invite all veterans eligible at prescreening --even those who had a prior documented history of alcohol treatment --to screening visit 1. Based on the ADS score (and any other possible exclusions e.g. blood pressure or specific medical exclusions), inclusion or exclusion would then be determined.

4. Alcohol Intake During Screening

No encouragement to alter alcohol intake will be undertaken during this phase.

5. Procedures for Prescreening and Screening Visits

Before scheduling any screening visits the prescreening questionnaire will be administered. If eligible for formal screening, the first screening visit will be scheduled or, if on antihypertensive medications, the screening consent will be obtained and the washout phase will be initiated.

At Screening Visit 1, the following will be obtained:

a. Screening Consent, if not previously obtained.

b. Two random-zero sitting BPs, standing BP, sitting and standing heart rate, and weight.

Note: Continue screening if average sitting BP is 75-109 mm Hg diastolic with a systolic BP < 200 mm Hg. If excluded because of BP, complete Data Collection Form, Form 2 and stop the screening visit.

c. Demographic Characteristics.

d. ADS-10 (Alcohol Dependence Scale or Alcohol Use Form) and focused medical history.

Note: Withdraw participant if he meets specific alcohol dependence or medical history exclusion criteria or if he cannot be withdrawn from contraindicated medication after consultation with Principal Investigator. Provide participant with referrals for appropriate follow-up care or screening.

Forms to be completed in order: Screening consent Form 87
Data Collection Form 2
Demographic Characteristics Form 3
Alcohol Use Questionnaire Form 4
Medical History Form 5

Approximate time needed: 30-35 minutes.

Participant Instructions:

a. Give written instructions on not eating for 12 hours prior to the next screening visit. The participant may have beverages, but should avoid fats such as milkshakes. A participant who is using insulin or hypoglycemic medication must be instructed to postpone use of this medication that day until after a blood sample has been drawn and he has eaten.

b. A blood sample will be drawn at the next visit.

c. Make appointment for screening visit 2 in two weeks but no less than six days from the first visit.

At Screening Visit 2, the following will be obtained:

a. Two random-zero sitting BPs, standing BP, sitting and standing heart rate, and weight.

Note: Continue screening if the sitting diastolic BP is 75-109 mm Hg with a systolic BP <200 mm Hg for the average of the four readings of this visit and screening visit 1. If excluded because of BP, complete Data Collection Form, Form 2, and stop the screening visit.

b. Local laboratory tests: standard urinalysis; qualitative screen for illicit drugs; CBC (Hgb, Hct, RBC indices, platelets, and WBC); biochemical profile to include: cholesterol, urea nitrogen, creatinine, uric acid, glucose, electrolytes, albumin, total bilirubin, SGOT (AST), LDH, alkaline phosphatase, calcium, and phosphorus. See Form 10 for complete list.

Note: Record results for laboratory tests on Form 10. Review of laboratory tests and assessment of a positive urine illicit drug screen by clinical interview will be done at screening visit 3. **Results must be reported on Form 10 even if the participant is excluded during screening visit 2.**

c. LDH (Lifetime Drinking History).

Note: The alcohol intake inclusion criteria of $\geq$21 drinks per week over the prior six months is determined by the LDH at this visit. If the participant does not meet this criteria, he is withdrawn from the study at this time.

d. Physical Activity Questionnaire, Psychosocial and the Health Habits questionnaire, and Beck Inventory.

Note: If a participant responds positively on the Beck Inventory Suicide question (#9), an immediate psychiatric consultation should be obtained.

e. Standard 12-lead electrocardiogram (reviewed by physician at screening visit 3).

f. PA chest x-ray, if it has not been performed within the previous year or if clinically indicated (results reviewed at screening visit 3).

Forms to be completed in order:
Data Collection Form 2
Local Laboratory Data Form 10
Lifetime Drinking History Form 6
Physical Activity Form 7
Psycho Social & Health Habits Form 8
Beck Inventory Form 9

Tests to be done at visit 2: Local Lab, ECG, Chest X-Ray (if warranted and/or not done)

Approximate time needed: 2.5 hours

Participant Instructions:

a. Give written instructions and collection materials for an overnight urine sample.

b. Give instructions on not eating 12 hours prior to screening visit 3 if Central Lab is to be drawn at visit 3 (participant may have beverages, but needs to avoid fats such as milkshakes).

c. Make appointment for screening visit 3 in two weeks but not less than six days from previous visit.

Note: When the participant advances to SV3, follow guidelines for prior approval of forms for registration with the Study Chairman's Office. (See IX.D.)

At Screening Visit 3, the following will be obtained:

a. Two random-zero sitting BPs, standing BP, sitting and standing heart rate, weight, and height.

Note: Participant meets the inclusion blood pressure criteria if sitting diastolic BP is 80-99 mm Hg with a systolic BP <180 mm Hg for the average of the six readings of the three screening visits. If not, exclude participant from the study at this time.

b. Overnight urine sample for time of collection, volume, creatinine, sodium, potassium and magnesium. Two aliquots will be obtained: send one to the lab, save the other (see Section XIII.G.).

c. Physical examination with review and, if necessary, completion of the focused medical evaluation and review of the local laboratory tests and urine drug screen.

Note: If results suggest an exclusion, the Principal Investigator will make a judgment (in consultation with the Chairman, if necessary) about participant exclusion.

d. Study consent, if participant meets eligibility criteria.

Note: The Perry Point VA Cooperative Studies Program Coordinating Center (CSPCC) will be called by the Data Collector to confirm eligibility for randomization. However, treatment group assignment will not be revealed to the Data Collector.

e. Diet questionnaire and Chronological Drinking Record (CDR).

f. Blood samples, if eligibility confirmed. Plasma and serum will be prepared and will be sent to the Central Lipid Laboratory for determination of biochemical markers.

Note: If preferred, these samples may be drawn on a separate day, e.g. when the echocardiogram is performed. However, this must be completed before participant is notified of randomization assignment.

Forms to be completed in order: Data Collection Form 2
Physical Exam Form 11
Study Consent Form 88
Diet Questionnaire Form 12
Chronological Drinking Record Form 13

Approximate time needed: 2.5 - 3 hours

Participant Instructions:

a. Make appointment for the study echocardiogram (should be within one week of visit).

b. Make appointment for the first (one-month) postrandomization follow-up data collection visit.

D. Participant Randomization

Once the participant has advanced to SV3, the SV1 and SV2 forms must be checked and approved by the Study Chairman's Office before registration can occur. These procedures will remain in effect until the computer-assisted registration system is implemented at the Perry Point CSPCC. The following procedures should be carefully followed:

1. Send in all verified and signed data every Friday.

2. Every week, when reporting on the site's screening activity, the Study Coordinator will ask for a list of the participants advancing from SV2. Please provide the name(s), study number(s) and SV3 appointment date(s). SV1 and SV2 forms for these participants will be reviewed and approved prior to the SV3 appointment. Perry Point CSPCC will be called by the Study Coordinator with approvals for registration. Only those on this approval list will be registered by Perry Point.

3. To avoid delays in registering a participant, **Forms 2, 6 and 8 from SV2** should be sent as soon as possible following SV2 for participants who are advancing to SV3 and should not be held out for the routine weekly data mailings.

4. Checking these forms will get top priority. Once the forms are checked, the Study Coordinator will call approval or disapproval of the participant's eligibility. If problems or errors are

found, the Study Coordinator will inform the Data Collector and/or Interventionist so that the form(s) can be reviewed. Be sure that forms are reviewed before submitting them to the Study Chairman's Office as well.

As soon as the screening process has been completed and the participant's eligibility has been established by the Study Chairman's Office, the Data Collector must call the Perry Point CSPCC at **(301) 642-1087 and ask for Cathy Lucas or Debbie Davis.** If this number is busy, call **FTS 956-6131 or FTS 956-5375**. The Data Collector must identify his medical center (by number) and must indicate that a participant is ready to be registered for Study #996. The participants' screening forms will be reviewed in this order:

Form 2 - SV1, 2 and 3
Form 3 - SV1
Form 4 - SV1
Form 5 - SV1
Form 6 - SV2
Form 11 - SV3
Form 88 - SV3

and the participants' eligibility will be confirmed. The registration process will be concluded by providing the participant's name, participant's number, mailing address, telephone number and Social Security Number. Note: Be sure to provide the correct spelling of the participant's name and the participant's correct participant number to CSPCC. This process should take no more than 10 minutes. Finally, the Data Collector must notify the Study Interventionist that the participant has been registered.

Treatment assignments will be determined by the CSPCC, which will notify the Study Interventionist directly by mail. Both the Data Collector and the Participating Investigator must remain blinded to treatment assignment. The Study Interventionist must call the CSPCC if a treatment assignment has not been received within one week of the registration.

The Data Collector must notify the Study Interventionist as soon as the echocardiogram has been obtained. The Study Interventionist will then contact the participant either to schedule the first intervention visit or to notify him that he is in the group that will not be coming in for instruction sessions and that will not be asked to change drinking patterns. The first intervention visit should occur within two weeks of the randomization visit. A schedule of follow-up data collection visits will be generated by the CSPCC and will be sent to the Data Collector. The Data Collector should call CSPCC if the schedule of follow-up visits has not been received within one week of the registration.

X. PROCEDURES FOR INITIAL TREATMENT PHASE

A. Initial Procedures

1. As soon as the screening process has been completed and participant's eligibility has been established, the Perry Point CSPCC will randomly assign a treatment group, intervention or control.

2. Treatment assignment will be revealed only to the Interventionist by the CSPCC. Both the Data Collector and the Participating Investigator will remain blinded to treatment assignment.

3. All participants will be told not to reveal their randomization status to the Data Collector.

4. Interventionists and Perry Point CSPCC will retain a copy of randomization assignments for each site.

5. The first appointments to be made are for the study echocardiogram and the first post randomization follow-up data collection visit. The Data Collector will notify the Interventionist of the dates for these visits.

6. The Interventionist will contact each participant after his echocardiogram has been performed. Participants who have been randomized to the intervention group will be scheduled for their first intervention visit. Participants who have been randomized to the control group will be reminded about their first follow-up data collection visit.

7. Interventionists should create a sequentially numbered note card (3x5) file with participant's full name, address, telephone number and social security number by randomization assignment for their use only.

B. Criteria for Referring Participant to an Alcohol Treatment Program and/or for Other Medical Care and Criteria for Withdrawal from the Study

1. Development of any of the following will justify an investigator calling the Chairman about referring a participant to an alcohol treatment program and/or for other appropriate care at any time after randomization:

Any of the exclusion criteria listed in Section VII.B, or other intercurrent illness. These participants should be referred for appropriate care; however, study data collection and intervention sessions, if appropriate, should continue, if possible. The participating investigator is responsible for referrals.

2. The following will justify an investigator calling the Chairman about withdrawing the participant from the study:

a. Participant moves or is lost to follow-up.

b. Participant requests termination from the study. If possible, data collection will be continued, as acceptable to the participant, even if some data collection visits are missed.

c. Death. If a participant dies during the study, a copy of the death certificate will be forwarded to the CSPCC.

If the participant must be withdrawn from the study, the termination form will be completed and, whenever possible, blood pressures, heart rate, weight, local and central laboratory analyses, CDR, food frequency questionnaire, echocardiogram, ECG, psychosocial and health habits assessment, and overnight urine collection will be obtained. Appropriate follow-up or referral should be arranged as clinically indicated. All participants should be seen for a complete six-month visit, whenever possible.

C. Clinic Visits

A participant will have six data collection visits at one-month intervals during this phase. Random zero sitting and standing blood pressure, heart rate, and weight will be determined at each visit.

D. Interim Visits

An interim visit in one week will be scheduled if diastolic BP exceeds 104 mm Hg or systolic BP exceeds 199 mm Hg. For coding rating period on Form 2 for an interim visit, use the rating period for the most recent prior BP visit. For example, if an BP interim visit is needed after the F5 visit but before the F6 visit, **code the interim visit as an F5.**

E. Test Procedures

Self-reported alcohol intake (CDR), food frequency questionnaire and central laboratory tests will be obtained at the three-and six-month visits. Echocardiogram, local routine lab, ECG, psychosocial and health habits assessment and overnight urine collection will be repeated only at the six-month visit.

F. Intervention Procedures (See Section XIV).

G. Blood Pressure Escape

If blood pressure exceeds the safety limits described in Section VIII.B., open treatment for hypertension will be initiated. The participant will continue to be followed according to the study protocol.

H. Maintaining Treatment Blind

It is important that both the Data Collector and the Participating Investigator remain blinded regarding participants' treatment assignments. At the beginning of every visit the participant will be reminded that the Data Collector must not know which treatment group the participant is in. If the Data Collector becomes aware of a participant's treatment assignment, the Perry Point CSPCC must be notified. The Principal Investigator should prepare a brief memo stating that the blind has been broken. The medical center number and participant study number should be provided along with the circumstances.

XI. PROCEDURES FOR MAINTENANCE PHASE

A. Criteria for Referring Participant to an Alcohol Treatment Program and/or for Other Medical Care and Criteria for Withdrawal from the Study

The criteria are the same as outlined in Section X.B. All termination procedures outlined in Section X.B. should be followed, except no echocardiogram will be obtained.

B. Clinic Visits

A participant will have six data collection visits at three-month intervals during this phase. Random-zero sitting and standing blood pressure and heart rate, and weight will be determined at each visit.

C. Interim Visits

Interim visits will be scheduled at one week intervals if diastolic BP exceeds 94 mm Hg or systolic BP exceeds 169 mm Hg. If the diastolic BP is elevated, a minimum of two interim visits will be required to obtain the diastolic BP averaged over three consecutive visits.

D. Blood Pressure Escape

If blood pressure exceeds the safety limits described in Section VIII.B., open treatment for hypertension will be initiated. The participant will continue to be followed according to the study protocol.

E. Test Procedures

Self-reported alcohol intake (CDR), diet questionnaire, local and central laboratory tests, overnight urine collection and psychosocial and health habits assessment will be obtained every six months during the maintenance phase. Echocardiograms will not be performed during this phase.

XII. ORGANIZATION OF CLINIC AND PREPARATION FOR VISIT

A. Organization of the Clinic and File Preparation

1. Initially, one five-drawer, metal filing cabinet should be sufficient to hold all the study related participants data collection information per site. Letter-size manila file folders are easiest to use. An ample supply should be obtained. The Interventionist must keep a separate set of files related to the intervention.

2. The data file should be divided into:

a. The screening section will include data forms for individuals who are currently being screened. Three folders could be used to denote SV1, SV2 advanced and SV3 advanced. The PATHS Recruitment Log, Figure 7, could be place in a separate folder in this section as an administrative guide to help manage the site's recruitment activities.

These folders would contain the entire packet of forms unique to each screening visit and arranged alphabetically by the participant's last name. Example: for the SV1 folder, arrange a packet of forms for the new participant using a 3 x 5 card clipped to them with the name, sequence number (ID number), appointment date and time, phone number and address. Do not write on the forms until the actual visit occurs. If the participant advances to SV2, remove the 3 x 5 card and store in a card box as a cross-reference. Sequentially arrange the SV1 forms, clip them and place them in the SV2 folder.

A separate sub-section for "wash-outs" (participants who have been on anti-hypertensive medications) should also be part of the screening section. These participants will be receiving weekly blood pressure checks before their SV1 can be scheduled. Once they have been cleared for screening, place their forms in the SV1 folder too. It is not necessary to use the Data Collection Form, Form 2 to record the interim blood pressures. They can be dated and completed on a progress note with the participant's name and ID number.

FIGURE 7

VA COOPERATIVE STUDY #996 - PATHS

PATHS RECRUITMENT LOG

Medical Center No. __ __ __

Participant Name	Part. No.	Social Security No.	Date of SV1 (Mo Day Yr)	Exclusion Date (Mo Day Yr)	Exclusion Code*	Randomization Date (Mo Day Yr)	Date Completed 6 Months (Mo Day Yr)	Date Completed Study (Mo Day Yr)

*See Codes in Operations Manual.

Please use the participant's VA medical record for documentation of: permission and approval to withdraw veterans from antihypertensive medication(s); progress notes on blood pressure measurements after withdrawal of antihypertensive medications and the original signed copy of the Study Consent Form VA 10-1086.

If these participants are excluded prior to SV1 or during screening, remove all of the forms and prepare an Exclusion Form, Form 20. Put these forms together with all others prepared for the weekly approval and signing by the Principal Investigator. They will then be sent to Perry Point CSPCC in the weekly mail-out.

During screening, veterans excluded from the study can be informed of their blood work and laboratory procedures (e.g. x-ray, cholesterol). If possible, and if time permits, please send them a brief note thanking them for their time and informing generally of their results. Also, a "reminder" could be sent about recommended follow-up treatment(s). However, this wording should be general and should not refer to specific treatments, if referring to a sensitive area, e.g.alcohol abuse. These guidelines will protect the person's' confidentiality in the study.

Also, an exclusion note should be written in the progress notes of the medical record for all veterans excluded at the screening visits. No reference should be made regarding a specific exclusion of a sensitive nature though (e.g. ADS, urine drug screen or psychiatric evaluations). A suggested note might be: Mr. X has been excluded from or declined to participate in VA CSP #996 on (give date). Have Principal Investigator co-sign the progress note. Remember to provide the specific reason(s) for the exclusion on Form 20.

b. **The participant section will include data forms for individuals who have successfully completed all three screening visits and whose eligibility has been confirmed by the Perry Point CSPCC.** These individuals will receive a treatment assignment which only the Interventionist knows. The following items should be legibly listed on the individual file folder tabs:

1. the participant's five digit I.D. number
2. the participant's full name
3. the participant's full social security number.

Each folder should be sequentially arranged by SV1, SV2 and SV3 forms and then by the follow-up visits, initial treatment and maintenance phases. Include the schedule for follow-up data collection visits prepared by the Perry Point CSPCC. Also include the Brief Screening Instrument.

c. The **prescreen section** will include the Form 1s (Brief Screening Instrument Log) which sequentially list all eligible and ineligible participants. The site should separate the eligible and ineligible veterans. Due to the large number of ineligible veterans prior to SV1, these BSIs should be arranged sequentially with a Form 20 and then boxed to save space for active participants. All other eligible veterans should be contacted by phone or by letter to schedule an SV1. Put these forms in the screening section, SV1 folder.

3. RESCREENING GUIDELINES

Participants who are excluded for blood pressures out of range or for exceeding the 30 day limitation between visits can be rescreened. A new participant number will be required and information from the participant's BSI must be entered with the new number in the BSI Log (Form 1). If rescreening occurs within three months of the prior SV1, some forms will not need to be repeated at SV1 and SV2. All forms need to be completed for SV3.

a. At SV1, complete Forms 2 and 3 and the Screening Consent Form -- 87. Take the old completed Forms 4 and 5 and write the new participant number and new date in the header area. Write across the top of these forms using large letters, "RESCREENING."

b. If the participant is advanced to SV2, arrange lab work and schedule next appointment as specified in the protocol. At SV2, complete Form 2. If the participant meets blood pressure inclusion criteria, proceed with blood tests and urine screening. Complete Forms 7,8,9, and 10. Take the old completed Form 6, and write new header information with the new date and new participant number. Write across the top of the form using large letters,

"RESCREENING." Photocopy and send the forms to Perry Point and the Study Chairman's Office.

c. Proceed with registration screening process by sending the SV1 and SV2 forms for review by the Study Chairman's Office.

4. All participants excluded prior to SV1 (except for those excluded by the BSI) and during the screening phase (SV1-SV3) must have a Form 20 submitted with the proper three-digit code(s). See Table 2 (Section VII) for Exclusion Codes. All forms pertaining to excluded participants should be stapled together and filed sequentially by the I.D. number. They can be boxed to save space.

5. **Do not discard or destroy any data.** Store and label boxes "CSP #996 Data Forms -- Exclusions."

6. Each individual who comes in for a screening visit should be identified in the PATHS Recruitment Log (Figure 7). This form will not be sent to the Perry Point CSPCC. Its major purpose is to help the participating medical center manage and evaluate its recruitment activities.

7. Any other patient records necessary to track a participant's progress throughout the study should also be stored in the file. The Participant Summary Sheet (Figure 8) should also be stored in the file. The original signed VA Form 10-1086's and the information sheets (Forms 87 and 88) must be filed in the participant's permanent medical record and not in the participant's study file.

8. Also, the participant's address and telephone number (or a telephone contact) should be obtained for the file. This information will be helpful to remind participants about visits.

9. Other file sections to be considered:
   a. An administrative section would include the proposal, budget and all correspondence to and from the Perry Point CSPCC and the Study Chairman's Office.
   b. A registration folder is a master list of participants registered for the study. It is arranged sequentially in the order the participants are registered. The participant's I.D. number and the date registered are listed on this sheet.
   c. The data mailing checklist section provides the weekly data mailing information for forms sent each week to the Perry Point CSPCC and the Study Chairman's Office. The data mailing checklist is also used to verify data sent to the Coordinating Center for the Missing Forms Report.

Figure 8

VA COOPERATIVE STUDY #996 - PATHS

PARTICIPANT SUMMARY SHEET

Medical Center No. _ _ _ Part. Name ____________________ Part. No. _ _ _ _ _ Social Security No. _ _ _-_ _-_ _ _ _

ANSWER ONLY ONE:

DATE EXCLUDED . . . . Mo _ _ Day _ _ Yr _ _
OR
DATE RANDOMIZED . . . . Mo _ _ Day _ _ Yr _ _

VISIT NUMBER	DATE OF VISIT (MO DAY YR)	KEPT APPT. (1=YES, 2=NO)	MEAN SBP/DBP	INTERIM VISIT NEEDED? (1=YES, 2=NO)	DATE OF INTERIM (MO DAY YR)
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B. Preparing for the Visit

1. To make the clinic visit run more smoothly and to minimize errors in I.D. codes, place copies of needed forms in participant's file ahead of time. Do not complete forms with I.D. number until participants check in for scheduled clinic appointments. Complete needed information once the participant has checked in.

2. The appointment log book should have the following information:

a) Participant's name and time of appointment
b) Type of appointment (e.g. S1, F1, F2, interim)

Care should be taken in scheduling appointments to prevent errors such as double-booking and long delays.

3. When scheduling appointments, participants should be informed about the details and duration of the forthcoming visit, e.g. blood samples, urine specimen needed, fasting instructions. If feasible, breakfast or lunch tickets should be provided to participants for those clinic visits when the participant must come in fasting. The feasibility of this will need to be determined locally at each participating center.

4. Data Collectors and Interventionists are to be responsible for the voucher system for payment for specified visits. While payment for each visit by the agent cashier is probably the easiest method, each center must implement a payment procedure that is consistent with local Fiscal Service policy.

5. Every effort should be made to schedule appointments during standard, working hours. Specific instructions should also be included about not smoking for a minimum of two hours before the blood pressure measurements.

6. If the Data Collector or the Interventionist is ill or must cancel appointments for clinic visits for any reason, scheduled participants must be contacted and notified if at all possible. If an appointment for an intervention visit must be canceled, the Data Collector and Participating Investigator must not be notified; some other staff member must be asked to notify the participant of the cancellation.

If a participant cannot be contacted about a canceled appointment and comes in for the visit, he should be paid for that visit. Whenever appointments are canceled, a sign should be posted at the appropriate office. The sign should provide information about rescheduling canceled visits.

7. At baseline and every six months thereafter, each participant will bring an overnight urine sample. Provide instruction sheet and container which will be returned by the participant at the next visit. Blood samples will also be collected seven times throughout the study. Instructions should be provided to the participant on eating and drinking before these tests.

8. Facilities required at each participating center include:

   a. An exam room which should be a quiet area where BP, height and weight can be measured and interviews can be conducted. There should be adequate space for two chairs and an adjustable table for arm support for BP measurement.

   b. Office space for storage of study data files either within or near the exam room.

   c. Access to freezer (-20°c) space for blood and urine samples. Urine samples may be stored in a refrigerator if there is not enough freezer space available.

   d. A private office where the Interventionist can meet with participants randomized to the intervention group and store the intervention records and forms. This office must be in a location where it would be extremely unlikely that either the Data Collector or Participating Investigator would be able to identify participants attending intervention sessions.

A complete list of equipment and supplies is found in section XIX.

9. If a participant withdraws from the study, Form 20, Termination Form must be completed indicating reason(s). Whenever possible, any available data such as blood pressures, heart rate, weight, laboratory data, etc., will be obtained.

10. If a participant experiences blood pressure exceeding safety limits as described in section VIII.B, open treatment for hypertension will be initiated. The participant will continue to be followed according to the study protocol, however. The Study Chairman's Office should be notified when open treatment begins for hypertension. An Intercurrent Illness Form, Form 19, should state the diagnosis, type of medication(s) dosage and length of time (if known) of treatment.

11. If a participant dies during the study, a copy of the death certificate must be obtained and sent to Perry Point CSPCC.

XIII. PROCEDURES FOR LABORATORY EVALUATIONS

A. Blood Pressure Measurement Procedures

At least once a week the random-zero (RZ) manometer must be inspected and, if necessary, cleaned. Specific instructions follow:

1. Check for mercury leaks. Take out of operation immediately if mercury droplets are found around the bottom. A leak is most likely due to major problems. Biomedical Equipment must repair mercury leaks.

2. Check for air leaks by pumping the mercury up to 200 mm Hg and closing the system. The mercury should not fall. If it does, there is an air leak.

3. Determine whether the column needs cleaning. A dirty column can be cleaned by inserting a "pipe cleaner" down to the level of mercury in the column. If the mercury is clean, leave the mercury in the column but make the mercury level as low as possible by trapping mercury via the **CLOSE** setting of the switch. Do not push the "pipe cleaner" into the mercury because the mercury will spill when the cleaner is removed.

4. Determine whether mercury needs cleaning. Obviously dirty mercury needs filtering. If the column remains clean, the mercury falls smoothly, and numbers can be read after cleaning the column, then the mercury does not have to be cleaned.

If the mercury needs to be cleaned, use the following procedure:

1. Set RZ manometer in a collecting bucket whenever mercury is being removed from or added to the column. It is impossible to catch mercury in a small container or to accrue small droplets.

2. Turn switch to **OPEN** and unscrew the screw at the bottom of the tall aluminum cylinder which contains the mercury. The mercury will come squirting out. Make sure you catch the mercury in some appropriate basin. Recover the screw from the basin. Occasionally, a small metal plug that is in the cylinder will also come out with the mercury.

3. Replace the small plug first, if it came out. Reinsert screw.

4. Clean the glass column with an appropriately sized "pipe cleaner".

5. Filter the mercury through filter paper or paper towel with small holes. The dirty mercury will collect at the end. Save it in a "dirty mercury" container.

6. Make sure all mercury is put into proper containers. Do **NOT** throw any away.

To fill the RZ manometer with mercury, use the following procedure:

1. Remove rear cover by unscrewing the 2 screws at the top front and 2 screws at the rear base. Take the cover off and to the right hand side to disengage from the thumb wheel.

2. Turn the Switch to OPEN.

3. Using a small funnel (or body of a plastic syringe) in the top of the column, fill the mercury up to the level of about 40 mm.

4. REPLACE THE CAP AT TOP OF GLASS TUBE. Never pump up with this cap off or loose.

5. Now set the cam at the maximum diaphragm position (lowest point on the cam) and apply pressure to the cuff and watch the diaphragm move out to its full extent. Turn the Switch to "CLOSE" and release the cuff pressure.

6. The mercury in the calibrated column should be at least '0' mm. Add more if necessary to bring it up to '0' mm. It is OK to be a few mm over '0'. This is a minimum 0 level.

7. With the Switch on "OPEN" and no pressure on the cuff, the mercury will settle at approximately 40 mm on the scale.

8. Check maximal zero level by setting cam at minimum diaphragm position (highest point on cam). Check this 3 times to make certain it is accurate. Record maximal zero level.

9. Replace rear cover.

Once the participant has had the procedures explained and the equipment has been checked, BP measurements may begin. The following steps must be followed precisely:

1. Record time of day and room temperature (°F).

2. If the participant indicates that there is a medical reason for not having BP measured on his right arm (injury or deformity), reverse chairs and use his left arm. Record on BP Form 2 that the left arm has been used.

3. Measure arm circumference by having the participant stand facing away from observer with arm bent 90 degrees at the elbow, hand on mid section. Locate the tip of the acromion (shoulder bone) and measure the length of the upper arm from the acromion to tip of elbow using the centimeter tape measure. Mark the midway point of the arm and then have the participant relax. Wrap the tape around the arm over the mid point mark, making sure that the tape is level. Measure the arm circumference to the nearest whole centimeter, and note this measurement on the data collection form. Then check the appropriate cuff size on the form. Thigh size should be rarely needed. If arm circumference is greater than 41 cm, borrow a thigh cuff.

4. Seat the participant in a chair with the back supported and with both feet resting on the floor. His arm should rest on the table with elbow bent and should be level with his heart. Palpate the brachial artery and mark this location lightly with a pen for stethoscope placement. Choose the correct size cuff and wrap it on the arm with the center of the bladder over the artery.

5. WAIT FIVE MINUTES

6. Take a 30-second pulse (radial artery) and record. Multiply x 2 for resting one-minute heart rate.

7. Establish the pulse obliteration pressure using a standard mercury manometer. Rapidly inflate the cuff to 70 mm Hg and then slowly inflate it 10 mm Hg at a time until the radial pulse can no longer be felt. At the point when the pulse is no longer felt, note number. Then deflate and disconnect the cuff. Record the pulse obliteration pressure.

8. Record the RZ maximum zero number, found next to the mercury column on the RZ device. Calculate and record the peak inflation level (pulse obliteration pressure + RZ maximum zero + 30). Note: If below 200 mm Hg., pump to or above the calculated peak inflation level but still record the information as usual on the form. Record the certification number of the RZ device.

9. Connect the cuff to the RZ manometer. Before inflating the cuff, check that the diaphragm tap for the random-zero sphygmomanometer is set at "open" and that the mercury has been allowed to settle for at least three seconds. Turn the wheel rim that projects from the right side of the rear cover down two or three strokes. If the wheel is not free to spin, the diaphragm is not completely deflated.

10. Inflate the cuff rapidly to the RZ peak inflation level. Note that the mercury will rise more slowly than in a standard sphygmomanometer. Holding the pressure steady in the bulb, count five seconds.

11. Turn the diaphragm tap to "close".

12. Make sure that arm is at approximately heart level and is supported. Place the bell of the stethoscope over the antecubital fossa and measure the blood pressure in the standard fashion. For systolic blood pressure (phase 1), record the first sound heard in a series of at least two sounds. For diastolic blood pressure (phase 5), record the first silence in a series of at least two silences, NOT the last sound heard.

NOTE: Record blood pressure in even numbers (with the exception of the calculated mean blood pressure). Record all readings to the nearest even whole number upward on the manometer scale, including the pulse obliteration point.

13. Release remaining pressure at the valve on the hand bulb and disconnect the cuff. After allowing the system to come to equilibrium, note and record the zero reading. Open the diaphragm tap and leave in the open position until mercury settles into the reservoir and manometer and the wheel is again free to spin.

14. Do not subtract the zero reading at this time.

15. Have the participant raise his arm above head level for 5 seconds. After waiting 25 seconds with his arm on the table, repeat steps 9 to 13 above.

16. STAND PARTICIPANT AND WAIT 60 SECONDS.

17. Repeat steps 9 to 13 while the participant is standing with his arm supported at heart level by an adjustable stand.

18. Subtract the zero values from the readings to get the actual (corrected) systolic and diastolic values. All arithmetic **must be done with a calculator after all three readings are completed.**

19. Record the sums of the two sitting blood pressures, divide the sums by 2 to obtain mean blood pressures.

20. If screening visit, review the blood pressure inclusion criteria for the particular screening visit. Follow criteria in Section IX.C.3.a.

During Phase I, some "quirks" have been found with the R-Z:

1. R-Z zero values **higher** than the maximum zero set for each R-Z have been recorded.

2. Zero values that are nearly the same for the two seated blood pressure readings and the one standing blood pressure reading have also been observed.

Recommendations were provided by both the Baum Companie, who distribute the Hawksley R-Z used in the study, and the blood pressure trainer. Please review this information and follow the recommendations carefully.

1. The higher than maximum zero values can occur when the blood pressure is taken with the bellows valve left open. This error allows the mercury to settle at approximately 40 mm Hg. on the scale. Other errors are:

a. not closing the bellows valve completely;
b. not waiting a full five seconds after inflating to the R-Z peak inflation level;
c. opening the bellows valve <u>before</u> reading the zero value;

d. not pumping the mercury column to or above 200 mm Hg with a low pulse obliteration point and

e. not turning the thumb wheel downward a couple of strokes to allow the mercury to settle.

Recommendations:

Follow blood pressure procedures carefully each and every time as outlined in this section. If a zero value higher than the maximum zero is found, retake that blood pressure after a rest period of between 30 seconds and one minute. This procedure should eliminate errors in blood pressure readings due to erroneous zero values. Also, be sure to check regularly for leaks and tears, and to clean the R-Z as needed.

2. Zero values that vary little between readings may be caused by a low pulse obliteration point of less than 100 mm Hg. When the R-Z is pumped up to **less than 200 mm Hg**, the R-Z reservoir may still be filled with mercury causing little variation in the zero value.

Recommendation:

Continue to record the pulse obliteration point plus adding 30 and the R-Z maximum zero on the Data Collection Form, Form 2. But if this number is **below 200 mm Hg**, inflate the cuff to at least 200 mm Hg when taking the blood pressure measurements. Thus, the change is to record the information as usual on the form, but to inflate to at least 200 mm Hg.

B. Alcohol Consumption Measures

The measures used in this study of the effects of reduction in alcohol intake on blood pressure are both different and interrelated. Each has an important and unique function either in the selection/ exclusion process or in the intervention itself. For this reason, please take every precaution to conform to the prescribed guidelines in the administration and scoring of each instrument.

1. Screening Instruments

a. Quantity Frequency Index. Individuals who report drinking in the past six months at least 10 drinks per week using the self-administered Brief Screening Instrument (Form 1) will be included in the screening pool.

b. Alcohol Dependence Scale (Form 4). This is a short questionnaire which should take no more than 10 minutes to complete. It is a much used, reliable and valid index of the alcohol dependence syndrome. The prime element distinguishing heavy social or nondependent drinkers from those who are alcohol dependent is their impaired control over alcohol which can be manifested in a number of ways which include signs of tolerance and withdrawal, a compulsion to drink excessively, and the emphasis on drink-seeking behavior.

A number of studies have validated the instrument. It has been found that patients scoring on the high end of the scale were less likely to keep their appointments, had severe psychosocial and medical problems especially at higher consumption levels, and could not envision cutting down drinking to a few drinks a day and thus chose abstinence as a treatment goal which was difficult to meet. Those at the lower end of the dependence scale were able to maintain a goal of moderate drinking over time. For this reason and to insure that the majority of heavy social drinkers would not be excluded, the cutoff score is 5. ALL INDIVIDUALS WHOSE SCORES ARE EQUAL TO OR GREATER THAN 5 ARE EXCLUDED FROM FURTHER SCREENING.

c. Lifetime Drinking History (Form 6). This is a structured interview which should take approximately 30 minutes to administer if there is sufficient rapport with the participant. It is designed to provide quantitative indices of the participant's alcohol consumption patterns from the onset of regular drinking through the present. Data on type of beverage, lone vs. social drinking, time of day, important life events, as well as quantity, frequency and variability are collected. The interview format should be followed as closely as possible. However, bear in mind that the best results will be obtained by maintaining a warm, empathic, knowledgeable therapeutic manner. Try to imagine that the participant is coming for alcohol treatment and that this is a major component of the intake evaluation. Such a format may enable you to more easily probe for and check information in a natural and relaxed manner. PARTICIPANTS WHO CONSUME AT LEAST 21 DRINKS PER WEEK (AN AVERAGE OF 3 OR MORE DRINKS PER DAY) OVER THE PREVIOUS SIX MONTHS QUALIFY FOR RANDOMIZATION.

2. Evaluation Instrument - Chronological Drinking Record (Form 13). The Chronological Drinking Record (CDR) (Form 13) is a self-reported measure of alcohol consumption which was developed by the Research Triangle Institute in collaboration with the National Institute on Alcohol Abuse and Alcoholism. The CDR provides a listing of the amounts of alcohol consumed on an event by

event basis for a specified time period by type of beverage, size, and number of drinks. In addition to alcohol intake, contextual data are recorded for type of beverage, number of persons present, time of day, duration of drinking, and occasion of use. The instrument also provides an index of how the participant's consumption of alcohol compared with that of others who may have been present in any given drinking event.

The CDR is a widely tested instrument that has been used in both research and clinical settings.

There is a specified period of one week for which data will be collected. The reference period will be the seven-day period ending on the day prior to the interview. Participant's recall is enhanced by the format which embeds the drinking events in their socio-ecological context. In addition, this method of data collection allows for the profile of any participant's drinking behavior, i.e., his drinking pattern, to emerge naturally. Indices of average weekly and daily consumption can also be calculated.

C. Universal Precautions

1. All study personnel are to strictly follow universal precautions in the care of all participants.

2. Anytime blood or body fluids are required during screening and the follow-up visits, use the appropriate barrier precautions to prevent skin and mucous exposure. These universal precautions include these steps:

a. Always wear gloves anytime contact with blood or infectious body fluids may occur. For example:
   1) When touching any mucous membranes or broken skin;
   2) When handling items or surfaces soiled with blood or other infectious body fluids;
   3) When doing veinpunctures -- use sharps properly in a puncture resistant container;

b. If advised by the Infectious Control Disease Section at your hospital, wear gloves, mask and eye protection when handling the blood or urine samples. These shields will help if there is a chance that blood or other infectious fluids may splash into your mouth, nose or eyes.

c. Contact the Infection Control Disease Section or Research Service about the availability of classes and information about universal precautions.

3. If exposed to blood or other infectious fluids, the following steps are recommended:

a. Wash the exposed area immediately with soap and water.

b. Save the sharps or other items involved for possible testing.

c. Report the incidents immediately to the PI and then to Employee Health. Be sure to report:

1) a needlestick injury or other cut or puncture;
2) splashing of blood or other body fluids into your mouth, eyes or nose;
3) direct contact with a large amount of blood or other infectious fluids;
4) prolonged contact with blood or other infectious fluids.

d. Follow procedures for testing and treatment as advised by Employee Health. If you have been exposed to HBV, you may be given immune globulin and/or hepatitis B vaccine to help prevent infection. You may also be tested for AIDS.

5. If your hospital Employee Health Service advises, you may want to be vaccinated for hepatitis B anyway. These injections are free of charge but are based on the health risks of the employee's work.

6. All study personnel for this study are recommended to review the materials on universal precautions, HIV infection and AIDS found in Appendix D. The Principal Investigator should review this material with any staff handling blood or body fluids. If classes are available at your site through Infectious Control, please attend them.

D. Biochemical Markers of Alcohol Intake

Samples for Central Laboratory analyses will be drawn at the third screening visit, after it is determined that the participant meets the eligibility criteria; at the three- and six-month follow-up data collection visits; and every six months thereafter until the end of the two years of follow-up. Participants will be instructed not to eat within 12 hours prior to the clinic visit. They may continue their usual beverage intake as long as fats (e.g., milkshakes) are avoided. The following procedure must be used for collecting and processing these samples.

1. Keep the participant in a sitting position and draw approximately 14 ml blood from the antecubital vein or, failing this, from some other convenient arm vein into two 7 ml vacutainer tubes (provided) containing liquid EDTA (Becton & Dickinson product #6450; lavender top tube with silicone lubricated stopper and NOT glycerol lubricated stopper!). Draw an additional 14 ml blood into a 15 ml vacutainer tube containing no additives (Becton & Dickinson product #6432; red top tube).

2. Spin the samples in the lavender top tubes IMMEDIATELY (if possible at 4°C) and separate the plasma (3 ml) into tightly sealing color coded plastic tubes (provided). DO NOT LET THE BLOOD OR PLASMA SAMPLES STAND AT ROOM TEMPERATURE MORE THAN AN HOUR.

3. Allow the sample in the red top tube to clot at room temperature for 30 minutes and then spin the sample to separate the serum. Transfer the serum (6-7 ml) into two tightly sealing color coded plastic tubes (provided). DO NOT LET THE BLOOD OR SERUM SAMPLES STAND AT ROOM TEMPERATURE MORE THAN AN HOUR.

4. Check to see that each tube is tightly capped so that the sample does not leak. Label each tube with the following information:

Medical Center Name and Number
Participant Name and Number
Rating Period
Date Collected

5. Store the plasma and serum samples at -20°C (freezer temperature). Each participant should have a color-coded set of samples.

6. When a sufficient number of samples have been collected each month, pack each set of samples in ziplock plastic bags and place them in a styrofoam cooler (provided). The cooler containing the sample bags should be completely packed with crushed dry ice and should be taped shut. Place all the paper work pertaining to the shipment outside the cooler in a large envelope. Use the Central Laboratory Data Checklist completing the header information, participant number and rating period for the sample.

Note: Form 14 header should be completed by the Data Collector. The date completed is the date of the visit and the section labeled "Completed by" should be the Data Collector's name.

7. Send the plasma and serum samples to:

   Dr. Raj Lakshman
   Chief, Lipid Research Laboratory
   CS#996, "Prevention and Treatment of Hypertension Study (PATHS)"
   Mail route #151T
   VA Medical Center
   50 Irving Street, N.W.
   Washington, D.C. 20422

   Ship the samples using an overnight delivery service on **MONDAYS** or **TUESDAYS**. **NEVER SHIP SAMPLES ON THURSDAYS OR FRIDAYS.**

E. Illicit Drug Screen

Urine samples will be collected during screening and follow-up and will be analyzed locally for the presence of marijuana, cocaine, opiates, amphetamines, barbiturates and benzodiazepines. Positive results during screening do not necessarily mean that the individual should be excluded. The significance of positive screening results must be assessed by clinical interview. Drug screen results are sensitive and confidential. They must not be included in any data files (e.g., the local laboratory's computer data file) other than the participant's study files.

F. Echocardiogram Methodology

1. Arrangements with the Local Echo Laboratory

The Data Collector will schedule the participant with the echocardiography laboratory. On the study day, it is suggested that he/she deliver the participant to the laboratory along with a Echocardiogram Worksheet (Form 15A) and the videocassette tape (format to be compatible with the lab VCR) used for PATHS echos. Tapes should be supplied by the participating clinic. Other material, such as strip chart paper, will be supplied by the local echo lab. It is also suggested that the Data Collector retrieve the tape and echo hard copy when the study is completed.

The Data Collector will record the information required at the top of the Form 15A. This form should be stored with the echo hard copy. Storage of the echo tapes and paper strip chart recordings by the Study Clinic will remove this responsibility from the echo lab to the PATHS investigator and hopefully reduce the likelihood of losing data.

2. Mailing to Echo Laboratory

When four studies have been recorded on the tape, envelopes containing the echo strip chart recordings, labeled with name and date, copies of the partially completed echo forms and a copy of the videotape (protected in a padded mailer) should be sent to the following address:

Physicians' Health Care Center
Division of Cardiology, 5th Floor
3800 Reservoir Rd. NW
Washington, DC 20007
Attn: Echo tapes VA CSP #996

Note: Form 15A header must be completed by the site Data Collector except for form completed by and date of reading. Be sure to record the rating period "00" or "06" accurately. Form 15A is sent to the Echo Lab at the same time with the echo tape.

Make sure that the echo technician has completed questions 3-15 and that questions 1 and 2 are also answered.

Complete the Central Laboratory Data Checklist providing the header information and the listing of the participant numbers and appropriate rating period, "00" or "06."

Send the echo tapes monthly to the Central Echo Laboratory. Do not send by certified mail. Other options are: overnight mail, priority regular mail, second day or regular.

G. Collection of Overnight Urines

At baseline and every six months thereafter, each participant will bring an overnight urine sample for determination of sodium, potassium, magnesium, and creatinine. The purpose is to determine if there are potential confounding effects on BP changes in sodium and potassium intake. Creatinine will be used as a check on the adequacy of urine collection.

Several studies have shown that results of overnight collections are significantly correlated with 24-hour collections. Overnight collections facilitate compliance because they are much simpler for patients.

Supplies that are needed for collecting overnight urines include:

1. participant instruction sheets,
2. 24-hour urine collection containers,
3. small capped containers for holding and transferring 30 ml aliquots to local laboratory for analysis,
4. 250-1000 cc graduated cylinder for accurate measurement of total urine volume, and
5. protective gloves for handling urine specimens.

Each participant must be given an instruction sheet and a labeled collection container for each overnight collection. The following instructions should be reviewed with the participant each time:

1. At bedtime on the evening before his next appointment, he should place the collection container in an obvious place near the toilet he will use during the night and upon arising in the morning. This will serve as a reminder to save the urine.

2. He should empty his bladder into the toilet before going to sleep. This urine is not to be saved. However, he should make a note of the time of this void (so that it can be recorded on Form 10).

3. All urine passed during the night and the entire first void when he arises in the morning should be saved in the container provided. He should also make a note of the time of the first morning void. This will allow the total hours of collection to be determined (data recorded on Form 10).

4. He should bring the urine collection with him to his appointment. The participant should be questioned to make sure that he followed the procedure correctly. If he did not, he should be reinstructed and asked to provide another overnight urine collection.

5. If the participant is female, ask her to collect the overnight urine when she is not menstruating. This information should be asked of each female participant when the overnight urine collection is done at baseline and at F6, F8, F10 and F12.

Overnight urines must be processed by the end of the day using the following procedure:

1. The <u>total volume</u> of urine is measured and recorded on Form 10.

2. Two 30-ml aliquots (or other amount if required by local laboratory) will be placed in the small capped containers. Send one to the local laboratory for determination of creatinine, sodium, potassium and magnesium concentration.

3. Freeze the second aliquot for resubmission in case the first aliquot is lost or the results appear inappropriate. Some of these aliquots will also be used for quality control analyses. Label this container with the hospital number, participant number and date of collection.

4. Discard remaining urine in an appropriate place. Do not discard into a sink.

5. When the laboratory results are posted, enter the concentration data on Form 10.

Send the first 10 samples of the second 30-ml aliquot to the Boston Renal Laboratory to be analyzed for quality control purposes. After that, send every 15th collection of the second aliquot from then on. If possible, send samples every month. Send the samples to the Renal Laboratory using Form 10A for shipping the samples to the lab. The header should be completed with the participant number listed in consecutive order. **Do not complete results section. This section will be completed by the lab.**

They should be packed in an insulated shipping container filled with dry ice. Samples should be sent using an overnight delivery service on **MONDAYS** or **TUESDAYS** and should never be sent on **THURSDAYS** or **FRIDAYS**. Mail these samples to:

Robert Hamburger, M.D. (DVACS #996)
Renal Laboratory, Room A7-90
VA Medical Center (111)
150 South Huntington Avenue
Boston, MA 02130

XIV. INTERVENTION PROCEDURES

All participants will be told not to reveal their randomization status to the study Data Collector, but to provide accurate responses to any questions asked by the Data Collector.

A. Alcohol Reduction Intervention

1. Model

There are a number of treatment models applied to addictive behaviors. These vary in setting (e.g., inpatient hospital care, outpatient psychiatric treatment, half-way house living, and self-help groups such as AA), in intensity, and in theoretical base. Studies of treatment effectiveness suggest that all work equally well, with length of treatment, usually in an outpatient clinic, being a critical factor. An examination of the elements in successful treatment programs indicates certain commonalities, viz. teaching or helping patients to (1) replace drinking with alternative coping behaviors, (2) develop techniques to deal appropriately with emotional states, social pressures, and interpersonal problems, and (3) increase or develop confidence in personal competency. As noted above, it has been observed that success in dealing with drinking problems was related to the length of time spent in outpatient treatment but did not require a goal of total abstinence for all patients. In such settings, patients develop a trusting relationship with counselors. They learn to understand reasons for drinking, explore and experiment with alternatives to drinking in the context of this safe relationship, and gradually take on full responsibility for managing their lives with confidence in their self-mastery. These changes are produced by the application of the principles of learning theory, regardless of the theoretical frame of the treatment offered. Unfortunately, therapists are not always aware that they do this or how to go about it effectively.

It is likely that brief, inexpensive, learning theory based treatment approaches, will, in this next decade, supplant the more expensive, and often very long term, outpatient treatment model just as the latter is overtaking the costly "AA illness" model of inpatient hospital care with its goal of abstinence. However, it may always be the case that severely impaired (psychologically or cognitively) or dependent drinkers will require more intensive care. Most of the cognitive-behavioral treatment models developed in the late 60s or 70s are rooted in principles of behavior modification. They have been applied with success to a wide range of drinkers. Because they rely heavily on self-mastery (in some ways helping the client to become his own therapist or problem-solver) which necessitates homework assignments or self-

paced tutorials and can be applied in group settings, these treatments should prove more successful and cost effective.

In the past 15 years, a number of investigators have developed models and studied the outcome of cognitive interventions in heavy drinkers. The components of these interventions are similar and emphasize self-monitoring, self-control, and self-mastery, all of which are developed and enhanced by homework assignments, behavioral record keeping, and practice outside the treatment setting. In each approach, patients are taught to analyze their drinking patterns, to learn alternatives to using drinking as a coping device, and to develop methods of "self-soothing" or relaxation. The most effective treatment models include strategies for initiating and maintaining behavior change, thus reducing the risk of relapse. The key element in preventing relapse seems to be a strong sense of self-mastery inculcated by the patient gradually assuming more responsibility for planning and implementing change. Thus, he not only experiences and comes to expect success on his own but also is less negatively impacted by occasional lapses or "failures". This approach towards self-efficacy may be enhanced by a goal of controlled drinking as opposed to abstinence. Sanchez-Craig and colleagues found no differences between subjects randomly assigned either to controlled drinking or to abstinence; in both groups, subjects moderated their drinking and generally maintained the improvement through two years of follow-up.

In summary, expanding one's repertoire in personal and social functioning and increasing self-confidence by planning and experiencing effective coping behaviors seems to protect individuals from returning to problem drinking (and other negative habitual behavior, as decreased alcohol consumption often results in improvement in other areas of life). A program based on principles of learning theory and applied in stages that allow progression from increasing motivation to change, initiating change, and maintaining change by preventing relapse through increased self-efficacy seems essential to the goals of this study. Because each segment can be strictly defined and operationalized, it will be a less difficult task to assess the effectiveness of a behavioral model in reducing alcohol consumption than if more "traditional" outpatient treatment modalities were to be applied.

The intervention model to be used will be adapted from the Sanchez-Craig brief treatment program for early intervention in alcohol abuse and alcoholism. Components of other behavioral models will be added to ensure sufficient attention to increased self-efficacy and relapse prevention. The self-help materials developed by Sanchez-Craig at the Addiction Research Foundation will be the mainstay for the participants' homework.

2. Role of Interventionist

Interventionists (GS-11 social workers, nurse clinicians/practitioners or masters level psychologists with some clinical experience) will be centrally trained at a one-week training workshop in the application of the model and the integrated use of other materials. The trainers, experienced clinicians, will carefully take personnel through the procedures, session by session, using didactic and experiential techniques. After determining that interventionists understand and have some degree of comfort with the materials, a few subjects will be selected who are representative of the patient population at each site. The trainer will then monitor interventionists' application of the procedure with these subjects in a manner similar to that used in clinical supervision. Quality assurance will be maintained throughout the study by periodic checks in the form of clinical supervision, videotaped sessions, conference calls, and/or site visits.

The Interventionist should see herself as a therapist, teacher, and role model whose prime responsibility is to assist the participant in becoming his own change agent. This means that she must learn to present succinctly the necessary techniques in a manner which the participant will readily comprehend. Thus, her examples should be taken from his life or at least should be concordant with his circumstances and her communications should be clear, concise, and framed in language which is neither beyond nor beneath his level. In addition, the Interventionist must guard against taking on any one of the multiple roles she must play to the exclusion of the others.

Regardless of her therapeutic style or different manners of interaction with each patient, the Interventionist must teach the participant to be self aware, i.e., to monitor his behavior on a daily basis; to exercise self control, i.e., to stop and think before engaging in a potentially harmful act; to plan ahead; and to implement alternative behaviors to drinking, or other harmful behaviors. This is best accomplished by using situation-specific issues that the participant brings to, or which arise in, the session, in addition to the systematic homework review in each of the interventions.

In addition, despite the order of presentation, interventionists should use the following guides to all sessions: elicit new information; answer questions; review the previous session; present new issues; give homework and review it to ensure that participants understand what is expected. There should be an appraisal of whether, how well, and with what degree of confidence the participant adheres to his goal throughout the entire process.

If a participant deviates from his goal or is negligent in record keeping, Interventionists should guard against evidencing disappointment or negative judgment. A firm reminder of its value and assistance in doing the assigned homework should suffice.

If a participant is persistently uncooperative and/or if a participant exhibits potentially serious problems, his suitability for participation should be reevaluated.

3. Intervention Sessions

Participants randomized to the alcohol intervention will receive six 60-90 minute individual sessions in the first three months and at monthly intervals for the duration of the initial six-month study phase. During the maintenance stage, they will be seen at one- to three-month intervals for review and booster sessions. This plan of gradually decreasing visits will permit participants to gain control over their own lives and increase their self-confidence in mastering situation specific behaviors which will accrue from learning experiences independent of the treatment.

Participants will learn to analyze their drinking behaviors in personally defined, situation-specific circumstances. They will identify high risk situations and review their current coping methods, generate new cognitive and/or behavioral approaches to these situations and apply these new coping strategies outside the treatment. This method will increase self-confidence towards meeting their drinking goals. The interventionist will be active in the treatment phase but will serve principally as an advisor to the participant who sees himself as the primary change agent. A self-help manual and daily drinking records will be used to assist the participant throughout the intervention.

The first intervention session should occur within two weeks of the participant's randomization visit (screening visit 3). The second intervention session will follow one week later. Intervention sessions 3 through 6 will follow at two-week intervals.

The only baseline information on alcohol consumption which the **Interventionist may use during the intervention sessions are the LDH, Form 6, and the baseline CDR, Form 13. Two other forms, the Medical History Form, Form 5, and the Physical Exam Form, Form 11 can also be used.** These instruments are not repeated throughout the study and would not impact on the primary endpoints of the study.

pattern, discuss where he falls on the dependence/problem range, factors related to this, and whether his drinking level and pattern is a "safe" one.

3) Clearly state the objectives of the intervention. Wherever it is relevant and consistent with the assessment data to which you are permitted access, use case material from this session to illustrate your summary of each segment. This is a particularly effective technique which should lead to improved receptivity by participants who will feel understood and may find it more meaningful to respond to personally relevant materials.

Outline the Objectives:

(a) to identify situations where drinking occurs or is excessive, i.e., "risk situations" and to begin to explore factors which might account for this,

(b) to develop strategies that allow coping with these situations without drinking/over-drinking,

(c) to establish a pattern of drinking that meets the study goals and does not interfere with important duties/daily functioning, and

(d) to learn to monitor progress objectively, i.e., self-monitoring.

Identify a few situations which have led to either heavy drinking or an urge to do so and ask the participant to generate as many alternative ways as possible in which the situation could be handled.

Discuss how these might help in establishing a reasonable drinking pattern, given the guideline of no more than two drinks daily.

4) Review, for as many times as necessary for comprehension, the Daily Drinking Record (DDR Figure 9). Explain how it can be used to think about all aspects of the intervention.

DAILY DRINKING RECORD

DVA COOPERATIVE STUDY #996 - PATHS Participant No. _____ Week # ____ Beginning ___ ___ (Mo Day) Ending ___ ___ ___ (Mo Day Yr)

DATE/EVENT	TIME	LOCATION	DRINK TYPE	AMOUNT	OCCASION/ REASON	PERSONS PRESENT			YOUR DRINKING			EFFECT	MOOD	PRESSURE
						No.	Drinking Yes/No	Who	Plan Yes/No	Compared To Plan	Compared To Others			

FIGURE 9

Stress the importance of careful self-monitoring for self-control and mastery in all areas of his life.

Sell him on the benefits of thinking this way! Give him a supply of forms with instructions and the examples completed in the session, encourage him to begin keeping records that evening, and remind him to bring this "homework" to his next session.

5) Close the session with a restatement of the program, e.g., that it is intended to demonstrate that a reduction of alcohol intake to two drinks daily will lead, without medication, to a concomitant decrease in blood pressure and a general improvement in outlook and health.

Help participant recognize that heavy drinking patterns have interfered with his health. Give encouragement that his participation in this program with its focus on drinking behavior and coping with situations associated with heavy drinking will help the participant learn to reduce stress levels and deal effectively with the problems of daily life, in addition to helping him maintain his drinking goal.

Remind the participant that he will be expected to attend, or reschedule with sufficient time and reason, each of the 5 additional 60 to 90-minute intervention sessions which will take place biweekly, the three monthly follow-up sessions, and the maintenance sessions at one- to three-month intervals for the remainder of the study period.

b. SESSION II:

1) Review questions and/or problems participant may have had in past week. Be sure he is as relaxed as possible and in a cooperative frame of mind. If there is resistance, deal with it immediately.

2) Review homework (DDRs) with participant. Help him to see his typical drinking behaviors/pattern. Discuss reasons why he drinks, why he drinks too much. Increase his awareness of problem situations. Check discrepancies against the material he originally presented. Give him the drinking pattern questionnaire (Figure 10).

Make it clear to the participant that these behavioral records will assist him in achieving and maintaining his goal by allowing him to note what situations are safe and which are dangerous in terms of drinking.

Demonstrate how these records help him cope by providing him an opportunity to "rethink" problem events and plan and rehearse alternative strategies.

If the participant has neglected to record his behavior for the entire period, ask him to recall with you the drinking events for the missing days. Repeat, with emphasis, the importance of keeping accurate daily records.

3) Discuss the need to establish a goal towards which he will work in the intervention. To this end, ask for a period of abstinence during which he will review the materials listed below and think about his goal so that he comes to the next meeting prepared to set one.

4) Give him and review: Steps for Reaching and Maintaining Moderate Drinking or Abstinence (Figure 11); Analysis of Function Questionnaire (Why Do People Drink? [Figure 12]); Reasons for Wanting to Reduce (Figure 13); an Activities List (Figure 14); and Marlatt Motivation Form (Figure 15) to use as tools in setting his goal.

Assess his level of confidence with respect to maintaining the goal of abstinence for the two-week period.

Do the Analysis of Function Questionnaire with him. Have the participant describe in detail each event where drinking was a problem. Be sure he delineates the antecedents and both the immediate and delayed consequences for each situation, including those with which he coped successfully. Ask him to generate a list of activities to replace drinking.

5) Emphasize that your role will be to assist him through the various steps illustrated in Figure 11. Stress that this approach has been successful in many cases and has produced the same results as long-term therapy. Empower participant by noting that he may progress at his own pace and in his own manner, based on his understanding of the principles learned in these sessions. Note that he will find the approach an effective one for all behavioral problems. Emphasize the importance of "self talk" as the essential step in coping. Stress that he can always make use of mental imagery no matter where or what his circumstances.

FIGURE 10

ASSESSING YOUR CURRENT PATTERN OF DRINKING

To help select a suitable drinking goal, it is useful to have an accurate picture of your drinking for the past three months. This is important because it will give you the baseline needed to assess your progress.

This form will help you to assess how much and how often you have drunk.

Some people find that using a calendar to mark special events such as holidays, birthday parties, sick days, etc., allows them to recall their drinking better.

QUANTITY AND FREQUENCY OF DRINKING (PAST 90 DAYS)

	Days	Usual number of drinks
# of abstinent days	_____	
# of moderate days (1-4 drinks)	_____	_____
# of heavy days (5-8 drinks)	_____	_____
# of very heavy days	_____	_____
Total # DAYS (this should = 90)	_____	

On how many of these last 90 days
did drinking cause you to have problems
(e.g. hangover, missed work, neglected
important duties, quarreled, etc.): _____ DAYS

On these days when drinking caused you problems,
what was your range of consumption: from _____ to _____ drinks

FIGURE 11

STEPS FOR REACHING AND MAINTAINING
MODERATE DRINKING OR ABSTINENCE

The following five steps have been identified by heavy drinkers who participated in a similar program as very useful for reaching and maintaining moderate drinking or abstinence.

1. ASSESSING YOUR CURRENT PATTERN OF DRINKING AND IDENTIFYING THE SITUATIONS OF "HIGH RISKS."

2. ABSTAINING FOR A PERIOD OF 2-3 WEEKS BEFORE DECIDING WHAT YOUR DRINKING GOAL WILL BE.

3. DEVELOPING SKILLS FOR COPING WITH URGES AND SOCIAL PRESSURES TO DRINK.

4. PRECISELY SPECIFYING THE LONG-TERM GOAL OF DRINKING.

5. LEARNING SKILLS FOR REGULATING AND FOR MAINTAINING THE SPECIFIED GOAL.

FIGURE 12

WHY DO PEOPLE DRINK?

This questionnaire will help you identify <u>your</u> reasons for using alcohol.

1. For each of the reasons outlined, indicate your level of drinking, given the following choices. If "B" and "C" are true for you, place an "X" in both boxes.

   A = No, I don't drink for this reason.
   B = Yes, I drink light-to-moderate levels (from #____ to # ____ drinks).
   C = Yes, I drink heavily or over-drink (from #____ to # ____ drinks).

2. Rank the reasons for which your choice was "C = Yes, I drink heavily or overdrink." Assign #1 to the most frequently occurring reason, #2 to next most frequently occurring reason, and so on.

	*Place an "X" to indicate choice.			
DRINKING TO COPE	A	B	C	Rank of C
To change feelings or moods, e.g., to feel less anxious, lonely, bored, angry, frustrated, guilty, to "forget"	( )	( )	( )	____
As an aid for dealing with difficult situations, e.g., to express anger or affection, to engage in sex, to do boring tasks, improve one's memory.	( )	( )	( )	____
As a medicine, e.g., to help sleep, to relieve hangover, physical pain.	( )	( )	( )	____
DRINKING FOR PLEASURE				
To be part of the crowd and be able to enjoy parties more.	( )	( )	( )	____
To enjoy the taste of beverages.	( )	( )	( )	____
To enjoy "getting high".	( )	( )	( )	____
To enhance meals, celebrations, leisure activities, socializing.	( )	( )	( )	____
DRINKING HABITUALLY				
Drinking usually occurs at the same time, in the same place, or in the company of the same people.	( )	( )	( )	____
Other: Specify _____	( )	( )	( )	____

FIGURE 13

REASONS FOR WANTING TO ABSTAIN OR REDUCE YOUR DRINKING

People give various reasons for wanting to reduce their drinking. Frequently given reasons are: concerns about their work, their marriages or family lives, their health, and self-disgust, i.e., having felt foolish or having embarrassed their friends and/or families in social situations.

It would be helpful to list the reasons for which it is particularly important for you to change your drinking habits.

JOB-RELATED PROBLEM: _____
_____
_____

FAMILY/MARITAL CONFLICTS: _____
_____
_____

FINANCIAL/LEGAL PROBLEMS: _____
_____
_____

CONCERNS ABOUT PHYSICAL OR
EMOTIONAL HEALTH: _____
_____
_____

SELF-DISGUST: _____
_____
_____

OTHER (Please specify): _____

FIGURE 14

LEISURE ACTIVITIES

People who have been successful after involvement in programs to reduce drinking replaced the time they spent drinking with leisure activities. These have included, but are not limited to, the following:

Physical Exercise: Fitness class, jogging, swimming, walking, dancing.

Hobbies: Refinishing furniture, knitting, crafts, woodwork, gardening.

Courses: Photography, art history, literature, cooking, mechanics.

Clubs: Bridge club, chess club.

Volunteer work: Hospitals, churches, community services.

MAKE A LIST OF ACTIVITIES THAT YOU WILL PURSUE:

FIGURE 15

MARLATT MOTIVATION FORM

A. How strong is your desire to change your current level of drinking to improve any drinking-related health problems? Please circle the number below corresponding to the strength of your desire to change:

1	2	3	4	5
not at all strong	slightly strong	moderately strong	very strong	extremely strong

B. Please indicate the amount of change you expect in your level of drinking as a result of participating in this program.

1	2	3	4	5
stop drinking	very large decrease	small decrease	no change	increase

c. SESSION III:

1) Assessment of progress to date. Review Drinking Records, review homework, and determine whether the participant is behaving in a manner consistent with and implementing steps necessary to maintaining his goal.

2) Establishment of long-term goal using from the manual: reasons for wanting to reduce (Figure 13), alcohol use questionnaire (Figure 10), and developing successful coping forms (Figures 16, 17, 18) as guides. Assess confidence in maintaining the long-term goal.

3) Specify rules and guidelines for moderate drinking or abstinence using the Sanchez-Craig manual as back-up. Discuss maximum quantity and frequency, beverages, appropriate and inappropriate drinking situations as they relate to the goal (see Figure 19).

4) Identify aids to facilitate moderate drinking or abstinence: skills for pacing drinking, learning to prepare in advance for drinking events, monitoring effects of drinking, developing new recreational activities.

5) Focus on functional analysis of drinking using information gleaned from interviews, DDRs, homework with special attention to:

(a) identifying problematic drinking situations (Figure 20),
(b) generating alternative behaviors and activities to eliminate or moderate drinking,
(c) coping with situations that tend to arise when drinking is significantly reduced (unexpected urges, social pressures and relapses).

Stress the role of cognitive behavior, i.e., self talk, mental imagery, rehearsal, etc. in problem solving.

6) Repeat the need to self-monitor and ask the participant to focus on aids to successful coping, i.e., what protects him from drinking too much, to note situations which may lead to goal violation, and to identify obstacles in goal maintenance. Give him Guidelines for Sensible Drinking (Figure 21).

FIGURE 16A

IDENTIFICATION OF RISK SITUATIONS AND REQUIRED COPING SKILLS

(for Interventionist's use in the session)

1. Specify the principal risk situations, and the functions attributed to alcohol in these situations:

2. Specify how the participant will cope in these situations. Identify particular cognitive and behavioral coping skills:

FIGURE 16B

IDENTIFICATION OF RISK SITUATIONS AND REQUIRED COPING SKILLS

(for participants's use at home)

1. List the types of situations in which you may have drunk too much or too heavily. Also try to recall, and list, why you may have done this and what you thought alcohol would do for you.

2. How might you handle these situations now and in the future? List the sort of things you might either think or do to change the outcome of these situations.

FIGURE 17

COPING WITH URGES TO DRINK

DATE: ___ ___ ___

Recording how you cope with urges to drink during the next few weeks can be very useful: It can increase your understanding of the role that alcohol has played in your life, and it can help you to identify the approaches that are most effective for avoiding drinking or overdrinking.

An urge to drink can be defined as a "strong desire" or a "strong temptation" to use alcohol. When you have found yourself struggling with such feelings, make a record of the situation:

Where were you when you had the urge to drink?

_____

Can you describe how you were feeling?

_____

What did you "say to yourself?" to overcome the urge?

_____

_____

_____

_____

What did you do instead of drinking?

_____

If someone invited you to drink, how did you refuse?

_____

_____

_____

How effective would you say your coping was in this situation?
Very effective ____ Moderately effective ____ Ineffective ____

FIGURE 18

SUMMARY OF YOUR BEST WAYS OF COPING

When you have completed several copies of the form on coping with "urges", make a list of the following:

Approaches that best counteract your own rationalizations (excuses to yourself) to drink or overdrink:

_____

_____

_____

_____

Approaches that best help you to resist social pressures:

_____

_____

_____

_____

Tricks that have been useful to avoid inappropriate drinking (e.g., having a full glass in my hand all the time to avoid invitations from friends; having a variety of non-alcoholic beverages available; drinking non-alcoholic beer):

_____

_____

_____

_____

Activities that have been useful for avoiding inappropriate drinking (e.g., going to shows, visiting friends, exercising):

_____

_____

_____

_____

FIGURE 19

SETTING YOUR GOAL OF MODERATE DRINKING. If you were successful in abstaining for 2-3 weeks, or have made significant reductions in your drinking, you should be ready to select your goal for moderate drinking. In doing so, make sure that you do not exceed the levels of drinking adopted by successful moderate drinkers. Specify your goal along the following dimensions:

Quantity: Maximum number of drinks you will take on any day. ____

Frequency: Maximum number of days on which you will drink during any week. ____

Weekly Quantity: Maximum number of drinks per week. ____

Types of Beverages: _____

Inappropriate Situations (Those you identified as causing you problems in the Why Do People Drink questionnaire; include those situations where drinking was sometimes a problem and sometimes not.):

_____

_____

_____

Appropriate Situations: _____

_____

_____

Assessment Period: Number of weeks _____ or months _____ during which you will assess how suitable this goal is.

CHECKING IF YOUR GOALS ARE REALISTIC. A good way of checking if the goals you have set are realistic is by asking yourself the following question.

"How confident am I that I will be able to drink within the limits of this goal?"

If you are <u>very confident</u> or at least <u>moderately confident</u> go ahead and give it a try. However, if your confidence is <u>low</u>, adjust the goal to make it more realistic.

FIGURE 20

SPECIFIC INCIDENTS OF PROBLEM DRINKING

Think about a situation in which you drank heavily or more than you have intended, then describe this situation in terms of the questions below. Make your description as concrete as possible.

Think first of the incident that you wish to describe, and then answer questions as concretely as possible:

1. BEFORE DRINKING

Where were you and with whom when the decision to drink was made?

_____

What were you feeling before you drank? _____

_____

Were you preoccupied by anything? _____

_____

What did you expect alcohol or drinking to do for you? _____

_____

2. DURING DRINKING

Where and with whom were you when the **actual** drinking occurred?

_____

3. AFTER DRINKING

After consuming your first two or three drinks, how did your thoughts, mood, behavior change? _____

_____

_____

_____

Were there further changes with continued drinking (e.g., felt sick, guilty, depressed, passed out, got into a fight, spent too much money, missed work, was charged with impaired driving)? _____

_____

_____

4. Develop Activities that Do Not Involve Heavy Drinking. Sensible drinking can be better achieved if you:

   * replace the times spent drinking with enjoyable activities (e.g., hobbies, physical fitness or educational programs)

   * avoid socializing with people who encourage you to drink or overdrink.

5. Cope with Problems of Daily Living. To maintain sensible drinking, do not use alcohol to:

   * cope with unpleasant emotions (e.g., when you feel depressed, bored, anxious, lonely, etc.)

   * help yourself do things that you find difficult (e.g., to express anger; to be more affectionate, sociable or assertive; to complete tedious tasks, etc.)

   * medicate yourself (e.g., to help sleep; to reduce physical pain).

Everyday problems can upset your plans to change your drinking. Therefore, it is important to find adequate solutions to those problems as quickly as possible. The rule to keep in mind is that alcohol should not be used to cope with problems.

GUIDELINES FOR SENSIBLE DRINKING

M. SANCHEZ-CRAIG Ph.D

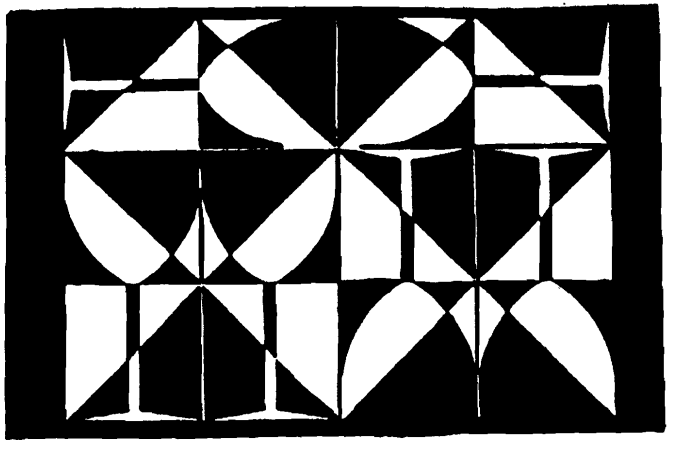


FIGURE 21

GUIDELINES FOR SENSIBLE DRINKING

A sensible drinking pattern does not interfere with your health or important duties. Of course, you may choose to abstain. If you drink, follow these recommendations:

* DO NOT DRINK DAILY

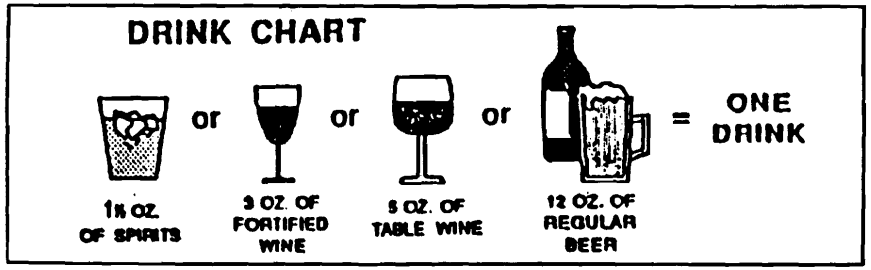
* DRINK NO MORE THAN 2 DRINKS/DAY

* TO BECOME/REMAIN HEALTHY,

  DRINK NO MORE THAN 12 DRINKS/WEEK

* TO REDUCE THE RISK OF HEALTH PROBLEMS,

  SET A SPECIFIC GOAL WITHIN THESE LIMITS



FIVE STEPS FOR SENSIBLE DRINKING

1. Keep records. To assess your progress:

   * maintain a daily record of how much you drink. As one needs an accurate scale when trying to lose weight, one needs an accurate record of drinking when trying to cut down.

   * keep records of the strategies you use to deal with your temptations to drink too much and the pressures from others.

2. Pace Drinking. To avoid intoxication:

   * measure drinks

   * dilute drinks, rather than drinking them straight

   * sip drinks, rather than gulping them

   * alternate alcoholic and non-alcoholic beverages

   * avoid drinking on an empty stomach.

3. Prepare Yourself to Avoid Heavy Drinking. In situations where your temptation and the pressures to drink are likely to be strong, prepare strategies to:

   * counteract temptations to go over your limit (e.g., "I have to work tomorrow." "I don't want to ruin my good record.")

   * refuse drinks without feeling guilty or antisocial (e.g., "I've reached my limit; I don't want another drink.")

   * leave the situation if your coping ability is doubtful (e.g., have an excuse at hand).

FIGURE 21 (Cont.)

WEEKLY SCHEDULE

	MONDAY	TUESDAY	WEDNESDAY	THURSDAY	FRIDAY	SATURDAY	SUNDAY
7 AM							
8							
9							
10							
11							
12 N							
1 PM							
2							
3							
4							
5							
6							
7							
8							
9							
10							
11							
12							
1 AM							

WEEK OF _____

COMMENTS: _____

_____

FIGURE 22

e. SESSION V:

1) Teach participants how to deal with high risk situations by encouraging them to:

(a) make decisions regarding their goals in the context of behavior in daily living,

(b) problem solve by individually defining risks and developing alternative coping strategies,

(c) make use of rehearsal, modeling, thought control, and self-soothing as relevant to situation and person specific risks be they environmental, interpersonal, or intra-personal.

2) Encourage participant to continue monitoring behavior. Have him generate a list of personally relevant situations (Figure 23) for each of the above steps and emphasize that you will expect him to report the outcome of his practice in the next session.

3) Give homework which includes weekly schedules as preventatives as well as the self reports yielded by the exercises in Section 2.

FIGURE 23

PERSONALLY RELEVANT SITUATIONS

If possible, in each of the three categories below, describe three specific incidents in which you have had either an urge to drink or an episode of heavy or problem drinking. Include in your description, what led to either the urge or the drinking. If you drank, what were the immediate and long term results? Did alcohol serve the purposes you had intended?

Use additional sheets where necessary.

Interpersonal Problems:

1. Conflict with your spouse, (friend, employer, employee).
2. Social pressure to drink.

_____

_____

_____

Negative Emotions:

1. When you feel depressed (or anxious).
2. When you feel tempted to break your drinking goals.
3. If you should actually violate your goal.

_____

_____

_____

Lifestyle Changes:

1. There you have difficulty developing new leisure activities.
2. There you find it difficult to make new friends, etc.
3. If you have trouble getting a new job, etc.

_____

_____

_____

f. SESSION VI:

1) Review Sessions I-V and assess progress and goal status. Train for a focus on self-management to head off potential problems by anticipation and rehearsal.

2) Discuss the Goal Violation Effect and its potential impact. Take participant through some examples to assess coping. Rehearse specific situations, especially where the participant is weak. Participant should be proficient in problem solving and self-monitoring. Assess this by reviewing several hypothetical situations.

3) Discuss need to schedule, on a regular basis, for leisure time and pleasant activities. Review possible weekly schedules with the participant.

4) Emphasize that all problems can be dealt with by a change in Action, Thought, or Emotion, or a combination thereof. Discuss need to plan ahead for all activities and anticipated risk situations to prevent relapse.

5) Review schedule for next phase of the program: time, number of visits, guidelines for telephone contacts, dealing with emergencies, etc.

This is the final treatment session. The interventionist should review progress and make recommendations as indicated by participant's improvement status and special needs. In addition, she should review and ensure that the participant has a supply of all materials needed to continue the program independently during the maintenance stage. She should also be sure that he knows how to use them and is convinced of the utility of doing so. It may be helpful to rephrase in a manner appropriate to the context, the talk you gave when introducing the Guidelines stressing the importance of self-monitoring, cognitive rehearsal and other behaviors helpful to maintaining self-mastery.

4. Between Session Contacts

Participants who have problems coping, doubts about maintaining their goals or a desire to change goals, or who are in any perceived emergency situation should be encouraged to call the Interventionist.

Interventionists should record all phone contacts and interim visits in the participant's record. This record should include date, length, type, and purpose of the contact. Topics discussed and participant's drinking status should be noted. If a phone call was followed by a visit, the length of time between the call and visit should also be noted. See Figure 24, Between Session Contacts, which should be used as a clinic guide.

5. Follow-up Sessions

Following the initial six sessions, intervention follow-up sessions will be arranged at one-month intervals during the remainder of the six-month initial treatment phase and at one- to three-month intervals during the 18-month maintenance phase.

The Interventionist should regard each of these sessions as a "Booster" which helps reinforce what the participant has learned in the initial treatment phase. Special attention should be given to areas in which the participant has had or anticipates having a problem.

In each of these sessions, the following points should be addressed and assessed: goal maintenance and confidence level, self-monitoring, problem-solving, new or old stressors posing problems, lifestyle changes, drinking status, problem status, temptations and urges to drink, and adherence to maintaining weekly schedules. The interventionist must remember to complete the necessary forms which assess the participant's status at these intervals.

FIGURE 24

BETWEEN SESSION CONTACTS

Name:					
DATE	TYPE	LENGTH	PURPOSE	TOPICS DISCUSSED	DRINKING GOAL/STATUS

B. Intervention Forms Orientation

1. General Overview on Forms 16, 17 and 18

These forms were devised to determine how closely both the participant and the Interventionist follow the study plan and to give some indication of what type of, and for what reason, changes were made. Thus, you will be able to follow your "therapeutic instincts," respond to particular participant's needs, etc. within the framework of the intervention. These variations will be documented on a session by session basis so that the effects, if any, on outcome can be measured. In addition, these forms will help assess whether the participant and Interventionist are "on the same track" with regard to goals and strategies for controlled drinking.

Forms 16 and 18 are measures of the Intervention and Follow-Up Sessions and are to be **completed only by the Interventionist**. The coding is self evident; however, for items 10 and 11 - Form 16, and item 6 - Form 18, it is essential that you use additional sheets to record any modifications made. For example, if the participant is not adhering to his goal (#9) and it is has been modified (#10), you should record why the modification was necessary, how it differed from the original, and how you think it will be more beneficial. If, for any reason at all whether for illness or the participant's inability to keep pace, etc., the intervention must be modified (#11), you must also detail how, why and to what end this was done. If on Form 18, you note that the participant has problems (#6), you must specify not only the particular problem but also the manner in which you and the participant have dealt, or plan to deal, with it.

Form 17 is to be completed **independently by both the Interventionist and the participant**. Responses should be based on the participant's homework, interactive exercises, and general in-session behavior. It is, however, understood that the Interventionist will apply her own professional judgements here, especially in the more prescriptive sections.

You will be more comfortable with these once you begin using the Intervention, and may have additional comments which you should feel free to include in your reports ... **in fact, your insights will be most welcome**. In the interim, you will find the sample forms to be helpful.

Note: Forms 16, 17 18 along with SCQ-39 are regular data collections forms to be sent jointly to Perry Point and to NIAAA. Dr. Stephen Bingham's address is listed in the Operations Manual, Section XVI.F. At NIAAA, send to:

NIAAA
Division of Biometry and Epidemiology
Attention: Eleanor Hanna, Ph.D., Research Psychologist
Room 14C26
5600 Fishers Lane
Rockville, Maryland 20857

2. Instructions for completing Intervention Forms

a. <u>Assessment of Intervention Sessions (Form 16)</u>

1) Participants randomized to the alcohol intervention group will receive <u>six</u> 60-90 minute individual sessions in the first three months. Form 16 is used to quantitatively and qualitatively evaluate the participant's progress. This form is completed by the Interventionist.

2) Complete header with the medical center name and number, participant name and number, form completed by and date completed. The date completed is when all six sessions are done.

3) Complete items #1-11 for each session (Note that items #6-10 are left blank for Session 1.). Individual sessions, 1-6, are listed in columns.

4) Code answers with: 1 = YES 2 = SOME 3 = NO for the session information except for questions #3, #10 and #11.

5) On question #3, the length of visit, record in 15 minute blocks up to 90 minutes.

6) On question #10, goal modification, specify in exact terms on a separate sheet for each session.

7) On question #11, intervention modification, specify in exact terms on a separate sheet for each session.

8) Upon the completion of the six sessions, review information, sign and send white original to Perry Point, pink copy to Dr. Eleanor Hanna at NIAAA and retain yellow copy for intervention files. Use Data Mailing Checklist to list forms. Do not delay in mailing forms.

9) Mark envelope confidential or privileged information when mailing to Perry Point. Send forms and checklist first-class to mailing address listed in Section XVI.F to Dr. Stephen Bingham.

b. <u>Interventionist or Participant Global Assessment Form (Form 17)</u>

1) Form 17 is completed independently by the both the Interventionist and the participant. The form is completed on the completion of the intervention sessions and if there are changes at the end of any follow-up session.

2) Complete header with medical center name and number, participant name and number, form completed by and date completed. The date completed is the date when the intervention is finished and each follow-up session visit (if changes are found).

3) Complete information on the weekly planner, including leisure activities. List by time blocks.

4) Review information on form, sign and prepare for mailing. Send white original to Perry Point, pink copy to Dr. Eleanor Hanna at NIAAA and retain yellow copy in the intervention files. Prepare Data Mailing Checklist and send forms and checklist first class to Dr. Stephen Bingham at Perry Point at the address found in Section XVI.F of the Operations Manual.

5) Mark confidential or privileged.

c. **Assessment of Follow-Up Intervention Sessions, (Form 18)**

1) Form 18 provides for assessment of follow-up intervention sessions which are a month apart. The form is also used to provide data during the maintenance phase where the sessions are at one to three-month intervals. The form is completed by the Interventionist.

2) Complete the header with the medical center name and number, participant name and number, form completed by and the date completed. The date completed is the date of the last follow-up intervention session.

3) The columns are for the individual sessions, 1-3. There are 11 questions which need to be coded. With the exception of questions #3 and #6, code the questions: 1 = YES 2 = SOME 3 = NO.

4) For question #3, length of session, record in 15 minute blocks up to 90 minutes.

5) For question #6, code the problems using:
   1 = Goal violation event(s) GVEs
   2 = Socio-Ecological
   3 = Interpersonal
   4 = Intrapersonal
   5 = Other, only if necessary

   Provide a brief narrative on the above problem(s) by each session and the date of the session, not the problem date event. There is space to code up to four problems for each session.

6) During the maintenance phase of the study, document those review and "booster" sessions which are at one to three-month intervals by the date of the visit beginning with Session 1 and using as many forms as necessary to completion of the study.

7) Review information, sign and prepare for mailing. Send white original to Perry Point, pink copy to Dr. Eleanor Hanna and retain yellow copy for intervention files. Prepare Data Mailing Checklist and send to Dr. Stephen Bingham at Perry Point to address listed in Section XVI.F of the Operations Manual. Mark confidential or privileged.

d. **Situational Confidence Questionnaire (Form SCQ-39)**

1) The SCQ-39 provides information on the participant's confidence level to abstain from or to reduce consumption of alcohol in particular situations.

2) Besides the initial SCQ-39 which is the baseline record for randomized participants in the Intervention group, two more will be requested: a) at the end of the initial treatment period (F6) from participants in the Intervention group and b) at the end of the Maintenance Phase (F12) from all participants.

3) The SCQ-39 should be completed by the randomized participant prior to or at the start of Intervention Session 1. Give the participant the booklet with the questions and an answer sheet and instruct him to circle the most appropriate number on the answer sheet (not in the booklet). Remind him to take care not to skip questions or answers, and to make sure that he circles the answer with the same number as the question. The participant's five-digit study ID number, the three-digit hospital number and a rating period must be recorded on the answer sheet as indicated in the example. For rating period, record "00" to indicated that this is a baseline record.

4) The top copy of the answer sheet must be sent to Perry Point only. Do not hold these forms -- send them once they are completed and reviewed. Please do not send to them to the Study Chairman's Office as the blind will be broken. The bottom copy should be retained in the Intervention files and not in the participant's regular study file. A third copy will need to be made and sent to Dr. Hanna at NIAAA.

5) Please do not score this questionnaire. They will be scored at the Coordinating Center at Perry Point.

6) The second SCQ-39 should be completed by the participant at the completion of the six sessions or as near to the six-month randomization point (F6) as possible. The rating period should be listed as "06". The second one is also facilitated by the Interventionist.

7) The third and last SCQ-39 should be completed by **all registered participants in both the intervention and control groups at the end of the Maintenance Phase at F12 or 24 months.** The rating period should be listed as "24". The **Data Collector** will facilitate the final SCQ-39.

8) Follow mailing instructions sending first class to Perry Point with the Data Mailing Checklist completed with the participant's number and rating period.

3 month Intervention Period

DVA COOPERATIVE STUDY #996
PATHS

FORM 16
ASSESSMENT OF INTERVENTION SESSIONS

Medical Center Name _____ Medical Center No. ___

Participant Name _____ Participant No. _____

Form Completed By _____ Date Completed __ __ (Mo) __ __ (Day) __ __ (Yr)

	SESSIONS					
	1	2	3	4	5	6
	CODING: 1=YES 2=SOME 3=NO					
1. DATE (Mo Day Yr)	04 02 90	04 09 90	04 23 90	05 07 90	05 21 90	06 04 90
2. APPOINTMENT KEPT	1	1	1	1	1	1
3. LENGTH OF VISIT[1]	90	90	90	75	60	90
4. COVERED ALLOCATED MATERIAL	2	2	1	1	1	1
5. PARTICIPANT GRASPED MATERIAL	3	2	1	1	1	1
6. PARTICIPANT COMPLETED ASSIGNMENTS		2	1	1	1	1
7. PARTICIPANT KEPT DDRs		2	1	1	1	1
8. PROGRESS MADE		3	2	1	1	2
9. GOAL STATUS		3	2	1	1	1
10. GOAL MODIFICATION[2]		1	2	3	3	3
11. INTERVENTION MODIFICATION[2]	2	2	3	3	3	3

[1]RECORD IN 15 MINUTE BLOCKS UP TO 90 MINUTES.

[2]WHERE THERE HAS BEEN MODIFICATION, SPECIFY EXACT TERMS ON A SEPARATE SHEET FOR EACH SESSION.

_____
Interventionist's Signature

VA FORM 10-29010(NR)q
AUGUST 1990

STUDY #996 - FORM 16 (Continuation) Medical Center No. ___ Participant No. ___ ___ ___ ___ ___

SESSION NO.	SESSION DATE (MO) (DAY) (YR)	GOAL/INTERVENTION MODIFICATION
1	04 - 02 - 90	#11 Too much material for S to grasp, so reduced it.
2	04 - 09 - 90	#10 S could not maintain goal of abstinence as recommended so will attempt to reduce consumption. #11 Carried over material not covered in Session 1.
3	04 - 23 - 90	#10 S continues to reduce consumption level but not at recommended rate.
___	___ - ___ - ___	

On completion of intervention and, if there are changes, at end of each followup period

DVA COOPERATIVE STUDY #996 FORM 17
PATHS

INTERVENTIONIST OR PARTICIPANT GLOBAL ASSESSMENT FORM

Medical Center Name _____ Medical Center No. ___ ___ ___

Participant Name _____ Participant No. ___ ___ ___ ___ ___

Form Completed By _____ Date Completed ___ ___ ___ ___ ___ ___
Mo Day Yr

PLEASE GIVE BRIEF AND SPECIFIC ANSWERS TO THE FOLLOWING QUESTIONS.

1. GOAL TO BE MAINTAINED: Abstinence or no more than 2 drinks and not on a regular basis.

	1	2	3	4	5
a. Satisfaction with Goal	Not at all Satisfied	Slightly Satisfied	Moderately Satisfied	Very Satisfied	Extremely Satisfied
b. Confidence in Maintaining Goal	Not at all Confident	Slightly Confident	Moderately Confident	Very Confident	Extremely Confident

2. RULES/GUIDELINES THAT WILL HELP YOU (PARTICIPANT) MAINTAIN THE GOAL:
   - A. Keep DDRs especially noting pressures/situations
   - B. that trigger "urge to drink".
   - C. Schedule plenty of daily exercise.
   - D. Announce goal & purpose to all relevant people.

3. AIDS TO MODERATE DRINKING (OR ABSTENTION):
   - A. Drink only soda water & lime in "risky situations".
   - B. Keep away from "risky situations", if possible; otherwise,
   - C. use various coping Rs learned for negative emotions.
   - D. Exercise 3X daily.
   - E. Plan to take a photography class.

4. IDENTIFY YOUR (PARTICIPANT'S) PROBLEM DRINKING RISKS:

INTERPERSONAL	SOCIAL PRESSURES: PEOPLE/PLACES/SITUATIONS	EMOTIONS
A. Rel & wife - if he	A. Bar at club.	A. Feels inadequate
B. has to take on	B.	B. after struggle
C. too much	C.	C. & wife.
D. "women's work"	D.	D.

VA FORM 10-29010(NR)r
AUGUST 1990

Medical Center No. ___ ___ ___

Participant No. ___ ___ ___ ___ ___

5. GENERATE A LIST OF COPING STRATEGIES TO DEAL WITH:

A. UNEXPECTED URGES: Self-statements: stop & think because he will feel so awful if he violates goal.

B. SOCIAL PRESSURES: Role play & rehearse explaining why he is not drinking ETOH and how he will stay away from club bar.

C. EMOTIONS: Relaxation exercises. Regular daily exercise. Dealing directly c family conflict as it arises.

D. INTERPERSONAL PROBLEMS: Try to understand wife's needs. Plan solution to problem which satisfies her needs without taking away too much of his free time, eg. more outside help, assigning chores to children.

6. FILL OUT THE FOLLOWING WEEKLY PLANNER, INCLUDE LEISURE ACTIVITIES:

6:30 - 7:00	Light breakfast
7:00 - 7:30	Run
7:30 - 8:00	Dress & Shower
8:00 - 8:30	Drive to work
8:30 - 9:00	Read newspapers
9:00 - 12:00	Work
12:00 - 12:30	Lunch
12:30 - 1:00	Walk briskly
1:00 - 6:00	Work
6:00 - 6:15	Drive to club
6:30 - 7:15	Play racketball c George
7:15 - 8:15	Shower, socialize
8:15 - 8:30	Drive home
8:30 - 9:30	Dinner c family
9:30 - 11:00	Assist wife c chores, spend time c children, etc
11:00 - 11:30	Watch news, get ready for bed.

Interventionist's Signature

VA FORM 10-29010(NR)r
AUGUST 1990

3 mos follow up

DVA COOPERATIVE STUDY #996
PATHS

FORM 18
ASSESSMENT OF FOLLOW-UP INTERVENTION SESSIONS

Medical Center Name _____ Medical Center No. ___ ___ ___

Participant Name _____ Participant No. ___ ___ ___ ___ ___

Form Completed By _____ Date Completed ___ ___ ___ ___ ___ ___
Mo Day Yr

		SESSION 1	SESSION 2	SESSION 3
		CODING: 1=YES 2=SOME 3=NO		
1.	DATE (MO/DAY/YR)	07 09 90 (Mo Day Yr)	08 13 90 (Mo Day Yr)	09 17 90 (Mo Day Yr)
2.	SESSION KEPT	1	1	1
3.	LENGTH OF SESSION[1]	60	30	30
4.	PROGRESS MADE	1	1	1
5.	GOAL STATUS	2	1	1
6.	PROBLEMS[2]	2 ___ ___ ___	3 ___ ___ ___	3 ___ ___ ___
7.	LIFE CHANGES	3	3	3
8.	STRESSORS	1	1	1
9.	NEEDS MORE INTERVENTION	3	3	3
10.	NEEDS TREATMENT	3	3	3
11.	ALCOHOL PROBLEMS	3	3	2

[1]RECORD IN 15 MINUTE BLOCKS UP TO 90 MINUTES

[2]CODE PROBLEMS: 1=GVEs
2=SOCIO-ECOLOGICAL
3=INTERPERSONAL
4=INTRAPERSONAL
5=OTHER, ONLY IF NECESSARY

VA FORM 10-29010(NR)s
AUGUST 1990

Medical Center No. ___ ___ ___

Participant No. ___ ___ ___ ___ ___

12. LIST PROBLEMS (FROM QUESTION 6) AND HOW YOU PLAN TO DEAL (OR HAVE DEALT) WITH THEM.

Session I (7/9/90) Socio Ecological Participant having difficulty keeping from drinking too much when socializing at the club bar after playing racquetball. Two options discussed:
1. not going to bar afterwards - role playing & rehearsal for dealing with pressures from others; discussed and elicited understanding of negative emotions (feeling sad, feeling different, worried about social acceptability) that might result from not going.
2. Drinking only soda water & lime, never permitting himself ETOH in this situation. Rehearsed excuses, self talk - e.g. exercising for health & has therefore cut out drinking for same reason. Needs to get home right away and doesn't want to drive too soon after drinking.

Session 2 (8/13/90) Interpersonal. Pt is having difficulty confronting feelings which arise when wife asks for help at night. Feels overwhelmed and angry and wants to drink. Reviewed specific incidents. Suggested relaxation techniques.

Session 3 (9/17/90) Interpersonal. Situation c wife is worse and has led to increased drinking in that situation from time to time. Reviewed coping strategies. Discussed need to directly confront issue keeping wife's agenda in mind.

Interventionist's Signature

VA FORM 10-29010(NR)s
AUGUST 1990

Maintenance 6 mos.

DVA COOPERATIVE STUDY #996 **FORM 18**
PATHS **ASSESSMENT OF FOLLOW-UP INTERVENTION SESSIONS**

Medical Center Name _____ Medical Center No. ___

Participant Name _____ Participant No. _____

Form Completed By _____ Date Completed __ __ __ __ __ __
Mo Day Yr

		SESSION 1	SESSION 2	SESSION 3
		CODING:	1=YES 2=SOME	3=NO
1.	DATE (MO/DAY/YR)	11 20 90 (Mo Day Yr)	03 26 91 (Mo Day Yr)	06 28 91 (Mo Day Yr)
2.	SESSION KEPT	1	1	1
3.	LENGTH OF SESSION[1]	60	30	15
4.	PROGRESS MADE	1	1	1
5.	GOAL STATUS	3	1	1
6.	PROBLEMS[2]	13	1	
7.	LIFE CHANGES	2	3	3
8.	STRESSORS	1	1	3
9.	NEEDS MORE INTERVENTION	3	3	3
10.	NEEDS TREATMENT	3	3	3
11.	ALCOHOL PROBLEMS	2	3	3

[1]RECORD IN 15 MINUTE BLOCKS UP TO 90 MINUTES

[2]CODE PROBLEMS: 1=GVEs
2=SOCIO-ECOLOGICAL
3=INTERPERSONAL
4=INTRAPERSONAL
5=OTHER, ONLY IF NECESSARY

VA FORM 10-29010(NR)s
AUGUST 1990

Medical Center No. ___ ___ ___

Participant No. ___ ___ ___ ___ ___

12. LIST PROBLEMS (FROM QUESTION 6) AND HOW YOU PLAN TO DEAL (OR HAVE DEALT) WITH THEM.

Session I GVE Participant had completed Intervention abstinent and elected to remain so as long term goal. Began drinking and, though controlled, it exceeded the 2 drink limit. He agreed on a moderate drinking goal and reviewed more appropriate responses to future "violations."

Interpersonal Participant's wife has been ill and had to be hospitalized. Because of this, he had to assume responsibilities for child care, housekeeping, etc. and finds himself feeling sad, overwhelmed and angry. Drinking helps him relax. We explored these feelings and alternative ways of dealing c them. Important to code now c holidays coming up.

Session II (3/26/91) Participant continued to drink beyond moderate goal he had set. We reviewed the coping strategies he had put in place last time and decided that, if he could extend the babysitter's hours so he could exercise before coming home (reclaiming time he had scheduled postintervention), there would be less likelihood of his drinking.

Interventionist's Signature

VA FORM 10-29010(NR)s
AUGUST 1990

EXAMPLE

MC#644 Participant No. 99999 Rating Period 06

ANSWER SHEET

I would be able to resist the urge to drink heavily—

Not at All Confident	0%	20%	40%	60%	80%	100%	Very Confident

NAME Joe Cool

DATE 7-9-91

AGE 40 YRS. SEX: (M) F

[redacted]

At the top of the form please write the Medical Center no, the participant no, the rating period and fill in the date in space provided as shown above on example form. Please also stamp as "CONFIDENTIAL".

1.		80 100	31. 0 20 40 60 80 100
2.		80 100	32. 0 20 40 60 80 100
3.		80 100	33. 0 20 40 60 80 100
4.		80 100	34. 0 20 40 60 80 100
5.		80 100	35. 0 20 40 60 80 100
6. 0 20 40 60 80 100		80 100	
7. 0 20 40 60 80 100	17. 0 20 40 60 80 100	27. 0 20 40 60 80 100	36. 0 20 40 60 80 100
8. 0 20 40 60 80 100	18. 0 20 40 60 80 100	28. 0 20 40 60 80 100	37. 0 20 40 60 80 100
9. 0 20 40 60 80 100	19. 0 20 40 60 80 100	29. 0 20 40 60 80 100	38. 0 20 40 60 80 100
10. 0 20 40 60 80 100	20. 0 20 40 60 80 100	30. 0 20 40 60 80 100	39. 0 20 40 60 80 100

SITUATIONAL CONFIDENCE QUESTIONNAIRE (SCQ-39)

EXAMPLE

MC#644 Participant No. 99999 Rating Period 06

ANSWER SHEET

I would be able to resist the urge to drink heavily—

Not at All Confident	0%	20%	40%	60%	80%	100%	Very Confident

NAME Joe Cool

DATE 7-9-91

AGE 40 YRS. SEX: (M) F

CONFIDENTIAL

At the top of the form please write the Medical Center no, the participant no, the rating period and fill in the date in space provided as shown above on example form. Please also stamp as "CONFIDENTIAL".

1.		80 100	31. 0 20 40 60 80 100
2.		80 100	32. 0 20 40 60 80 100
3.		80 100	33. 0 20 40 60 80 100
4.		80 100	34. 0 20 40 60 80 100
5.		80 100	35. 0 20 40 60 80 100
6. 0 20 40 60 80 100	16. 0 20 40 60 80 100	26. 0 20 40 60 80 100	
7. 0 20 40 60 80 100	17. 0 20 40 60 80 100	27. 0 20 40 60 80 100	36. 0 20 40 60 80 100
8. 0 20 40 60 80 100	18. 0 20 40 60 80 100	28. 0 20 40 60 80 100	37. 0 20 40 60 80 100
9. 0 20 40 60 80 100	19. 0 20 40 60 80 100	29. 0 20 40 60 80 100	38. 0 20 40 60 80 100
10. 0 20 40 60 80 100	20. 0 20 40 60 80 100	30. 0 20 40 60 80 100	39. 0 20 40 60 80 100

SITUATIONAL CONFIDENCE QUESTIONNAIRE (SCQ-39)

e. **Additional Intervention Forms**

The Intervention Drinking Record and the Follow-Up Intervention Drinking Record forms are not data collection forms. These are forms used by all of the Interventionists and the Research Psychologist, Dr. Hanna, at NIAAA to regularly evaluate the progress of each participant randomized in the alcohol intervention group. Data on alcohol consumption between sessions and baseline data from the Lifetime Drinking History (LDH) and Chronological Drinking Record (CDR) are summarized here. These forms provide the only baseline data which the Interventionist is allowed to review once the participant is randomized. No post-randomization data is reviewed by the Interventionist to prevent biases in the study regarding the intervention method.

1) **Intervention Drinking Record (Figure 25)**

a) Write the participant's name, person completing form (Interventionist), and the clinic site.

b) Record average number of drinks per week from baseline LDH and CDR and sessions 1-6.

c) Provide drinking goal at visit 3 and revised drinking goal.

d) Provide participant's response to the Marlatt Motivation Scale.

2) **Follow-Up Intervention Drinking Record (Figure 26)**

a) This form is an attachment to the Intervention Drinking Record.

b) The form provides a compilation of visit information by the number, date, between session interval and the average number of drinks per week per visit. List this information for each visit by the participant.

c) Place an asterisk (*) after any session which is additional to those planned for in the protocol.

d) Footnote any session in which the drinking goal was modified and specify new goal on the bottom of the form, or on a separate sheet.

e) Send original copy to Dr. Hanna at NIAAA and keep other copy in the intervention files.

FIGURE 25

DVA COOPERATIVE STUDY #996
PATHS

INTERVENTION DRINKING RECORD

PARTICIPANT: _____

INTERVENTIONIST: _____

SITE: _____

SOURCE	AVERAGE NUMBER OF DRINKS PER WEEK
Lifetime Drinking History	_____
Chronological Drinking Record	_____
Between Sessions 1 and 2	_____
Between Sessions 2 and 3	_____
Between Sessions 3 and 4	_____
Between Sessions 4 and 5	_____
Between Sessions 5 and 6	_____

Drinking goal at Visit 3: _____

Revised Drinking Goal: _____

MARLATT MOTIVATION SCALE

A. How strong is your desire to change your current level of drinking to improve your health?

1	2	3	4	5
Not at all	Slightly	Moderately	Very	Extremely

B. Please indicate the amount of change you expect as a result of this program.

1	2	3	4	5
Stop Drinking	Large Decrease	Small Decrease	None	Increase

FIGURE 26

DVA COOPERATIVE STUDY #996
PATHS

FOLLOW-UP INTERVENTION DRINKING RECORD

PARTICIPANT: _____

INTERVENTIONIST: _____

SITE: _____

VISIT NUMBER	DATE	BETWEEN SESSION INTERVAL	AVERAGE NUMBER OF DRINKS PER WEEK

Visit Number: Place an asterisk (*) after any session which is additional to those planned for in the protocol.

Footnote any session in which the drinking goal was modified and specify new goal below, or on a separate page.

C. Control Treatment

Control participants will receive the same assessment (data collection) procedures as the intervention group. Otherwise, contact will be minimal to decrease opportunities for "nonspecific" intervention, such as social support or feedback from clinic staff about lifestyle changes initiated by the participant.

Participants randomized to the control group will be informed that they have been assigned to the group which will not receive training to reduce alcohol intake. They will be reminded that we do not know what effects - favorable or unfavorable - changes in alcohol intake will have on blood pressure and other risk factors and, therefore, they are not being advised to change their drinking.

They will also be reminded that study staff will check blood pressures regularly for two years. Unlike the screening phase, the results of the blood pressure checks will not be reported to participants during the study. The rationale for this is that blood pressure can be higher at one visit and lower at another just from normal variation and we wish to control for any psychological effects of this variation. However, a participant will be informed immediately if his blood pressure goes too high. If this happens, treatment for hypertension will be initiated.

Control group participants will not have regular contact with the Interventionist after randomization. However, the Interventionist will be the contact person for all participants in matters not related to data collection or the data collection visits.

XV. *STUDY FORMS*

One of the most important tasks in any study is the complete, accurate, and timely recording of the data on the study forms. If all other study tasks are properly performed, but the data are not recorded accurately and legibly or some data are not recorded at all, the results of the study can be seriously affected. PATHS is a particularly complicated study with many forms and a variety of data collection requirements. In this section, fairly detailed instructions about each data collection instrument will be provided.

A. Brief Screening Instrument Log (Form 1)

The Brief Screening Instrument (BSI) is a short questionnaire that is designed to quickly eliminate individuals who are clearly ineligible for this study. Every individual who completes the BSI must be entered into the BSI Log.

Each line corresponds to one individual. By counting the number of lines completed, we will know the total number of individuals screened. The first column is used for the unique participant number (ID number from BSI) which is assigned locally at each participating center starting with 00001 for the first individual. ID numbers should be assigned consecutively as individuals complete the BSI. In the next six columns, record the answers provided on the BSI. If the individual failed to answer one or more of these questions, use a missing value code to indicate this. (The most appropriate missing value code will probably be U.)

Q10 and Q11 should be coded with a "U" if Q9 is answered No. If the individual answers them, record his answers. THE INDIVIDUAL'S ANSWERS MUST NEVER BE CHANGED EVEN IF THEY DON'T MAKE SENSE. If Q9 is answered Yes and Q10 and/or Q11 are blank, use a missing value code.

Race should be coded only if you know or are almost certain you know; otherwise leave it blank. Please remember to attempt to collect information on the race question #11. This information can be recorded during a prescreening interview or for eligible veterans for screening visit 1. For others, such as ineligible veterans identified during mass mail-out, use the hospital computer terminal as time permits. Source codes should be used as provided in Table 4. The final column is used to indicate whether

the individual is eligible for screening based on the BSI only. The column should be coded 1 for Yes unless at least one of the following is true:

1. the individual is not a veteran,
2. the individual is younger than 25 or older than 79,
3. the individual does not drink or does not drink enough (Q10 times Q11 less than 10)

All individuals who are eligible for screening based on the BSI must be scheduled for a first screening visit unless they are known to be ineligible for other reasons. The reason(s) for excluding these individuals must be documented using Form 20.

TABLE 4

SOURCE CODES

01 = Mailings (to all veterans in area)
02 = Ambulatory Care
03 = Scheduled clinic visit (not hypertension)
04 = Triage/Emergency Room
05 = Hospitalized patients (to be discharged)
06 = Hypertension Clinic
07 = Service Organizations
08 = Medical chart review
09 = Veteran referral (word of mouth)
10 = Advertising (newspaper, TV, radio)
11 = Churches
12 = Professional referral (social worker, nurse)
13 = Vet Center

B. Data Collection Form (Form 2)

There are three types of data collection visits. Screening visits are the three biweekly visits that are required for determining if an individual is eligible for registration in this study. Follow-up data collection visits are those visits that occur at predetermined points following registration (from one month through two years). Interim data collection visits are those visits that occur between follow-up visits and that are used to determine if a participant should be started on antihypertensive medication (see Section VIII.B). If a participant does not come in for a scheduled data collection visit, this will be referred to as a missed appointment.

Form 2 is required for all scheduled data collection visits (including missed appointments). The top section of page 1 (including medical center name and number, participant name and number, name of person completing form, date completed and rating period) must always be completed. Date completed should generally be the date of the visit. Immediately to the right of the name of the person completing the form, enter a code '1' if the form was completed by the data collector and '2' if by the interventionist. If the participant did not come in for the visit, date completed should be the date of the missed appointment.

The appropriate rating period must be determined for each visit. For screening visits, use codes 91, 92 or 93 as indicated on the form. Dates for follow-up visits will be computer generated following registration and randomization. Participants should be seen within one week of the target date. Screening visits 2 and 3 **must occur at least six days and no more than 30 days following the previous screening visit.** Participants who either cancel or fail to keep appointments should be rescheduled as soon as possible so as to avoid losing either individuals during screening or follow-up data after registration. Follow-up visits must be coded using only those numbers indicated on the form. A follow-up data collection visit that does not occur at or near the scheduled date must be coded using the rating period nearest to the visit date. The computer-generated follow-up schedule will indicate which rating period should be used. Both rating period and interim visit number must be recorded for interim visits. For rating period use the code for the most recently completed follow-up data collection visit. Interim visit number is a sequence number starting with 01 and increasing by 1 for each subsequent interim visit until the next follow-up data collection visit. The first interim visit in any subsequent series of interim visits would again be coded 01. Interim visit number should be left blank for visits that are not interim visits. During the quarterly follow-up visits, use prior rating period for coding. For example, if an interim BP visit is needed after the six month visit but before the nine month visit, code the rating period as 06.

The remainder of the form should be completed using the following instructions:

Item 1. Record if participant came for visit, yes or no.

Item 2. Preparation for Blood Pressure Measurements

a. Record time of day, circle a.m. or p.m.

b. Record room temperature in degrees Fahrenheit.

c. Measure arm circumference

For routine purposes, the observer should always use the same arm - the right arm - unless there is an injury or deformity. Code arm used. Measure arm circumference in centimeters with a tape measure following instructions in Blood Pressure Measurement Section (section XIII.A). Record arm circumference.

d. Code cuff size as provided on Form 2.

SEAT PERSON AND BEGIN 5-MINUTE REST

e. Record 30-second pulse.

f. Multiply 30-second pulse times 2 and record.

g. Record pulse obliteration pressure on Form 2.

h. Record random-zero (RZ) maximum zero number. (Calculate and record the peak inflation level + RZ maximum zero + 30).

i. Record random-zero peak inflation level. However, if below 200 mm Hg, remember to inflate cuff to at least 200 mm Hg when taking the blood pressure measurements.

j. Record certification number of random-zero device.

Item 3. First Random-Zero Sitting Blood Pressure

a. Take first reading. For systolic blood pressure (Phase 1), record the first sound heard in a series of two sounds. For diastolic blood pressure (phase 5), record the first silence in a series of at least two silences, NOT the last sound heard. Record blood pressure reading to the nearest even whole number upward on the manometer scale.

b. Obtain zero value after system has come back to equilibrium (usually a few seconds).

Note and record the zero reading.

c. Wait to subtract zero reading until all three RZ BP measurements have been recorded.

WAIT 30 SECONDS

Item 4. Second Random-Zero Sitting Blood Pressure. Repeat above steps and record readings.

STAND PARTICIPANT AND WAIT 60 SECONDS

Item 5. Repeat above steps. At this point, go back and calculate corrected values.

Item 6. Determine the sum of the two sittings BP (3c + 4c). Record both systolic and diastolic values.

Item 7. Get mean blood pressure by dividing item 6 by 2, record on form. An odd whole number may be recorded for the mean. Record both systolic and diastolic values.

Item 8. Answer Yes or No to participant meeting inclusion criteria for screening visit. If not screening visit 3, skip to Item 10.

Item 9. Take height measurement only at screening visit 3. Leave blank for all other visits. Participant's height and weight should be determined after removing shoes.

Item 10. Take weight to nearest pound. *Participants who are not ambulatory, leg amputees, wheelchairs, may be weighed once during the screening phase and every six months after randomization. Use missing value code U for visits when weight is not obtained. Heights of these participants may be self-reported. Refusals should be recorded as refusals and coded as R.

Item 11-16. Concurrent Medication

a. Use Drug Codes provided in Appendix E.

b. Record drug dosage by total milligrams per day. For drugs (such as insulin) that are not prescribed in milligrams, indicate total daily dosage using the units that are used for prescribing. Make sure that unit used is written in in these cases.

Item 17. If the participant has been ill, has had any medical or psychiatric treatment initiated, or has been hospitalized since his previous visit, Form 19 must be completed. Note medication(s) prescribed for treatment. Provide type(s), dosage and length of time prescribed. A Form 19 should be completed each time for each visit if the participant has a chronic condition which has required any medical attention. Once treatment stops, note on Form 19 with progress note.

Item 18. Record date of next visit by month, day, year.

Be sure to have Participating Investigator review and sign Form 2 and any other forms requiring signature.

C. Demographic Characteristics (Form 3)

This form is designed to provide a few demographic characteristics for study participants. It is an interviewer administered questionnaire and can often be completed by simply reading the questions and recording the participant's answers. It may occasionally be necessary to explain the question in more detail so that an appropriate answer can be obtained. If a question cannot be answered,

use the most appropriate missing value code. Questions 6 and 7 should be left blank if question 5 is answered No. An individual who expects to move within the following six months (Q17) is not eligible for the study and no additional data should be collected. A Form 20 should be completed using exclusion code #671.

There is an open-ended question at the end of Form 3 which is not numbered. The question asks if the interviewer notes any language or possible literacy problems. If there are reasons, list them. **If none are noted, leave blank.**

D. Alcohol Use Questionnaire (Form 4)

This questionnaire is designed to be self-administered. Each participant must be instructed to choose the one response that most accurately describes himself. The participant should be told that drinking means drinking of alcoholic beverages. The data collector must not explain questions or responses to participants. The participant should be encouraged to select the most appropriate response even if he doesn't completely understand the question. Participants who will not or cannot complete this questionnaire should generally be excluded. However, the study chairman's office must be contacted before excluding an individual for this reason. After completion of the interview, the coded responses to the 10 questions must be added up. If the sum is at least 5, the individual is ineligible and Form 20 must be completed.

E. Medical History (Form 5)

The primary purposes of the Medical History form are to identify problems that potentially exclude the participant from continuing in the screening process and to obtain relevant hypertension history. This form will usually be administered by the Data Collector and/or the Interventionist at **Screening Visit 1**. However, the Principal Investigator or [another] physician or health professional may need to be consulted for review and clarification at this or subsequent visits. In addition, Form 5 is to be reviewed (and further completed, if needed) by the physician performing the physical examination **(at Screening Visit 3)**.

Although a number of the problems on this form are complications from alcohol excess and are intended to exclude individuals who should not enter a trial where they may continue to drink, you should not question the participant specifically concerning treatment for, or other problems that

may be considered, alcoholism or alcohol dependency. This is because Form 5 will be administered at the same time as Form 4 (Alcohol Use Questionnaire), which is an alcohol dependency scale, and we do not want to focus more attention on the participant's alcohol intake than is necessary. These forms are administered together (without a break between them) in order to de-emphasize the alcohol questions.

A "yes" answer to any one of questions #3-27 may indicate an exclusion criteria. The specific criterion should be carefully reviewed to determine its applicability (for example, some of the criteria depend on how recent the problem occurred or whether medications were given). If a participant is currently pregnant, she must be excluded from the study. Complete a Form 20 and use the exclusion code 690.

Much of the medical screening may be done by reviewing available medical records. However, you should also obtain a history from the participant by asking open ended questions about any health problems, and asking questions in the relevant areas in terms he understands. For example, in addition to asking if someone has had cirrhosis or alcoholic hepatitis, you might ask if they have had any problem with their liver, yellow jaundice, or swollen stomach. Instead of asking about the various specific psychiatric diagnoses, you might ask if they have ever been treated for their "nerves," depression, a mental problem, or a "nervous breakdown." The Principal Investigator or other examining physician should demonstrate as often as necessary how to obtain this history.

Question #29 relates to a <u>prior diagnosis</u> of hypertension, usually indicating some duration of treatment, regardless of whether the participant is hypertensive or on antihypertensive medications at the time of screening. If the blood pressure is in a "hypertensive" range at the time of screening, but the participant has not previously received a diagnosis of "hypertension," the answer to this question is "no." If the participant's hypertension was first detected and/or treated within the previous year, then A and/or B should be coded 01.

A "Drug Code" list for coding the antihypertensive medications is included in Appendix E.

In Appendix F, a list of questions can be found that have been prepared in layman language to help participants understand the medical terminology.

F. Lifetime Drinking History (LDH) (Form 6)

This instrument is administered by the Data Collector at screening visit 2. The LDH is a structured interview which should take about 30 minutes to administer.

It is the instrument used to determine whether the participant qualifies for inclusion in the study. The alcohol consumption inclusion criterion is an average of 21 drinks or more per week over the past six months.

The LDH will always begin with questions about the past week followed by the same questions about the past six months. For participants who meet the alcohol intake inclusion criterion, the LDH will be continued starting with the time when the participant first began drinking regularly (i.e., at least once a month) and continuing to the present (including the past week).

Specific instructions for each item within the LDH are as follows:

1. PHASE - FOR PAST WEEK and PAST SIX MO., record beginning and ending dates for these periods. For an interview that occurred on 3/11/90, these dates would be 3/4 to 3/10/90 and 9/11/89 to 3/10/90. For a complete LDH, the participant's drinking history is divided into phases. Phase 01 is the earliest phase and subsequent phases are numbered consecutively from 01. Each phase is distinguished from both the prior and the following phase by the presence of significantly different drinking behavior. Since this drinking history is aimed at detecting major changes in drinking behavior, some judgment will be necessary in differentiating important from minor changes in drinking patterns. For each phase, record age at the beginning of the phase and age at the end of the phase in whole years. Note that these phases must be in chronological sequence with no gaps. At the end of the interview, record the total number of phases (the number of the last or current phase) at the top of the first page (in the space indicated). For a participant who does not meet the alcohol intake inclusion criterion, this space would be left blank.

2. FREQUENCY - Ask the participant how many days per month he generally drank during the particular phase. When asking about the PAST WEEK, ask him how many days he drank during the previous week. Record his response.

3. QUANTITY - Discuss with the participant the concept of a "standard" drink (i.e., 14 grams of ehtanol, e.g., 12 oz. of beer, 5 oz of table wine or 1.5 oz of distilled spirits). Make sure that the participant understand this concept. Ask him to recall the average number of drinks consumed per day on days when he drank and the maximum number of drinks consumed on a single day during the particular phase. If there is any doubt about whether he is reporting number of "standard" drinks, ask him to describe his drinks.

   Note: To determine if the participant meets the alcohol consumption inclusion criterion, using the following procedure. From the PAST SIX MO. phase, multiply FREQUENCY (Days/Mo.) times Average QUANTITY (Drinks/Day). Divide this result by 4.3. Round the result to the nearest 10th. If the final result is at least 20.5, the participant is eligible for further screening. Circle YES at the bottom of the page and continue the interview. Otherwise circle NO and terminate the interview.

4. TYPE - Ask the participant about the types of alcoholic beverages he would consume in a typical month for the particular phase. Record the relative percentages of drinks represented by the three categories (beer, wine, or liquor). These percentages should add up to 100%.

5. STYLE - Ask the participant to rate his usual style of drinking during an average month during the particular phase. Circle the most appropriate code on the form.

   1 = Occasional (less than 15 days per month)
   2 = Weekend mainly
   3 = Binge (at least three consecutive days of heavy drinking)

4 = Frequent (at least 15 days per month). If more than one code is appropriate, determine which one seems most appropriate. Do not circle more than one code. If the participant has been abstinent during the phase, do not circle any of the codes.

6. LIFE EVENT OR CHANGES - Ask the participant to recall any events in his life that may have particularly affected the drinking pattern represented by this particular phase. Examples of such events would include loss of spouse, unemployment, prison term and hospitalization. Table 5 contains many more examples. Circle the appropriate code numbers for any such events. If no important event occurred that influenced the person's drinking behavior, this section should be left blank. For each important event reported, ask the participant if it had a positive (desirable), negative (undesirable) or neutral (no) effect on his life. Code 1 for positive effects and 2 for negative effects. Leave blank for neutral effects.

7. CONTEXT - Ask the participant to report what percentage of the time when he drank, he drank alone and what percentage of the time he drank with at least one other person. Record his responses. These percentages should add up to 100%.

8. TIME - Ask the participant to recall what time of day he does most of his drinking. Record approximate percentages of the time when he drank in the morning, in the afternoon and in the evening. These percentages should add up to 100%.

Table 5

Description of Life Event Codes

Code	Event Description	Examples
1. Marital/Family	Any changes in marital status or family functioning that precipitated a shift in alcohol consumption level	1. got married (divorced or separated) 2. illness in the family 3. new baby in the family
2. Work	Any changes or events associated with employment status and demands	1. started work 2. lost job, became unemployed 3. promotion, new pressures
3. School	Events related to school	1. quit school 2. academic problems 3. changed schools
4. Medical	Onset of a medical problem or change in medical status	1. drinking to kill pain 2. hospitalized for broken leg 3. told had alcoholic liver disease
5. Residence	Change in residential location or status	1. moved to Canada 2. moved out from parent's home 3. change in residence
6. Legal/Jail	Changes in legal status and/or incarceration	1. sent to jail 2. on probation/parole 3. awaiting trial
7. Financial	Financial problems or increase in personal wealth	1. lost money on stock market 2. won a lottery 3. many debts, little money to buy booze
8. Peer Group	Pressure from one's peers either to start drinking, increase consumption, or decrease drinking	1. all kids were trying it 2. new friends don't drink 3. drank to be "one of the boys"
9. Drug Abuse	Started using drugs as a substitute for alcohol or stopped drugs and commenced alcohol abuse	1. drank more since couldn't get drugs 2. no money for drugs, thus drank 3. stopped drinking when started drugs
10. Treatment	Alteration in consumption level while under "treatment" for alcohol or drug dependency	1. in a residential treatment program 2. on antabuse 3. joined Alcoholics Anonymous
11. Death	Death of someone close which influenced drinking behavior	1. death of family member 2. child died 3. death of close friend
12. Emotional	Emotional-psychological changes or problems that altered consumption level	1. drank to relieve tension 2. felt very lonely 3. cut down drinking since less depressed

Note. Code an event only if the patient agreed that this occurrence actually influenced his drinking pattern. Only code the principal life event or events, not all minor changes that may have occurred.

G. Physical Activity (Form 7)

Physical activity is determined using a brief interview to obtain information about leisure time physical activity. The items are from the Centers for Disease Control National Health Information Survey. They have been used previously in both person-to-person and telephone surveys. The information obtained is sufficient to allow calculation of approximate kilocalorie expenditure. Although there are a number of items, most subjects will have engaged in very few of the activities listed, so administration takes only a few minutes.

Specific procedures for the interview are:

1. Begin the Physical Activity interview by reading the directions to the participant: "These questions are about physical exercise. In the PAST SEVEN DAYS (show him on a calendar) have you done any of the following exercises, sports, or physically active hobbies?"

2. Then read the first item, "walking for exercise". If the participant indicates he has walked for exercise, code 1 for "YES" and proceed to column A, which quantifies the number of times. Ask "How many times in the past week did you walk for exercise?" Before you enter the response in 1A, verify it by repeating it back to the participant. For example, if he says "three times", check by asking, "Which days did you walk for exercise?"

3. Then proceed to column B, which assesses how long he engages in the activity each time. Ask "On the average, about how many minutes did you actually spend walking for exercise?" Verify the response by repeating it back to the participant, and take an average if the amount of time varied from one time to another. Then enter the response in 1B.

4. Complete item 1C by asking the participant, "What usually happened to your heart rate or breathing when you were walking for exercise? Did you have a small, moderate, or large increase, or no increase at all in your heart rate or breathing? After verifying the participant's response, code the appropriate response at 1C.

5. If the participant indicates that he did not walk for exercise, code 2 for "NO" and leave 1A, B and C blank.

6. Complete all additional items in the same manner as above. Note that items 24 and 25 allow spaces to add activities which are not listed on the form. Question the participant until you are confident of the activity he is describing and then enter the description in the space provided.

7. Before terminating the interview, review the entire form to make sure all relevant data has been entered.

Complete this form at SV2, F6, F8, F10 and F12.

H. Psychosocial and Health Habits (Form 8)

The Psychosocial and Health Habits Questionnaire is an instrument devised to obtain information about a variety of psychosocial habits and health-related behaviors. The information requested in this questionnaire is similar to that obtained in other large clinical trials. Many of the questions concern either behaviors associated with cardiovascular disease risk or alcohol and other substance use. Others assess factors which may be associated with participants' success or failure in adhering to the study requirements or with change in drinking habits. The Smoking Habits questions, taken from a WHO study, are designed to provide sufficient information to determine the participant's pack-year history. Some of the items may also indicate the extent to which the participant is dependent upon tobacco. The Caffeine section is designed to provide enough information about caffeine intake to allow determination of a change from baseline. Exercise items are combined from the WHO and TOHP studies. An item was added to assess changes within the past three months. Other items evaluate typical level of activity at work as well as during leisure time and therefore add important information not obtained in the interview assessment of physical activity. The Medications section is taken from the WHO study. Although it is specific about use of illegal drugs, the placement of the item is far enough into the assessment process that the participant should have developed rapport with the study staff and trust in the confidentiality of the data he provides. The Stress items are modified from the WHO study. Social Networks provides an evaluation of social support. The section on Coping Function and Alcohol assesses the participant's self-reported reasons for using alcohol. These items are closely related to the intervention. Sleep items are from the WHO study and Sexual Function items are from questionnaires used routinely in assessment of sexual dysfunction at the Jackson VAMC and other VAMC's.

The Psychosocial and Health Habits Questionnaire is designed for self-administration. It may take some participants 15 minutes or more to complete. Arrange for a private office or a place set apart from other people for the completion of this questionnaire. The participant must be allowed privacy (i.e., a seat apart from other patients or staff who might try to read his responses) for completion of the instrument since very private information is requested (e.g., about drug use) and confidentiality is essential. Ask him to complete all the questions to the best of his ability, but to let you know if there are any items or words he does not understand.

Upon completion of the questionnaire, it must be reviewed thoroughly before the participant leaves to insure that all questions are answered and that responses are legible.

This interview is completed at SV2, F6, F8, F10 and F12. Copies should be made for the Study Chairman's Office and the participant's file and the original should be sent to the Perry Point Coordinating Center.

I. Beck Depression Inventory (Form 9)

The Beck Depression Inventory (BDI) is one of the best-known self-report instruments for assessing depression. It was originally designed to be administered orally by a clinician, but has been primarily used as a self-report questionnaire and is easy to administer in this manner. The BDI has been used in many studies and considerable psychometric data have been accumulated showing adequate test-retest reliability and good correlations with other self-report depression scales and clinician ratings. Cautious use of cutoff scores to categorize patients as depressed or nondepressed is recommended because recent studies indicate that about 50% of those who initially score above a cutoff criterion will change classification when retested a short time later. Although the BDI will not be used for clinical diagnosis or to categorize patients in the current study, it may be helpful for the assessors to keep in mind the following guidelines for interpretation: Scores from 0 to 9 are usually considered indicative of normal mood, but patients with diagnosable psychiatric disorders may have very low scores. Scores from 10 to 20 are associated with mild levels of depression; however scores less than 17 typically indicate dysphoria more often than diagnosable depressive states. Scores of 20 to 30 reflect moderate depression and scores greater that 30 reflect severe depression. In general, patients scoring 10 or above, and particularly 16 or above, should be assessed carefully to rule out mood disorders and the patient's response to item 9 referring to suicide should always be noted to determine if further evaluation of suicidal risk is indicated.

The BDI (like Form 8) is designed for self-administration and, therefore, may be administered with Form 8. Review the instructions with him and emphasize that he should choose the response which best describes how he has been feeling for the past week, including the day of the assessment.

After he has completed the questionnaire, review it to make sure every item has been completed. Note his response to item 9 (regarding suicide) to determine if further evaluation of suicidal risk is indicated.

This instrument is completed by the participant at SV2, F6, F8, F10 and F12. Copies should be made for the Study Chairman's office and the participant's file and the original should be sent to the Perry Point Coordinating Center.

J. Local Laboratory Data (Form 10)

Form 10 is designed for use in reporting local laboratory results for study participants. Specimens for the standard urinalysis and for the biochemical profile should be obtained and tests should be ordered using standard procedures implemented within each participating center. Participants will be asked to not eat for 12 hours prior to obtaining blood specimens but will be allowed beverages that do not contain fat. Procedures for collecting overnight urine samples are described in Section XIII.G. A qualitative urine drug screen is required for all study participants. This data is highly sensitive and confidentiality of results must be maintained. Drug screen results must not be entered into any nonstudy files. They must not be filed with the participant's medical center records and results must not be entered into the hospital's computer system. A standard 12-lead electrocardiogram must be obtained. The PI must make arrangements for reading the ECG and for obtaining the information required for Form 10.

When recording results on this form, be certain that results are reported using the units indicated on the form. Results should be reported using the spaces provided on the form. When necessary, results should be rounded either to the nearest unit or to one decimal as indicated on the form. Results that are exactly halfway between two values should be rounded to the nearest even number. For results that need to be coded, use the codes that are printed on the form. Missing value codes must be used if any results are missing for any reason.

Even if the participant is excluded at SV2 due to blood pressure or the LDH, local lab values are to be reported on Form 10. Since overnight urines are not collected until SV3, use missing value codes for those results which cannot be obtained because the participant was excluded at SV2.

K. Physical Examination (Form 11)

Since many of the participants in this study will be free of significant medical problems, only one physical examination is required during the study. This is to be performed at **Screening Visit 3** by a physician. The primary purpose of the examination is to recognize findings suggestive of diagnoses which may exclude the participant from the study. Of course, it is also a benefit that may be mentioned to the participants during screening, since many of them may not have recently been in another situation to receive a physical examination.

The physician will review the medical history with the participant, including recent or concomitant medication usage and nonalcoholic substance abuse, especially if the urine illicit drug screen is positive. If the screen is positive, a clinical judgment will be made as to whether dependence is indicated (the study interventionist may be very helpful in making this judgment).

Indicating an abnormality on Form 11 does not automatically exclude the participant from the study. A description of the specific abnormalities should be recorded and an assessment of whether the participant is excluded on the basis of the answers on this form must be made (See Section VII.B.) Abnormalities observed for any of the following items need to be reviewed to determine if the participant should be excluded: 2, 4, 5a, 5c, 6, 6a, 10, 12, and 13.

Question 6a (liver span) will be assessed as follows: in the mid-clavicular line the vertical span of the liver (in cm) will be from the upper level of dullness to percussion to the lower edge as determined from palpation (or percussion if not palpable) during the same phase of the respiratory cycle.

The chest x-ray (CXR) will be obtained at **Screening Visit 2**, if not performed within the previous year or if otherwise clinically indicated, and the results recorded by **Screening Visit 3** on this form. If an earlier CXR is acceptable, the results must be available to the physician and will be used for questions 13 and 14.

Before **Screening Visit 3** is complete, a determination will be made as to whether the participant is eligible for randomization. **Note: female participants will be excluded if they are pregnant during screening or plan to be during the study. A pregnancy test can be offered if the participant is unsure or does not know if she is pregnant. If she becomes pregnant after she is registered for the study, please notify the Study Chairman's Office immediately. The participant will be referred for appropriate care (see Section X.B.)**

Equipment and supplies that will be needed for the physical examination include: ophthalmoscope; stethoscope; centimeter ruler; disposable gloves, lubricant and hematest cards; flashlight and tongue depressor; and disposable pins, tuning fork and reflex hammer.

L. Food Frequency Questionnaire (Form 12)

The Food Frequency Questionnaire (FFQ) was developed at the National Cancer Institute to provide a relatively brief instrument for obtaining information about dietary components in epidemiologic studies and clinical trials. The questionnaire can be completed in less than 30 minutes. The FFQ is designed to obtain diet data that represents an individual's usual intake and, in this study, will be used to detect potentially important, confounding dietary changes.

The FFQ was developed using information from large national surveys and has been shown to produce very useful results. The food items were chosen so as to yield good estimates of a wide range of nutrients. They don't include all of the possible foods a person could have eaten, but they are the most important foods in most people's diets.

The time frame that it covers is "the past three months or so". This is deliberately a little vague, because it is not expected that anyone could remember exactly what they ate during the past several months. The idea is just to get a usual pattern -- their current diet at this point in their life. Some people raise the objection, "Oh, I can't even remember what I ate yesterday; how could anyone answer what they ate in the past couple of months?" If participants have this concern, it's important to make clear to them that the idea is not to remember, but to think about their usual pattern of frequency. For example, they don't have to remember how many times they had eggs in the past several months. Instead, what they can tell you with reasonable accuracy is, "Oh, I have eggs about twice a week."

The portion size part of the questionnaire was also worked out based on national diet data, and there too what seems quite imprecise actually does the job quite well. For most of the items, all that is really needed is whether the person's usual portion is "small, medium or large." If participants ask you what you mean by medium, it is fine to tell them. But you won't usually need to read to them what the "medium" portion is for most foods, because very few people really know what a half cup is, or what six ounces are. But they can tell you, "Oh, I don't really like that very much, so when I have it at all, I only have a small portion." What is actually used in the calculations is based on what a 10,000-person sample chose as their portion sizes for all these foods. (A few medium portions represent units of items, such as two pork chops; for those foods, you should read the medium portion to the respondent. In some cases, such as number of eggs or number of hot dogs, you could also simply ask "How many eggs?", and then check off small, medium, or large as appropriate.)

It is important that you ask "small, medium or large?" for each food. Never assume that medium is the appropriate portion size.

Now let's turn to some scenarios, some difficult respondents or situations, and how to handle them.

Some of the more likely problems that you may encounter are the following:

1. Participant volunteers seasonal information. This will not happen terribly often, and you should NOT probe for it. However, when the participant volunteers the information it is appropriate to use it. Do not probe for how long the respondent thinks a season is, but simply assume three months, 1/4 of a year.

Q: (How often do you eat) corn?
A: Well, most of the time I have it about once a month. But in the summer I eat fresh corn about once a week.
Q: Once a week in season, once a month the rest of the time?
A: That's right.

You should write down the response verbatim. Then, either during the interview if there is time, or after the interview, calculate how many times per year that averages out to. In this

example, it would be (1/week)x(4 weeks in a month)x(3 month season)

+ (1/month)x(9 remaining months in the year)

= 1x4x3 + 1x9

= 21 times per year.

Divide 21 by 4 to get times per quarter and enter 5 in the "LAST THREE MONTHS" column.

2. Participant gives a frequency which seems unreasonable. You should not doubt the participant repeatedly or probe regularly. However, it is appropriate to use some common sense if the participant appears to have misspoken or misunderstood.

Q: (How often do you eat) liver?

A: Four times a day.

Q: Four times a day?

A: Oh, I mean four times a week.

3. Participant gives a frequency that seems to be very high, such as "30 times in the last three months." Such answers are likely to be inaccurate, so ask the participant to express it per week or per month.

Q: (How often do you eat) hamburgers, cheeseburgers or meatloaf?

A: 30 times in the last three months.

Q: Could you tell me in terms of number of times per week or per month?

A: Well, I guess it would be about twice a week.

or

A: Well, I eat it more than twice a week -- maybe 10 times a month.

4. Erroneous frequency of the three dry cereals (or of the three breads, or the three milks). Do not attempt to make other groups of foods add up to something you think is reasonable; however, for the three dry cereals (or the three breads or the three milks), some participants may triple count their frequency. Avoid this first by alerting the participant that there are several types of this food which will be asked about; and be alert for indications he may have nevertheless triple counted.

Q: (How often do you eat) whole milk or drinks made with whole milk, not including on cereal? (I'm going to ask you about 2%, 1% and skim milk separately).

A: Three times a day.

Q: Small, medium or large?

A: Medium.

Q: 2% milk, not including on cereal?

A: Three times a day.

Q: Skim milk, 1% milk or buttermilk, not including cereal?

A: Three times a day.

Q: Let's see, you've told me you drink <u>each</u> of those different kinds of milk three times a day. That would be milk nine times a day. Is that right?

A: Oh, no, it's just that sometimes I have one kind and sometimes another kind.

Q: Oh, I see. Well, let's go back and find out how often you drink each of those different kinds. How often do you drink whole milk or beverages made with whole milk, not counting cereal?

A: Well, whole milk I guess I only have about five times a week.

Q: What about 2% milk, not counting on cereal?

A: That would be most of the time, about twice a day.

Q: And what about 1% or skim, not counting on cereal?

A: That would be pretty rarely, maybe twice a week.

(Milk on cereal, by the way, will be added by the program automatically based on the number of times the participant reports eating cereal and on the types of milk he drinks.)

M. Chronological Drinking Record (Form 13)

The Chronological Drinking Record is an instrument administered by the Data Collector at Screening Visit 3 and at designated follow-up visits and is used to document the participant's baseline alcohol intake and any changes that may occur during follow-up. Each time the CDR is administered, all drinking events during a seven-day period must be documented. Form 13 was designed for documenting these events. Form 13 is a one-page form and each drinking event will require the completion of a Form 13. If a participant reports 16 drinking events, Form 13 will need to be completed 16 times.

Question 15 (TOTAL NUMBER OF EVENTS) would be answered 16 for this example and would only be recorded on the form for EVENT NUMBER 16. If a participant reports no drinking events, Form 13 will still need to be completed once. However, you would not need to answer questions 2 through 14. Question 15 would be answered 00.

Events must be numbered consecutively beginning with the most recent; i.e., the very last event on the day prior to the interview is Event Number 01. Several Form 13s may be necessary to record each day's events. Be sure to fill in the correct identifying data at the top of each form. Don't assume that you will have accurate recall for this information, no matter how trivial it seems, at the end of the interview.

It is important that you correctly identify the seven-day period covered by the CDR. This period is the seven days prior to **and not including** the day of the intervention. If the interview was conducted on Wednesday, October 3, the correct interval would be Wednesday, September 26 through Tuesday, October 2. **Remember that the very last event on the day prior to the interview is Event #1**.

If the participant's last event occurred in the early morning hours, and prior to retiring or during a night's sleep which was interrupted, **record that event as having occurred on the night before, i.e., 2 a.m. on 10/3 = 11:59 p.m. on 10/2.**

If it's obvious or if the participant reports drinking on the day the CDR is administered, simply make a note of that fact and give some approximation of how able he is to respond accurately. For example, do not include drinking events on 10/3 on the CDR as described above.

Use the questions printed on Form 13. This will both help to keep your probes consistent and ensure that the information you record is complete.

The concept of a drinking event is critical to the proper administration of the CDR. The data collector must be familiar with the definition and must be able to explain it to the participant precisely and without any doubt or equivocation and must be able to give examples as necessary.

A DRINKING EVENT is a situation within which the participant drinks. Several variables are used to describe each such situation. A change in any of these variables marks the end of one drinking event and may also mark the beginning of another. These variables are the following:

1. LOCATION - Any movement from one place to another, even within the same building or locale, e.g., from one room to another or indoors to outdoors, and vice versa, at a private home or cocktail lounge to dining room in a restaurant, or stadium to street or bar marks the end of a drinking event. Location (Item 5) must be reported using codes from Table 6.

2. OCCASION - Any change in the activities going on or the special reason given for drinking marks the end of a drinking event. If Mr. X attends a wedding, drinks at different points in time and place at this function, sometimes with different people and drinks while engaging in various activities, such as the toast, talking with old friends, greeting his in-laws, the wedding dinner, he would need to report at least four drinking events. If, following the wedding reception, Mr. X meets a colleague at a nearby club to deliver materials for a proposed joint venture, and then returns home where he discusses the wedding with his wife, and finally spends the rest of the evening relaxing in his room and drinks during each of these occasions, he would need to report three more drinking events. Occasion (Item 6) must be reported using codes from Table 7. Codes 01 through 05 should be used only for occasions that occur within the participant's own home.

3. TYPE OF FOOD - Any change from one type of food such as full meal, snack, type of meal, etc. to another marks a change in event.

4. PEOPLE - Any change in the identity or number of individuals present or a change in the drinking behavior of individuals present during a drinking event marks the end of a drinking event.

The duration of each drinking event (Item 4) must be recorded. Duration is recorded using the time when the participant first started drinking (FROM) and the time when he stopped drinking (TO). If there are periods within this interval when he was not drinking, then the interval must be divided into several drinking events.

For each drinking event, item 7 is used to record the type and quantity of alcoholic beverage consumed. Participants will frequently consume only one type of beverage in a standard size during a single drinking event; item 7a can be used to document this and the rest of item 7 would be left blank. If a participant consumes several types of beverage or the size of the drink varies, each variation must be documented within item 7. Record the type(s) of beverage that the participant consumed, the size(s) of the drinks in ounces and the number(s) of drinks consumed of each indicated type and size. Code type of beverage using the codes printed on the form. For mixed drinks, use the beverage code appropriate for the alcoholic beverage used in the drink and report size in ounces of alcoholic beverage included in the drink. Do not report amount of non-alcoholic mixer. If a mixed drink contains two different types of alcoholic beverage (e.g., a cordial and a liquor), each of these components must be reported separately. For example, if a participant reported drinking three Black Russians (includes 1 1/2 oz Vodka and 1/2 oz Kahlua) during a drinking event, this would be coded as follows:

Type Black Russian 5	Type Black Russian 6
Size 0 0 . 5 Number 0 3	Size 0 1 . 5 Number 0 3

Be careful about not being judgmental about what is reported on alcohol consumption. But be sure that you are absolutely accurate in recording what the participant reports. When probing for additional drinking episodes and amounts, determine whether you have correctly understood the participant's responses. It is important that you not make assumptions. This is particularly important when an unusually high number of drinks is reported. For example, if the participant reports having consumed several six packs, you must ask him about how many cans were drunk. Do this by asking for more precision in his terms, not by making your own estimate of the number of beers he drank: ask how many six packs do you mean when you say several?; then were the six packs full/complete?; then, did you finish each of the cans? Let's see now, that makes X cans... is that right? Then what size cans were they, etc.

It frequently may not be easy to complete Form 13 while actually interviewing the participant. Two alternatives are to record the participant's responses on a notepad or to make an audio tape of the interview. The participant's responses can then be reviewed and Form 13s can be completed after the interview. If either of these alternatives are used, it is important to be certain that all required information for documenting drinking events is obtained and recorded during the interview so that the Form 13s can be completed.

Some participants may be more difficult than others to interview. Your technique will always have to be adopted to each specific participant. If problems occur with a particular participant, type(s) of participant or response category(ies), please call Dr. Hanna at NIAAA, FTS 443-3306.

TABLE 6

PRIVATE HOME (INCLUDING BACK YARD):

01 - In my own home

02 - Home of someone I work with

03 - Neighbor's home

04 - Relative's home

05 - Friend's home

NOT IN PRIVATE HOME:

06 - Night Club (dinner and entertainment, floor show)

07 - Restaurant (serves lunch/dinner with drinks. May have a bar in same room. No live entertainment.)

08 - Restaurant/cocktail lounge (patrons often drink here while waiting for dinner)

09 - Bar/cocktail lounge (no food other than snacks)

10 - Neighborhood bar, pub, or tavern (snacks an/or light lunch)

11 - Private club or bar (for members and guests)

12 - Parks, picnic areas, street, etc.

13 - Other

TABLE 7

IN HOME:

01 - Listening to radio, watching TV, reading

02 - With or before a meal

03 - Just relaxing

04 - Party for friends, acquaintances, etc.

05 - Other

AWAY FROM HOME:

06 - Sports events

07 - With or before a meal

08 - On the way to or from work, a party, etc.

09 - Party

10 - Special event (wedding, awards, etc.)

11 - Other

N. Central Laboratory Data (Form 14)

The top section of Form 14, the header, needs to be completed by the Data Collector. The information to be completed is: medical center name and number and participant name and number. The Data Collector's name goes in the space for "Form Completed By". The date completed is the date of the visit.

Complete appropriate rating period (month). The choices on the form are:

00 (Pre) for screening visit 3

03, 06, 12, 18, 24 (Post) for follow-up visits after randomization

Complete question 1 which is the date the specimen was collected. It must be the same date as the visit date during follow-up. During screening, the laboratory data can be delayed and may not be the same as the visit date.

Questions 2 through 12 and comment section are completed by the Central Lipids Laboratory.

The form is signed by the Laboratory Director.

Form 14 needs to be completed for each participant who is registered. Follow-up central lab blood tests are ordered for each participant at the 3, 6, 12, 18 and 24-month visits.

Complete the Central Laboratory Data Checklist (Figure 27) completing the header information, participant number and rating period for each sample sent.

Follow packing and shipping instructions given in Section XIII.D. Please use only the labels provided by the Central Laboratory. If more are needed, please call the Central Lipids Laboratory at FTS 921-8462.

O. Echocardiogram Worksheet and Report Form (Forms 15A and 15)

Form 15A header should be completed by the Data Collector **except for form completed by and the date of the echo.** The date of echo should be the date when the echocardiogram was recorded. The rest of the header listing the medical center name and number and participant name and number should be completed by Data Collector. The participant's Social Security number should be written in the right-hand corner just above the header but must not obscure header information.

The Data Collector must also code appropriate rating period, 00 (pre) or 06 (month). The echo should ideally be completed no later than two weeks following SV3 completion. The Data Collector must notify the Study Interventionist as soon as the echo has been completed.

Questions #1 and 2 can be provided by the Echo Technician if adequate scales are available to accurately record the participant's height and weight. If not available, the Data Collector should collect this information.

Question #3 on the two supine blood pressure measurements should be done by the Echo Technician at the local echo lab. The Echo Technician also completes questions #4-15 at the site.

It is the responsibility of the Data Collector to retrieve the echo tape and Form 15A for review, processing and mailing.

Carefully follow packing and shipping instructions listed in Section XIII.F of the Operations Manual. Be sure to include Form 15A and list the echo tapes on the Central Laboratory Checklist providing the header information, listing each participant's number and appropriate rating period, 00 or 06.

Form 15 is completed by technicians at the Central Echo Laboratory.

Figure 27

CENTRAL LABORATORY DATA CHECKLIST

MONTHLY ECHOS ____
MONTHLY LIPIDS ____
QA URINES ____
(CHECK ONE)

CSP #996 - PATHS

MEDICAL CENTER NO. ___ ___ ___

DATE SENT: MO __ __
DAY __ __
YR __ __

PARTICIPANT NO.	RATING PERIOD	PARTICIPANT NO.	RATING PERIOD
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P. Intercurrent Illness Form (Form 19)

If a participant has been ill or hospitalized, Form 19 must be completed. Form 19 must be completed as often as necessary to document all illnesses and/or hospitalizations. It also must be completed whenever question 17 on Form 2 is answered YES. Questions 1 through 28 must all be coded 1 for YES and 2 for NO. Briefly describe any illness or hospitalization. For hospitalizations, give discharge diagnosis, if known, length of stay and briefly describe any procedures done.

If the participant has been placed on a prescription medication, provide type, dosage and length of treatment time. It is extremely important to document any concurrent medication(s) for each and every visit on Form 2 and Form 19. Progress notes should be completed to clarify medical treatment, prognosis and when the medication(s) are stopped.

If non-prescription drugs are recommended, e.g., motrin, aspirin on a daily basis or prn for chronic conditions such as allergies or arthritis, these should be listed on the Form 2 with a Form 19 and progress notes completed until the treatment ends. Occasional prn drugs do not need to be listed.

Q. Exclusion/Termination Form (Form 20)

Form 20 documents reasons why participants are excluded from the study during prescreening (prior to SV1) and during screening. Form 20 also provides a termination section for post-randomized participants. The Data Collector and/or Interventionist can complete Form 20. The header information should include the following: the medical center name and number, participant name and number, form completed by and date completed.

For participants excluded as a consequence of a screening visit, date excluded would be the date of the visit. For other individuals, such as those excluded prior to SV1 and identified as eligible on the BSI, date excluded should be the date when the exclusion was determined. Code up to 3 reasons for the exclusion in order of importance, starting with the most important. Use Table 2 (see Section VII) which provides a three-digit code for medical, psychiatric and other reasons for the exclusion(s). Call the Study Chairman's Office about any exclusion not explicitly listed or with questions about coding the exclusion(s). Complete only the header and exclusion section (questions 1 and 2) for participants excluded from the study. If there are less than three reasons for the exclusion, leave 2b and/or 2c blank. No missing code is needed.

There are specific criteria for registered participants who are terminated from the study. They are:

1. Participant has completed scheduled follow-up visits through month 24.
2. Participant has moved or is lost to follow-up.
3. Participant requests termination from the study.
4. Participant died during the course of the study. (Send copy of death certificate to Coordinating Center).
5. Other which must be specified.

The date terminated should be the date of the last follow-up visit that the participant attended. The Study Chairman's Office must be called before terminating any participant prior to the 24-month visit. Any data that can still be obtained from these participants should be obtained. Code questions 4 through 8 "1" for YES or "2" for NO.

Participants may be excluded during the prescreening phase of the study but cannot be terminated post-randomization for non-compliance or because of the development of medical problems.

An open-ended comment section is provided at the end of form which can be completed as required. If none, leave blank.

Any terminations must be reviewed with the Principal Investigator who must also sign the form.

XVI. PROCESSING OF FORMS

A. PURPOSE

Your contribution is crucial to the success of the study although some of the chores are necessarily repetitious and clerical in nature. However, we have found that the data will be processed most efficiently when all Data Collectors follow the same basic guidelines. Please do not hesitate to call the Computer Assistants at Perry Point if you have any problems concerning edit reports, forms submissions or if you need additional forms. Your contacts for CS #996 are: Cathy Lucas at FTS 956-6131; Debbie Davis at FTS 956-5375 or Liz Spence at FTS 956-5313. The following advice will eliminate much paperwork involving forms and Edit Reports.

B. Data Handling

1. Items located at the top of the forms including the medical center number, participant number, date completed and rating period are referred to as header information. These are used by the computer to uniquely identify a particular record in the data base. Therefore, it is imperative that this information is accurate, complete and legible. Otherwise, the entire form may be returned to you for correction.

2. Most study forms are printed on 3-part NCR paper that include an original (white), a second copy (yellow), followed by the third copy (pink). It is important for all of the information entered onto the forms to be legible on all three copies. Upon completion, the copies of the forms are to be separated by color. *The original (white) must be sent to CSPCC, the yellow retained at your medical center, and the pink copy sent to the Chairman's Office.

* The exceptions are:

a. The original (signed) copy of the Study Consent forms are legal documents that must be retained in the participant's hospital record. The second copy (yellow) is sent to the CSPCC and the third copy (pink) is sent to the Chairman's Office.

b. The original copy of the VA10-1086 must be retained in the participant's hospital record and a photocopy of this form should be sent to the CSPCC. Please assure

that the 3-digit medical center number and participant number are written clearly at the top of the VA10-1086 before submitting the consent form to CSPCC.

c. Copies of the Psychosocial and Health Habits Form (Form 8) and Beck Inventory (Form 9) will be sent to the Study Chairman's Office. A copy will also be retained at the site but the original forms are sent to the CSPCC.

3. The pages of each multi-page form must be in proper order and securely stapled in the top left corner. Do not staple the sets of multiple forms for one participant together such as screening visit 1 and 2.

4. Before the forms are ready to be mailed, assure that like forms are placed together in ascending form order, (e.g., all Forms 1's, all Forms 2's together, etc.). Each set of like forms are then placed in ascending participant number order, (e.g., Participant number 01005, 01006, 03009, etc.) Please prepare the Data Mailing Checklist and the Brief Screening Instrument Log each time the weekly data is sent. Instructions are:

a. The Data Mailing Checklist (Figure 28) provides a record of forms mailed to Perry Point and to the Study Chairman's Office. Every form except Form 1 must be listed consecutively by form number and by rating period. In addition, the number of PHASES are required for a complete Form 6 (or for a participant who passed the inclusion criteria for Form 6). The column INT is only used for Form 2 interim blood pressure checks. Record the rating period and the interim visit number. The EVENT column is only used for Form 13. Each Form 13 must be identified on the checklist by both rating period and event number.

b. Like the other NCR forms, the Checklist comes in three parts. As listed in B.2 above, send appropriate color to Perry Point, Study Chairman's Office and retain a copy at your site for your records. The Data Mailing Checklist is also useful in verifying forms sent against the Missing Forms Report.

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MEDICAL CENTER NO. ___

DATE SENT: MO 04 DAY 23 YR 90

FORM #	PARTICIPANT NO.	RATING PERIOD	PHASE (Form 6 only)	INT. (Form 2 only)	EVENT
02	00001	92			
02	00001	01		02	
02	00002	01			
02	00003	03			
03	00001				
03	00002				
03	00003				
04	00001				
04	00002				
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05	00001				
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07	00002	06			
07	00003	18			
8	00001	00			
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13	00003	18			

CSP #996 - PATHS

MEDICAL CENTER NO. ___

DATE SENT: MO ___ DAY ___ YR ___

FORM #	PARTICIPANT NO.	RATING PERIOD	PHASE	INT.	EVENT
14	00001	00			
14	00002	06			
14	00003	18			
15	00001	00			
15	00001	06			
15	00003	06			
16	00001				
16	00002				
16	00003				
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18	00003				
19	00001				
19	00002				
19	00003				
20	00004				

FORM #	PARTICIPANT NO.	RATING PERIOD	PHASE	INT.	EVENT
20	00005				
20	00008				
20	00009				
20	00010				
20	00012				
20	00014				
20	00017				

5. The data should be mailed every Friday, both to the Study Chairman's Office and to the CSPCC via first class mail.

Mailing address to CSPCC:

Stephen F. Bingham, Ph.D.
Study Biostatistician
Cooperative Study #996
CSPCC (151E)
VA Medical Center
Perry Point, MD 21902

**** Note: Data mailing is required every Friday. If problems occur, the Study Chairman's Office should be informed. If the problems persist, the Principal Investigator will be called by the Study Chairman. Data Forms should not be held at the site and should be promptly reviewed each week by the Data Collector for the Principal Investigator to approve and sign. Data management is considered one of the highest priorities in this study and strict observance will be maintained throughout the study.**

C. FORMS COMPLETION

General instructions for completing study forms are as follows:
Take sufficient time to enter all information carefully. Any information on the forms is that is illegible, will be entered as an "I" which will cause an edit to come out on the Edit/Clarification Report and you will be asked to reenter that information.

Do not write over incorrect entries. Line out the incorrect entry and rewrite the corrected entry to the right of the line.

All comments and descriptions must be legible, clear and concise.

All numbers should be entered "right justified" with leading zeroes, so that each space for a response has a number in it. (Example: If the field has a two position possible answer such as MO _ _, and the response is January, please enter 01, not 1.)

When a scheduled visit is missed such as a follow-up visit and cannot be rescheduled in the correct time frame, Form 2 must be submitted with the correct header information and question 1 answered "2" (No). A large "A" should be printed across the top of Form 2 but not obscuring the header information. The remainder of Form 2 should be left blank and it will not be necessary to complete other follow-up forms for that rating period.

Questions that need not be answered should remain blank. Follow all instructions on the forms (e.g., if yes, go to page 5, q.59). For any question that cannot be answered for reasons other than these given on the form, a missing value code system has been devised. The appropriate letter should be placed on the left most column of the field provided (e.g., U).

The coding system is as follows:

U = Answer is unknown
F = Rater forgot to obtain the data
L = Record or test result was lost
A = Participant was not available for testing
R = Participant refused to answer or take the test
T = Participant was not testable or unable to answer

D. Edit/Clarification Procedures

1. The Edit Report/Clarification Request is provided as a means to correct or change data detected by range or cross edits. This report will show questionable values detected in the data that currently exists in the study database. A data value listed as the "current value" may in fact, be correct but is considered questionable according to the Edit/Clarification Report. This will occur because the current value has either failed a range check or a validity check against one or more other data values, which are referred to as cross-edits. These items must be verified as correct by entering "OK" as the corrected value or modified as you find it necessary.

2. The Edit Report/Clarification Request is usually printed on 3-part NCR (noncarbon reproducing paper) computer printouts. The following guidelines should assist you in answering the report:

a. Keep the report intact until all items have been answered.

b. It has proven useful to place a piece of cardboard behind the page you are currently working with.

c. Use a dark (blue or black) ball point pen and apply pressure to assure all answers appear clearly on all 3 copies.

d. When working with the report, please refer to the forms in question. This should help to identify what other question or questions may be affected by any changes that you make. We strongly advise that you make the same changes on the study forms that you made on the edit report.

e. Data starting from the left of the printout identifies the form in error. The columns are represented as:

1) * PART. NO - the Participant Number in question.
2) * FORM NO - the Form Number containing the error.

3) * RATING PERIOD - represents the follow-up period as forms listed on follow-up, remembering that PRE will be represented as 00.

4) * INT/EVENT - (INT) represents interim visit for Form 02 - the rating period should be answered and the interim visit should be a sequential interim visit number within the initiating rating period. (EVENT) represents the event number as listed on Form 13 for a given rating period.

5) DATE COMPLETED - represents the date listed at the top of the form as Date Completed or on Form 15 as Date of Echo.

* The items 1) - 4) are to be considered critical information, as these are used to uniquely identify the form in the data base, and will only be recognized by the computer if all items are correct.

6) The "variable name" (appearing to the left of the edit message) is the item to be acted upon. In most cases the variable name will be a question number. It will never exceed 8 characters, and will have no spaces between characters. In some cases, we have used several variations of the question number due to the multiple part questions. In such cases you may see a bar (_) between characters, this is an underscore, not a dash.

7) EDIT MESSAGE TO BE ACTED UPON - this is a brief explanation of the error found on the variable name listed to the left of the message.

8) CURRENT VALUE - indicated the value that currently exists in the study data base. An "I" listed under "Current Value" indicates that the value for this particular question (variable) was either illegible, incomplete, or incorrect. This is often caused by writing over an original response, entering more digits than spaces provided, or by entering them in the incorrect spaces. A period (.) or an underscore (_) represents a missing value for the variable.

9) CORRECTED VALUE - this provides the means for verifying existing data or for making modifications you feel are necessary. Each line printed under "corrected value" must be responded to by entering a new (corrected) value, or an "ok". If you wish the value to be blank, please enter the word "blank". On special edits and cross-edits, our computer incorporates a "3 time process" in which you may be asked to "ok" a value 3 times prior to its being accepted as correct.

f. When you have answered all lines under the "Corrected Value" column, the report can be separated. The top (original) copy must be sent to CSPCC, the second copy retained at your medical center, and the third sent to the Chairman's Office.

g. It is important to attend to this report and return it to the CSPCC as soon as possible so that we have a timely and accurate data base available for data analysis.

E. SUPPLEMENTAL CORRECTIONS

1. The "Supplemental Correction" sheets are located at the end of each Edit Report/Clarification Request. These are only to used for items to be changed that will not be caught by the editing procedures. If errors are found, make note of them and wait until you have received two Edit Report/Clarification Requests. Check these reports, if the editing procedures failed to catch the errors, it then should be safe to follow through on a "Supplemental Correction" sheet.

2. It is of utmost importance that the "Supplemental Correction" sheet be filled out legibly, properly and as it currently exists in the data base. All identifying information must make a perfect match in the data base; otherwise, the changes will not take place.

3. If a change is submitted (via Supplemental Corrections) and entered into the system before the actual form has been entered this will result in a "Not Found" report. This notifies you that the change you have submitted did not make a match in the data base, and the change was subsequently not made. Another reason a change may appear on this report is due to incorrect variable names being entered on the "Supplemental Corrections" on the form. You must refer to the Variable Name Listing for legitimate variable name. NOTE: Variable Name must be coded EXACTLY as it appears on the Variable Name Listing.

4. The columns on the "Supplemental Correction" sheet are represented in the same fashion as the Edit Report/Clarification Request, and the same guidelines should be followed.

F. EDITS ILLUSTRATED USING FORM 2

There are three basic types of edit messages. Two of them, out of range edits and missing value edits, are fairly easy to understand and resolve; the third type, which we refer to as cross-edits, can be much more complicated.

1. Out of Range Edits

There are two types of out of range edits. One type involves answers that are impossible by design, e.g., a "3" for Questions 1,8, or 17. An appropriate answer ("1" or "2" for these 3 questions) must be provided or a missing value code (either U or some other more appropriate code)

must be used. The second type involves answers that are extreme but may be correct, e.g., an uncorrected systolic blood pressure less than 100. There are three ways of responding to this type of message. If the value is correct, write "OK" in the CORRECTED VALUE column. If the value is clearly incorrect, the correct value should be entered in the CORRECTED VALUE column. If the value is clearly incorrect but you do not know the correct value, then a missing value code must be used in the corrected value column. If you change a value that is used for calculating other values, you may also need to change the calculated values using the SUPPLEMENTAL CORRECTIONS form which will be discussed later.

2. Missing value edits

Missing value edits are more elementary than out of range edits and are used to identify variables for which we need a value. Some form items do not always require an answer and these will not be listed as missing. When a value is listed as missing, you must either supply the missing value or use a missing value code. There is a second type of missing value edit that is handled as described above but is caused not by failure to enter a value for a particular item but by reporting a data value in such a way that it could not be processed. The CURRENT VALUE column will use the letter "I" to indicate when this has happened. You should usually be able to determine what caused the problem by looking at your copy of the form. If you cannot, you should call one of the Computer Assistants at Perry Point.

3. Cross edits

Cross edits are used to detect situations where the answer to one question is in conflict with the answer to another question. Sample Form A is an abbreviated Form 2 that was prepared to illustrate several different cross-edit situations.

a. Example 1

The most common problem with Question 1 is caused by failure to explain why a participant did not come in for a visit (Q1 = 2). If the participant did not come in for his appointment on that day, you would indicated in the "CORRECTED VALUE" column that the "2" is "OK" and briefly explain what happened, e.g., "didn't show up" or "canceled appointment" or even, if necessary, "I don't know why."

should be ignored and you should put a large X in the CORRECTED VALUE column. You should also indicate on the edit report that the form was to be deleted. If a Form 2 for a screening visit needs to be deleted, it may be necessary to change the rating period for a subsequent Form 2 (e.g., from 92 to 91 if the deleted Form 2 had been for rating period 91.) This would be done using the SUPPLEMENTAL CORRECTIONS form.

e. Example 5

The last question on Form 2 asks for the date of the next visit. The most common edit message for this question indicates that the date of the next visit is prior to the date of the current visit. This is usually caused by indicating the wrong year for the date of the next visit.

f. Example 6

The SUPPLEMENTAL CORRECTIONS form will need to be used whenever the value of a particular variable needs to be changed and the variable is not listed in an edit report. This example shows how this form can be used to deal with several problems that were referred to earlier. The first line is being used to correct a calculated blood pressure reading. I am assuming that Q5A_DBP had been listed in the edit report because it was an odd number (121) and had been corrected there. Assuming that the zero value was 26, then the corrected DBP should be 94. The second line is being used to change the value of Q12 from 1 to "BLANK". "BLANK" indicates that the drug should not have listed on the form and this change is necessary to make Q12 consistent with the corrected value of Q12_A in Example 3. The third line is being used to change the rating period for a Form 2 (dated 3/15/91) from 92 for screening visit 2 to 91 (screening visit 1) following the decision to delete the Form 2 (dated 3/1/91) as indicated in Example 4.

SAMPLE FORM A

DVA COOPERATIVE STUDY #996
PATHS

FORM 2
DATA COLLECTION FORM

Medical Center Name _____

Participant Name _____

Form Completed By _____

Medical Center No. ___ ___ ___

Participant No. 9 9 9 9 9

Date Completed 0 3 0 1 9 1
Mo Day Yr

CODE APPROPRIATE RATING PERIOD ..... ___ ___

SCREENING: S1=91 S2=92 S3=93 FOLLOW-UP MONTH: 01 02 03 04 05 06 09 12 15 18 21 24

2. PREPARATION FOR BLOOD PRESSURE MEASUREMENTS

e. Resting 30-second heart rate ..... 3 9 /30 sec.

f. Resting one-minute heart rate (2 x e) ..... 7 8 / 1 min.

3. FIRST RANDOM ZERO SITTING BLOOD PRESSURE SBP / DBP

a. Reading ..... 1 5 0 / ___ ___ ___ mm Hg

b. Zero Value ..... 1 4 / ___ ___

c. Corrected value (a - b) ..... 1 4 6 / ___ ___ ___ mm Hg

STUDY #996 - FORM 2 (Page 2 of 2) Medical Center No. ___ ___ ___ Participant No. ___ ___ ___ ___ ___

CONCURRENT MEDICATION:

	DRUG NAME	A. DRUG CODE
11.	Matrin	___ ___ ___
12.	Lasix	J H G

VA FORM 10-29020 (NR)b
AUGUST 1990

EXAMPLE 1

PART_NO	FORM	RAT_PER		DATE FORM COMPLETED	VARIABLE NAME	>><<EDIT MESSAGE REQUIRING RESPONSE>><<	CURRENT VALUE	CORRECTED VALUE
				YR-MO-DA				*MUST RESPOND*
99999	02	91	...	90-12-11	Q1	FAILED CROSS EDIT WITH COM1	2	OK
					COM 1	FAILED CROSS EDIT WITH Q1	-	cancelled appointment

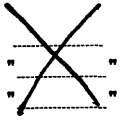
EXAMPLE 2

PART_NO	FORM	RAT_PER		DATE FORM COMPLETED YR-MO-DA	VARIABLE NAME	>><<EDIT MESSAGE REQUIRING RESPONSE>><<	CURRENT VALUE	CORRECTED VALUE *MUST RESPOND*
99999	02	91	...	91-03-01	Q2F	SHOULD BE EQUAL TO Q2E x 2 DOES NOT AGREE WITH CALCULATED VALUE OF 74		
					Q2E	PLEASE CORRECT AS NECESSARY	37	39
					Q2F	PLEASE CORRECT AS NECESSARY	78	OK
					Q3C_SPB	SHOULD BE EQUAL TO Q3A_SBP - Q3B_SBP DOES NOT AGREE WITH CALCULATED VALUE OF 136		
					Q3A_SBP	PLEASE CORRECT AS NECESSARY	150	OK
					Q3B_SBP	PLEASE CORRECT AS NECESSARY	14	OK
					Q3C_SBP	PLEASE CORRECT AS NECESSARY	146	136

EXAMPLE 3

PART_NO	FORM	RAT_PER		DATE FORM COMPLETED YR-MO-DA	VARIABLE NAME	>><<EDIT MESSAGE REQUIRING RESPONSE>><<	CURRENT VALUE	CORRECTED VALUE *MUST RESPOND*
99999	02	91	...	91-03-01	Q11_A	NO DRUG CODE GIVEN		
					Q11	PLEASE CORRECT AS NECESSARY	1	OK
					Q11_A	PLEASE ENTER APPROPRIATE DRUG CODE		"HBB"
					Q12_A	*INVALID DRUG DURING SCREENING PHASE*	JHG	"BLANK"

EXAMPLE 4

PART_NO	FORM	RAT_PER		DATE FORM COMPLETED YR-MO-DA	VARIABLE NAME	>><<EDIT MESSAGE REQUIRING RESPONSE>><<	CURRENT VALUE	CORRECTED VALUE *MUST RESPOND*
99999	02	91	...	91-03-01	Q11_A	NO DRUG CODE GIVEN		
					Q11	PLEASE CORRECT AS NECESSARY	1	
					Q11_A	PLEASE ENTER APPROPRIATE DRUG CODE		
					Q12_A	*INVALID DRUG DURING SCREENING PHASE*	JHG	

168 Form to be deleted per memo dated 4/5/91.

EXAMPLE 5

PART_NO	FORM	RAT_PER	...	DATE FORM COMPLETED YR-MO-DA	VARIABLE NAME	>>><<EDIT MESSAGE REQUIRING RESPONSE>>><<	CURRENT VALUE	CORRECTED VALUE *MUST RESPOND*
99999	02	91	...	90-12-03	Q18_DATE	OF NEXT VISIT, PRIOR DATE FORM COMPLETED		
					Q18MO	PLEASE CORRECT AS NECESSARY	3	OK
					Q18DAY	PLEASE CORRECT AS NECESSARY	4	OK
					Q18YR	PLEASE CORRECT AS NECESSARY	90	91
					MONTH	PLEASE CORRECT AS NECESSARY	12	OK
					DAY	PLEASE CORRECT AS NECESSARY	3	OK
					YEAR	PLEASE CORRECT AS NECESSARY	90	OK

EXAMPLE 6

PART_NO	FORM	RAT_PER/ PHASE	...		VARIABLE NAME/Q #	CURRENT VALUE	CORRECTED VALUE
99999	02	91		YR 91 MO 03 DAY 01	Q5C_DBP	95	94
99999	02	91		YR 91 MO 03 DAY 01	Q12	1	BLANK
99999	02	92		YR 91 MO 03 DAY 15	RAT_PER	92	91
				YR__ MO__ DAY__			

G. AUDIT FILE REPORTS

The audit consists of several different reports. These reports are informational and are not meant to be returned to CSPCC.

The audit reports allow us to keep track of records we've received for each participant and to inform each Medical Center of records not yet received. It also provides you with information on participants who are due for follow-up visits during the upcoming 30 days.

1. Missing Forms Report

When working with the Missing Forms Report, there are a few issues you should remember:

a. Data can be listed as missing if there are any errors in the header information such as the Participant Number or Rating Period. Check your Edit Report/Clarification Request to see if that particular record appears with errors involving the header information.

b. Check the participants folder to make sure that the original is not there, but that your copy is and enough time has elapsed to allow for the data to have been received and processed at CSPCC.

c. Check your correspondence, Data Submission Corrections and memorandums to see if the form has been deleted and returned to your facility and has not been re-submitted.

d. Each new report replaces the preceding one. Any old ones that you may still be working on then become obsolete.

e. If there are records that are listed as missing and one of the above situations are true, please make note of this and check the next two listings of missing records. If the records(s) are still listed as missing, please contact CSPCC.

f. The Missing Forms Report is sent from CSPCC every month. The Data Collector is to review this report every month. If there are problems, please call Perry Point CSPCC for assistance. Data management is considered an important function of the site. If these reports are not reviewed regularly, the Principal Investigator will be informed.

2. Forms Due Report

This report determines which participants are due for follow-up in the month following the report. It can be helpful in reminding you of what forms are to be done or of any procedures that should be scheduled for the participants.

3. Duplicate Forms Report

A duplicate form can exist if the header information is exactly the same on two or more forms. If duplicates exist, they are automatically removed from the data base and all copies are returned to the Medical Center to determine the accuracy of the header information. The Data Collector should then make appropriate changes to all copies of the form and resubmit the forms to CSPCC.

4. Changes Not Found

A change submitted via Supplemental Corrections and entered into the system before the actual form has been entered will result in a "Not Found" report. This notifies you that the change you have submitted did not make a match in the data base, and the change was subsequently not made. Another reason a change may appear on this report is due to incorrect variable names being entered on the Supplemental Correction Sheet. The message will notify you that the variable name does not exist in the data base.

All changes listed on this report must be resubmitted via another Supplemental Correction in order for these changes to be reflected in the data base. These problems create additional work for all involved and must be avoided. Therefore, you should always make sure that the form has been entered into the system before submitting the "Supplemental Corrections" on the form, and that you refer to the Variable Name Listing for legitimate variable names. NOTE: Variable Name must be coded EXACTLY as they appear on the Variable Name Listing.

5. Outstanding Edit Report

This is an informational report to let you know of an Edit Report/Clarification Request which has not been received at CSPCC. Please return all completed Edit Report/Clarification Requests back to CSPCC as soon as possible. Check your records to assure that enough time has elapsed for the report to have been received and processed. If you have questions, please feel free to call CSPCC.

XVII. ETHICAL CONSIDERATIONS

A. Human Studies and Ethical Considerations

The primary ethical issues presented by this study are: the withdrawal of any existing antihypertensive therapy, the risk of mildly elevated levels of blood pressure for six months, the risk of blood pressure going too high, and the risk of continued moderate to heavy alcohol intake.

Participants in this study will have upper normal BP (80-89 mm Hg) or be in the lower two-thirds of the mild hypertension range (90-99 mm Hg). Although the cardiovascular risk for individuals in the upper normal BP range is more than for those <80 mm Hg, it has not been considered feasible to study the effects on morbidity or mortality of treatment to lower BP in these individuals because of the very large sample sizes that would be required to demonstrate a significant decrease in the very low individual risk for those with BP in this range. Pharmacologic antihypertensive treatment is therefore not currently recommended.

Nevertheless, candidates for the study will be advised of that finite risk during the informed consent procedure. Safety criteria are established to initiate treatment with antihypertensive medications if a participant's BP exceeds the mildly hypertensive level during the initial six-month treatment phase or if a participant becomes or remains frankly hypertensive during the maintenance phase. (See Safety Monitoring, Section VIII.B)

Alcohol intervention or even advice to modify drinking is rarely pursued in moderate to heavy drinkers who do not present with manifestations of dependence. Therefore, even though our control group will receive no advice concerning their drinking, some of these participants may benefit from their participation in this study, although their changes in alcohol intake should not be nearly as large as for those participants in the intervention group. Many individuals who drink heavily will be recognized by our screening procedures who would not otherwise have been detected. If adverse health consequences of continued drinking are detected within the study, there are safety criteria for referring the participant for more intensive alcohol treatment. However, the participant will continue in the study and continue to participate in data collection visits, if possible.

In summary, we believe this study is organized in such a manner that it is ethically prudent and that the small potential for risk is outweighed by the benefits that may accrue to many

individuals participating in the study and for large groups of alcohol drinkers who may be benefitted by the results of the study.

B. Informed Consent Procedure

The informed consent documents have been approved by the Perry Point CSPCC Human Rights Committee and must also be approved by the equivalent Institutional Review Board (Human Rights Committee) at each of the participating centers.

Appropriate informed written consent for screening (see Form 87) will be obtained from all participants prior to entering the screening phase of the study and prior to withdrawing any existing medications, unless the latter is clinically indicated, regardless of the individual's participation in the study. Medication withdrawal may be indicated, for example, in a patient with low blood pressure on little antihypertensive medication or in one for whom medication was begun with inadequate documentation of "hypertension." A separate written informed consent to enter the study (see Form 88) will be obtained at the end of the screening phase for participants who meet the eligibility criteria for randomization prior to entering the randomization/intervention phase of the study.

Each candidate will be given ample time to read or have read to him the consent documents. Clinic personnel will summarize for him the nature of the study, including the time commitment involved, the frequency of visits, and the fact that blood samples and overnight urines will be collected and questionnaires about nutrition, health practices and lifestyle will be administered. Possible risks, limitation of benefits, monitoring procedures, confidentiality and right to withdraw from the study will be communicated to the candidate. Study candidates will be advised that they are not required to participate in this experimental protocol, but may avail themselves of "standard" treatment for hypertension (if present). They will also be informed that any VA benefits for which they may be eligible will not be jeopardized by their participation in the study or by their refusal to participate.

At the beginning of each phase, after the candidate has stated that he understands what his participation requires and that he is willing to participate, he will be asked to sign the appropriate consent documents. These forms will also be signed by the participating investigator and a witness. For participants who meet eligibility criteria and are randomized, two sets of consent documents will have been signed: one for screening and, when necessary, washout of antihypertensive medications; and a second for participation in the randomized controlled trial.

XVIII. CONTRAINDICATED MEDICATIONS

Introduction

The purpose of this section is to provide the investigator with a list of drugs that are contraindicated because of possible hypotensive effects. If any of these drugs are used infrequently a participant should not be excluded.

The reason for contraindication is given after each class of drugs.

A. ANTIPSYCHOTIC DRUGS

A-1 Phenothiazines:

Drug (Generic Name)	Trade Name(s)
Acetophenazine	Tindal®
Butaperazine	Repoise®
Carphenazine	Proketazine®
Chlorpromazine	Thorazine®
Fluphenazine	Permitil, Prolixin®
Mesoridazine	Serentil®
Perphenazine	Trilafon®
Prochlorperazine	Compazine®
Promazine	Sparine®
Promethazine	Phenergan®
Thiethylperazine	Torecan®
Thioridazine	Mellaril®
Trifluoperazine	Stelazine®
Triflupromazine	Vesprin®

Reason: These drugs produce alpha-adrenergic blockade which produces a decrease in peripheral resistance and a decrease in arterial pressure.

A-2 Thioxanthenes:

Drug (Generic Name)	Trade Name(s)
Chlorprothixene	Taractan®
Thiothixene	Navane®

Reason: Same as A-1.

A-3 Butyrophenones:

Drug (Generic Name)	Trade Names(s)
Droperidol	Inapsine®
Haloperidol	Haldol®

Reason: Same as A-1.

A-4 Dihydroindolone:

Drug (Generic Name)	Trade Name(s)
Molindone	Moban®, Lidone®

Reason: Same as A-1

A-5 Dibenzoxazepine:

Drug (Generic Name)	Trade Name(s)
Loxapine	Loxitane®

Reason: Postural hypotension may occur.

A-6 Diphenylbutylpiperidine:

Drug (Generic Name)	Trade Name(s)
Pimozide	Orap®

Reason: Postural hypotension may occur.

A-7 Miscellaneous:

Drug (Generic Name)	Trade Name(s)
Lithium Carbonate	Lithane®, Eskalith®, Others

Reason: Lithium may cause hypotension.

B. ANTIDEPRESSANT DRUGS

B-1 Tricyclics:

Drug (Generic Name)	Trade Name(s)
Amitriptyline	Elavil®
Amoxapine	Asendin®
Desipramine	Norpramin®, Pertofrane®
Doxepin	Sinequan®, Adapin®
Imipramine	Presamine®, Tofranil®
Maprotiline	Ludiomil®
Nortriptylline	Aventyl®, Pamelor®
Protriptyline	Vivactil®
Trimipramine	Surmontil®

Reason: Orthostatic hypotension is commonly observed with therapeutic doses.

B-2 Monoamine Oxidase Inhibitors:

Drug (Generic Name)	Trade Name(s)
Isocarboxazid	Marplan®
Pargyline	Eutonyl®
Phenelzine	Nardil®
Tranylcypromine	Parnate®

Reason: A major side effect of these drugs has been postural hypotension. Under certain conditions, the ingestion of foods containing tyramine (fermented cheeses, herring, broad beans, chicken liver and certain fermented beverages) and these drugs will produce a hypertensive crisis.

B-3 Miscellaneous:

Drug (Generic Name)	Trade Name(s)
Carbamazepine	Tegretol®
Fluoxetine	Prozac®
Trazodone	Desyrel®

Reason: Hypertension and hypotension have been reported with these drugs.

C. AMPHETAMINES

Drug (Generic Name)	Trade Name(s)
Amphetamine	Benzedrine®
Dextroamphetamine	Dexedrine®
Hydroxyamphetamine	Paradrine®
Methamphetamine	Desoxyn®

Reason: Their CNS stimulation in addition to peripheral alpha and beta action common to sympathomimetic drugs will raise both systolic and diastolic blood pressure.

D. VASODILATOR DRUGS

D-1 Nitrites and Nitrates:

Drug (Generic Name)	Trade Name(s)
Amyl Nitrite	Amyl Nitrite®
Erythritly Tetranitrate	Cardilate®
Isosorbide Dinitrate	Isordil®, Sorbitrate®, Others
Nitroglycerin	Nitro-Bid®, Nitrol®, Nitrostat®, Transderm Nitro®, Others
Pentaerythritol Tetranitrate	Duotrate®, Metranil®, Pentritol® Peritrate®, Vasitol®

Reason: Decreases blood pressure.

D-2 Miscellaneous:

Drug (Generic Name)	Trade Name(s)
Diazoxide	Hyperstat®
Hydralazine	Apresoline®
Minoxidil	Loniten®
Sodium Nitroprusside	Nipride®
Trimethaphan Camsylate	Arfonad®

Reason: Decreases blood pressure.

E. ANTIADRENERGIC DRUGS

E-1 Antiadrenergic Drugs - Centrally Acting:

Drug (Generic Name)	Trade Name(s)
Clonidine	Catapres®
Guanabenz	Wytensin®
Guanfacine	Tenex®
Methyldopa	Aldomet®

Reason: These drugs decrease blood pressure.

E-2 Antiadrenergic Drugs - Peripherally Acting:

Drug (Generic Name)	Trade Name(s)
Alseroxylon	Rauwiloid®
Deserpidine	Harmonyl®
Guanadrel	Hylorel®
Guanethidine	Ismeline®
Mecamylamine	Inversive®
Phenoxybenzamine	Dibenzyline®
Phentolamine	Regitine®
Prazosin	Minipress®
Rauwolfia, Whole Root	Raudixin®
Rescinnamine	Moderil®
Reserpine	Serpasil®
Terazosin	Hytrin®

Reason: These drugs decrease blood pressure.

E-3 Antiadrenergic Drugs - Beta Adrenergic Blockers:

Drug (Generic Name)	Trade Name(s)
Acebutolol	Sectral®
Atenolol	Tenormin®
Betaxolol	Betoptic®
Esmolol	Brevibloc®
Labetalol	Normodyne®, Trandate®
Metoprolol	Lopressor®
Nadolol	Corgard®
Pindolol	Visken®
Propranolol	Inderal®
Timolol Maleate	Timoptic®, Blocadren®

Reason: These drugs have been reported to produce hypotensive effects.

F. CALCIUM CHANNEL BLOCKING AGENTS

Drug (Generic Name)	Trade Name(s)
Diltiazem	Cardizem®
Nifedipine	Procardia®, Adalat®
Verapamil	Isoptin®, Calan®

Reason: Decreases blood pressure.

G. DIURETIC AGENTS

Drug (Generic Name)	Trade Name(s)
Amiloride	Midamor®
Bumetanide	Bumex®
Ethacrynic Acid	Edecrin®
Furosemide	Lasix®
Spironolactone	Aldactone®
Thiazide Diuretics	Naturetin®, Diuril®, Others
Triamterene	Dyrenium®

Reason: Decreases blood pressure.

H. ACE INHIBITORS

Drug (Generic Name)	Trade Name(s)
Captopril	Capoten®
Enalapil	Vasotec ®
Lisinopril	Prinivil®, Zestril®

Reason: Decreases blood pressure.

XIX. EQUIPMENT AND MATERIALS

TO BE PROVIDED CENTRALLY

All Forms

Instruction Sheets

Venipuncture Supplies

Labels

* 2 Hawksley Random Zero Sphygmomanometer
* 2 Standard Adult Cuff
* 2 Large Adult
* 2 Small Adult
* Mercury Refill

Refrigerated Packing Boxes

* Ordered Centrally by Perry Point for Sites.

TO BE PURCHASED/PROVIDED LOCALLY BY SITES

1. Clinic Appointment Diary (2)
2. Calendars (3)
3. Large (250-1000 ml) Graduated Cylinder for measuring overnight urine samples.
4. Loose-fitting gowns for BP measurement, if participant clothing restricts arm.
5. Littman Stethoscopes: two of model 2100 or 2101 (3M Company)
6. Cleaning supplies for cuff and RZ
7. Extra Mercury (either Triple Distilled Mercury or Analytic Grade Mercury, in excess of 99.99% pure.
8. Medical Scale for height and weight
9. Stopwatch or watch with second hand for measurement of pulse
10. Non-powdered gloves
11. Distilled Vinegar

12. Bio-degradable Detergent to wash urine bottles
13. Carrier Bags or cases for use during urine collection
14. Large (>1 liter) plastic reusable containers with screw top lids to collect overnight urine samples
15. Small Beaker or pipette for transferring urine into aliquots
16. Laboratory Racks for storing blood samples upright for freezing
17. Refrigerator (4°C) or freezer (-20°C) on site
18. Access to photocopier and fax machines for clinic use
19. Marking Pens: black indelible oil-based pens for use on labels
20. Room Thermometer
21. Non-refrigerated Centrifuge
22. Trash Containers and bags for hazardous waste disposal
23. Adjustable table (e.g., Mayo Stand) for support of participant's arm
24. Clipboards (3)
25. Shelves for forms
26. File Cabinet(s) for record storage
27. File Folders
28. Desks (2)
29. Telephones (2)
30. Video cassette tapes for echocardiograms
31. Diary for local/central laboratory form processing
32. Measuring Tape

XX. QUALITY CONTROL

In Fundamentals of Clinical Trials by Drs. Friedman, Furberg and DeMets (2nd. edition, 1985), one statement sums quality control best:

"No study is better than the quality of the data." There are several areas in quality control such as standardization of clinic visits at multi-sites, data form entry, missing data and incomplete data and timeliness of data forms and reports. Coupled with these issues, regular communication to and between the sites, the Study Chairman's Office and the Perry Point Coordinating Center must be maintained throughout the study.

To assist the study personnel and the Principal Investigators, the following outlines the major data quality control areas in our study. A recruitment report is also discussed which is prepared weekly by the sites. The Study Chairman's Office and the CSPCC will monitor each site's progress on all these issues through regular reports which will be provided to the sites. Once weaknesses and errors have been identified, performance can be improved.

A. Standardization of clinic visits - Annual study-wide meeting and training meetings will be held to review the protocol, operational changes, provide recertification and certification (if needed for new personnel) for blood pressure training on the R-Z sphygmomanometer and alcohol forms review. Since this meeting is only held once a year, regular written and verbal information will be provided to the sites on any changes in the Operations Manual on forms, reminders about reports due etc. All study personnel are to review the Study Protocol and the revised Operations Manual (1991) as their guides to follow the procedures for clinic visits, recruitment, inclusion and exclusion criteria during screening and post-randomization procedures for follow-up visits.

B. Data entry on forms submitted to CSPCC - At the current time, there is one edit report finalized on the Data Collection Form, Form 2. This report is submitted by CSPCC each month and due back by the first week of the next month. Follow the guidelines listed in Section XVI to complete this report. For assistance, the Data Base Management personnel should be called first to review any issues with the report.

Since only one computer-assisted program exists to review data entry, the sites must take extra time to check all forms for accuracy, completeness, internal consistency and consistency with other

forms. While all forms are important to the study, special attention on inclusion and exclusion forms such as Form 2, 3, 4, 5, 6 and 11 should be scrutinized by the study personnel. Of similar importance, the Local Lab Form, Form 10, and the baseline CDR, Form 13, should be carefully checked before submitting to CSPCC. Check alcohol consumption and dates on Form 13 and review extreme lab values completing all spaces listed and correct placement of decimals on Form 10.

C. Missing forms reports - This is a regular monthly report on all missing forms by all sites on all data forms and central lab data reports, lipids and echos. The report guidelines are described in Section XVI and for assistance, call the CSPCC personnel. There are monthly cut-offs to up-date the data base once these forms are submitted. It is advised to review this report along with the edit report as soon as received by the sites and submit by the first week of each month.

D. Data report timeliness - There are specific time frames for data forms and central lab data reports. The following checklist outlines these requirements:

1. Missing Forms Report - Forms are due back **each month** to update the data base. Send to CSPCC and Study Chairman's Office.

2. Edit Report - **Due each month.** As above.

3. Central Laboratory Reports (QA urines, Echos, Lipids) - Due the **first week of each month** as specified by shipping instructions in Section XIII. Send to appropriate central laboratory.

4. Data Forms Mailing - Processed each Friday and due at CSPCC and the Study Chairman's Office the following week.

A monthly compilation by each site's data submission will be provided to the study group.

Non-compliance with these data report submissions is considered a serious site violation. If these problems persist, the Study Chairman will review them with the Principal Investigator. The Principal Investigator is expected to provide an action plan to resolve the problems.

Additional feedback will be provided to the Principal Investigator to identify weaknesses and errors at the site. The Principal Investigator should also rely on the regular reports sent by CSPCC and the Study Chairman's Office to evaluate the site on a monthly basis.

E. Recruitment Worksheets

During Phase I, a recruitment worksheet was prepared and implemented by the Operations Committee. Each site provides cumulative prescreening activities and weekly screening visit information to the Study Chairman's Office. This information is compiled into report prepared by the CSPCC and sent to each site. This information was valuable in determining reasonable recruitment activity rates to help produce the number of weekly and monthly randomized needed in our study.

Please follow these instruction for this weekly report. Submit this information by each Monday of the following week and no later than Tuesday, close of business to the Study Coordinator.

1. **Prescreening Section** has four sections:

   a. **# prescreened** is determined using the Brief Screening Instrument, Form 1. Provide cumulative total.

   b. **eligible for SV1** is number of veterans who stated they drink 10 or more drinks a week. Take this number from the BSI and provide cumulative total.

   c. **excluded prior to SV1** are those veterans who are eligible for SV1 but have been excluded for medical or psychiatric reasons or who have decided not to participate in the study. Provide cumulative total.

   d. **scheduled SV1** are those veterans who have agreed to the first screening visit. Provide the current weekly total for the scheduled SV1s.

2. **Screening Section**

a. This section has three parts on screening visits 1-3: the weekly number of completed visits, the weekly number of participants excluded at a specific visit and the number advancing to SV2 and randomized into the study.

b. Provide this information by using the current weekly totals on screening visit activity for SV1, SV2 and SV3.

c. There are three rows on the recruitment worksheet (need an SV1 and pending SV2 and SV3) that are computer-generated but are based on the information provided by the site.

d. If a person advances to SV3, provide participant's name, study number and SV3 appointment if known to the Study Coordinator. These forms will be reviewed prior to registration at CSPCC.

e. The number pending means that the participants successfully completed a prior visit meeting all inclusion criteria. They then advance to SV2 or SV3. If the person is excluded because he exceeds the thirty day maximum period between visits, the person is counted as excluded at the next screening visit. For example, if an individual successfully completes SV1 and is consequently advanced to SV2 but fails to keep an appointment for SV2 within 30 days, he is counted as excluded at SV2.

f. The number randomized is based on all inclusion criteria met at SV3 by the screened participants and approved by the Study Chairman's Office and CSPCC. Regardless of when the SV3 was completed, the CSPCC registration date counts as the approved randomization for the site total.

g. Please call the Study Chairman's Office with questions about the completion of this weekly report.

FIGURE 29

PATHS RECRUITMENT WORKSHEET

For week ending: __ __ __ __ __ __

	BALTIMORE	JACKSON	NEW YORK	PHOENIX
PRESCREENING:				
No. Prescreened	__ __ __	__ __ __	__ __ __	__ __ __
Eligible SV1	__ __ __	__ __ __	__ __ __	__ __ __
Excluded < SV1	__ __ __	__ __ __	__ __ __	__ __ __
Scheduled SV1	__ __	__ __	__ __	__ __
SCREENING VISIT 1:				
Completed SV1	__ __	__ __	__ __	__ __
Excluded at SV1	__ __	__ __	__ __	__ __
Advanced to SV2	__ __	__ __	__ __	__ __
SCREENING VISIT 2:				
Completed SV2	__ __	__ __	__ __	__ __
Excluded at SV2	__ __	__ __	__ __	__ __
Advanced to SV3	__ __	__ __	__ __	__ __
SCREENING VISIT 3:				
Completed SV3	__ __	__ __	__ __	__ __
Excluded at SV3	__ __	__ __	__ __	__ __
Randomized	__ __	__ __	__ __	__ __

APPENDIX A

PATHS DIRECTORY

July 17, 1991

DIRECTORY

PREVENTION AND TREATMENT OF HYPERTENSION STUDY (PATHS)

VA-NHLBI-NIAAA Cooperative Study #996

List of Participants

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July 17, 1991

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APPENDIX B

RECRUITMENT LETTERS

Medical Center

First Avenue at East
24th Street
New York NY 10010

Department of
Veterans Affairs

In Reply Refer to: 630/11A/

Dear Veteran:

The New York VA Medical Center is participating in a large national study of factors which increase the risk of heart attack and stroke. We are currently looking for subjects for this study.

We would like to have you complete the following questionnaire, and return it to us as soon as possible in the enclosed envelope, so that we can determine if you might be a suitable participant in the study.

YOUR COMPLETION OF THIS QUESTIONNAIRE IS STRICTLY VOLUNTARY.

Any information you provide will be confidential.

Sincerely,

LOIS ANNE KATZ, M.D.
Associate Chief of Staff
for Ambulatory Care

Enclosure(s)

Medical Center

First Avenue at East
24th Street
New York NY 10010

Department of
Veterans Affairs

In Reply Refer to:

630/11A

Dear Veteran:

Thank you for filling out the VA Cooperative Study #996 questionaire on risk factors for heart disease and hypertension. After having reviewed your completed form, we have found that you may be eligible to participate in this study.

For further information regarding this study, and to schedule an appointment for a screening visit, please contact Rosalinda Ojeda or Lisa Szymanowicz at (212) 686-7500 Ext. 7567.

Thank you for your cooperation.

Sincerely,

LOIS ANNE KATZ, M.D.
Associate Chief of Staff
for Ambulatory Care

DEPARTMENT OF VETERANS AFFAIRS
Medical Center
1500 East Woodrow Wilson
Jackson MS 39216

April 8, 1991

In Reply Refer To:

Dear Veteran:

The Jackson Department of Veterans Affairs Medical Center is currently involved in a new research program, the Prevention and Treatment of Hypertension Study (PATHS). PATHS is a study of risk factors for the development of high blood pressure and diseases of the heart and is sponsored by the Department of Veterans Affairs and the National Institutes of Health.

Participants in PATHS will have their blood pressure checked on a regular basis. They will also have an electrocardiogram (EKG), a physical examination, and standard laboratory tests (blood and urine analyses). If any medical complications are detected, appropriate referrals will be made.

Veterans selected for this study will receive these services without cost. You do not have to have high blood pressure to be selected. If you are taking medication for your blood pressure, treatment will be provided by the study during the time you participate. To help defray expenses, participants will receive payments of $10.00 per visit beginning with the second scheduled screening visit.

If you are interested in learning more about this study, simply complete the enclosed pre-screening questionnaire and return it in the envelope provided. All information provided by you is confidential and will be seen only by the research staff. This form will not become a part of your permanent medical record. Should your responses indicate that you are eligible to participate further in the study, a PATHS representative will contact you to schedule an appointment. If you are not contacted within three weeks after sending your questionnaire, you can assume you are not eligible.

If you would like more information, please call 362-4471 and ask for extension 1495 (Karen Cooper) or extension 1436 (Rufus Rawls). Extension 1495 has an answer machine if you care to leave a message. We regret that we will not be able to see you to discuss the study without an appointment.

Thank you for your assistance in making this important study a success.

Sincerely,

Karen M Cooper

Karen M. Cooper, RN
Prevention and Treatment of Hypertension Study

Medical Center

3900 Loch Raven Blvd.
Baltimore MD 21218

Department of
Veterans Affairs

Dear Veteran,

In Reply Refer to:

The Department of Veterans Affairs is offering *FREE* Health Screenings to eligible male veterans as part of a Cooperative Study Program. The purpose of this study is to identify lifestyle factors related to high blood pressure and heart disease so that illnesses in veterans like yourself can potentially be prevented.

In order to participate in the free health screenings, you must be eligible. Your eligibility is determined by the lifestyle you report on the brief questionnaire which is enclosed. The program is particularly aimed at individuals with lifestyles that include increased levels of cholesterol or salt in the diet, excessive smoking or alcohol intake.

Depending on eligibility, the screening visits will consist of a detailed medical history, a physical examination, repeated blood and urine tests, and more... We will also be asking you questions about lifestyle, including your eating, drinking and exercise habits.

In addition to these benefits, you will receive *$10.00* per visit for each of the regular visits (with the exception of the first visit).

Enclosed is a brief questionnaire. Please take 5 minutes to complete the questionnaire and then return it in the stamped self-addressed envelope. We will contact you to tell you more about the research and ask you about your willingness to participate, if it is determined that you are eligible.

If you have any questions concerning the free health screenings or the research, please contact Mary Whittle or William Hatten at 467-9932, extension 5607 or 5608 for further information.

Sincerely,

Bruce P. Hamilton, M.D.

Carl T. Hayden
VA Medical Center

650 E. Indian School Road
Phoenix AZ 85012

Department of
Veterans Affairs

In Reply Refer to:

Dear Veteran:

The Phoenix VA Medical Center is participating in a large national study of factors which increase the risk of heart attack and stroke. We would like to have you complete the following questionnaire and return it to us as soon as possible in the enclosed envelope, so that we may determine if you might be a suitable participant in the study. YOUR COMPLETION OF THIS QUESTIONNAIRE IS STRICTLY VOLUNTARY.

If you have previously received this questionnaire, and have already returned it to us, it is not necessary to fill out another one. Please accept our thanks for having sent it in.

Thank you very much.

APPENDIX C

VA CIRCULAR 10-89-58

TELEGRAPHIC MESSAGE

NAME OF AGENCY	PRECEDENCE	SECURITY CLASSIFICATION
VACO WASHINGTON, DC	ACTION: P INFO:	
ACCOUNTING CLASSIFICATION	DATE PREPARED: 5/23/89	FILE
FOR INFORMATION CALL		
NAME: STUART E. MOUNT	PHONE NUMBER: 373-2143	TYPE OF MESSAGE: ☐ SINGLE ☐ BOOK ☒ MULTIPLE-ADDRESS

THIS SPACE FOR USE OF COMMUNICATION UNIT

MESSAGE TO BE TRANSMITTED (*Use double spacing and all capital letters*)

TO: DIRECTORS, ALVAMC, ALVAMDD, ALVAOPC, AND REGIONAL OFFICES WITH OUTPATIENTS CLINICS (REGIONAL DIRECTORS)

00/136 THIS IS VHS&RA CIRCULAR 10-89-58 (DTD: 6/13/89)

SUBJ: MEDICAL CARE FOR CATEGORY B AND C PATIENTS AND NON-VETERAN CONTROL PATIENTS

1. PURPOSE: THE 1989 BUDGET POLICY ESTABLISHED AN OBJECTIVE OF REGIONAL EQUITY OF ACCESS TO CARE. THIS POLICY WAS DRIVEN BY THE NEED TO CONSTRAIN TOTAL WORKLOADS TO AVAILABLE LEVELS OF FUNDING WHILE STRIVING FOR REGIONAL EQUITY OF ACCESS. BECAUSE OF CONTINUING BUDGET CONSTRAINTS AND IN ATTEMPTING TO COMPLY WITH THE EQUITY OF ACCESS BUDGET POLICY, MANY MEDICAL CENTERS HAVE BEEN REVIEWING PATIENT ELIGIBILITY AND HAVE CUT BACK ON DISCRETIONARY WORKLOAD, PARTICULARLY INPATIENT AND OUTPATIENT SERVICES FOR CATEGORY B AND C PATIENTS. THIS POLICY HAS CREATED DIFFICULTIES IN RELATION TO CERTAIN CONTRACTUAL AND OTHER OBLIGATIONS.

SECURITY CLASSIFICATION	PAGE NO	NO. OF PGS
	1	5

TELEGRAPHIC MESSAGE

NAME OF AGENCY	PRECEDENCE ACTION	SECURITY CLASSIFICATION
ACCOUNTING CLASSIFICATION	DATE PREPARED	FILE
FOR INFORMATION CALL		
NAME	PHONE NUMBER	TYPE OF MESSAGE ☐ SINGLE ☐ BOOK ☐ MULTIPLE ADDRESS

THIS SPACE FOR USE OF COMMUNICATION UNIT

MESSAGE TO BE TRANSMITTED (Use double spacing and all capital letters)

TO:

THIS HAS BEEN PARTICULARLY TRUE OF PARTICIPANTS IN RESEARCH PROJECTS. THE PURPOSE OF THIS COMMUNICATION IS TO CLARIFY AND REDEFINE WORKLOAD OF PATIENTS WHO ARE NOT WITHIN CATEGORY "A" BUT WHOSE CARE WILL NOT BE SUBJECT TO REDUCTION ARISING FROM THE REGIONAL EQUITY OF ACCESS TO CARE POLICY. THIS CIRCULAR WILL NOT BE INCORPORATED INTO A MANUAL.

2. POLICY:

A. THE FOLLOWING VETERANS AND NON-VETERANS ARE TO BE PROVIDED MEDICAL CARE OR TREATMENT ON A DISCRETIONARY WORKLOAD BASIS FOR:

(1) OUTPATIENT CARE - CATEGORY B AND C AND NON-VETERANS.

(2) INPATIENT CARE - CATEGORY C AND NON-VETERANS.

B. THE FOLLOWING VETERANS ARE TO BE PROVIDED MEDICAL CARE OR TREATMENT ON A NON-DISCRETIONARY WORKLOAD BASIS: (THESE VETERANS

SECURITY CLASSIFICATION		
	PAGE NO 2	NO. OF PGS 5

TELEGRAPHIC MESSAGE

NAME OF AGENCY	PRECEDENCE ACTION INFO	SECURITY CLASSIFICATION
ACCOUNTING CLASSIFICATION	DATE PREPARED	FILE
FOR INFORMATION CALL		
NAME	PHONE NUMBER	TYPE OF MESSAGE ☐ SINGLE ☐ BOOK ☐ MULTIPLE ADDRESS
THIS SPACE FOR USE OF COMMUNICATION UNIT		

MESSAGE TO BE TRANSMITTED *(Use double spacing and all capital letters)*

TO:

ARE NOT TO BE COUNTED IN THE DISCRETIONARY TOTALS LISTED IN A (1) & (2) ABOVE.)

(1) PATIENTS PROVIDED MEDICAL CARE OR TREATMENT NECESSARY TO THE CONDUCT OF RESEARCH STUDIES IN DESIGNATED CATEGORIES OF RESEARCH. THIS APPLIES TO PARTICIPANTS IN ANY OF THE FOLLOWING CATEGORIES OF RESEARCH EFFORTS:

(A) VA FUNDED COOPERATIVE STUDIES, MERIT REVIEWS AND CAREER DEVELOPMENT PROGRAMS.

(B) VA-SUPPORTED CLINICAL RESEARCH CENTER PROJECTS. RESEARCH CENTERS INCLUDE SCHIZOPHRENIA CENTERS, CLINICAL ALCOHOLISM CENTERS AND GRECCS.

(C) NATIONAL INSTITUTES OF HEALTH OR ALCOHOL DRUG AND MENTAL HEALTH ADMINISTRATION SUPPORTED CLINICAL RESEARCH CENTER PROJECTS.

(2) PATIENTS PROVIDED CARE UNDER APPROVED SHARING AGREEMENTS. THIS APPLIES TO SHARING WORKLOAD THAT IS REIMBURSED BY A SHARING PARTNER. THIS INCLUDES THOSE AGREEMENTS AUTHORIZED UNDER THE PROVISIONS OF PUB.L. 97-174, EXCHANGE OF USE AND

SECURITY CLASSIFICATION		
	PAGE NO	NO OF PGS
	3	5

TELEGRAPHIC MESSAGE

NAME OF AGENCY	PRECEDENCE ACTION INFO.	SECURITY CLASSIFICATION
ACCOUNTING CLASSIFICATION	DATE PREPARED	FILE
FOR INFORMATION CALL		
NAME	PHONE NUMBER	TYPE OF MESSAGE ☐ SINGLE ☐ BOOK ☐ MULTIPLE-ADDRESS
THIS SPACE FOR USE OF COMMUNICATION UNIT		

MESSAGE TO BE TRANSMITTED *(Use double spacing and all capital letters)*

TO: SPECIALIZED MEDICAL RESOURCE USE AGREEMENTS. SHARING WORKLOAD SHOULD NOT BE INCLUDED IN OFFICIAL RESOURCE ALLOCATION MODEL WORKLOAD COUNTS.

(3) EMPLOYEE HEALTH AND COLLATERAL VISITS. COLLATERAL VISITS ARE EXPLICITLY DISCRETIONARY FOR OPT-NSC CARE.

(4) EMERGENCY HUMANITARIAN NON-VETERAN PATIENT CARE.

(5) HEALTH CARE SERVICE PROVIDED BY AGREEMENT TO ASMRO (ARMED SERVICES MEDICAL REGULATING OFFICE) ACTIVE DUTY REFERRALS.

(6) VETERANS ON WHOM A MEANS TEST WAS NOT DONE BECAUSE OF A MEDICAL CONDITION.

(7) OUTPATIENT CARE FOR DOMICILIARY PATIENTS. SICK CALL VISITS SHOULD NOT BE COUNTED AS OUTPATIENT VISITS.

(8) ALL 10-10 EXAMS ARE TO BE CONSIDERED MANDATORY.

SECURITY CLASSIFICATION		
PAGE NO.	NO. OF PGS	
4	5	

TELEGRAPHIC MESSAGE

NAME OF AGENCY	PRECEDENCE ACTION INFO	SECURITY CLASSIFICATION
ACCOUNTING CLASSIFICATION	DATE PREPARED	FILE
FOR INFORMATION CALL NAME	PHONE NUMBER	TYPE OF MESSAGE ☐ SINGLE ☐ BOOK ☐ MULTIPLE ADDRESS

THIS SPACE FOR USE OF COMMUNICATION UNIT

MESSAGE TO BE TRANSMITTED *(Use double spacing and all capital letters)*

TO:

(9) ALL ALLIED BENEFICIARIES ARE CONSIDERED MANDATORY.

ASMRO ARE CONSIDERED MANDATORY.

3. ACTION: THE FACILITY DIRECTOR SHALL DEVELOP AND IMPLEMENT PROCEDURES TO ASSURE THAT ALL AFFECTED PATIENTS ARE IDENTIFIED AND PROCESSED IN ACCORDANCE WITH THE POLICY STATED IN PARAGRAPH 2.

4. REFERENCES: NONE

5. RESCISSIONS: THIS VHS&RA CIRCULAR WILL BE RESCINDED ON MAY 31, 1990. THIS VHS&RA CIRCULAR WILL NOT BE CONFIRMED BY PRINTED ISSUE.

6. FOLLOW-UP RESPONSIBILITY: DIRECTOR OF ADMINISTRATION. 136F

John A Gronvall, M.D.

DISTRIBUTION: COA: (10) only
SS (136F) FLD: 200-2
EX: Boxes 44-6 & 88-2, Boxes 104, 60, 54 & 52-1 each and 63-5

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	PAGE NO 5	NO OF PGS 5

STANDARD FORM 14
REVISED 11-80
GSA FPMR (41 CFR) 101-35.306
Previous editions usable NSN 7540-00-634-3966

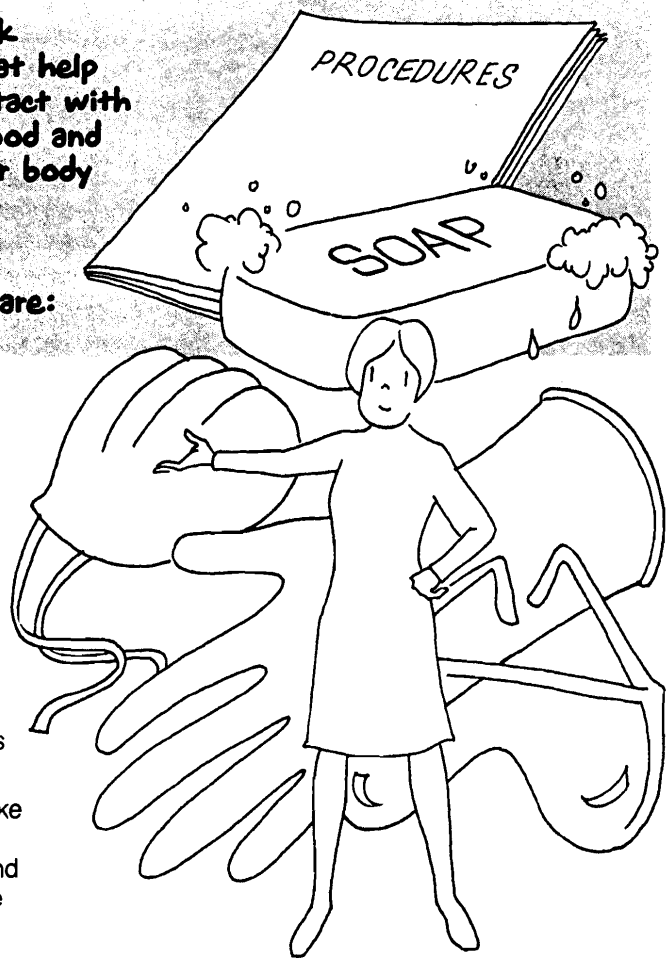
APPENDIX D

UNIVERSAL PRECAUTIONS

WHAT ARE UNIVERSAL PRECAUTIONS?

They're work practices that help prevent contact with patients' blood and certain other body fluids.

Universal precautions are:



YOUR BEST PROTECTION
against AIDS, hepatitis B and some other infectious diseases.

RECOMMENDED FOR USE WITH ALL PATIENTS,
since it's not always possible to tell who is infected.

These precautions take the guesswork out of protecting yourself and others as you provide essential health care.

NOTE: This booklet is not a substitute for federal, state or your employer's infection control guidelines.

A SCRIPTOGRAPHIC BOOKLET by CHANNING L. BETE CO., INC., South Deerfield, MA 01373 U.S.A.

Lithographed in U.S.A. 1990 Edition 37671A-12-89
To reorder phone 800-628-7733 and request booklet number 37671.

WHY SHOULD I KNOW ABOUT THEM?

Because universal precautions are a key part of infection control. They help protect:

HEALTH-CARE WORKERS AND STAFF,
including physicians, dentists, nurses, nursing assistants, laboratory workers, housekeeping and maintenance personnel, and everyone else on the health-care team.

PATIENTS
and their families, who depend on you to prevent the spread of infectious diseases.

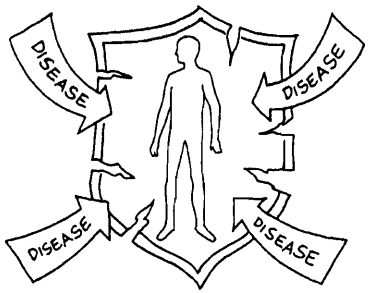
Universal precautions can help prevent illness and save lives -- including your own!

HOW UNIVERSAL PRECAUTIONS WORK

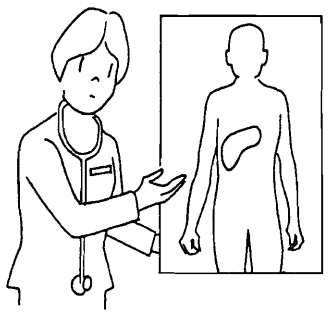
CERTAIN INFECTIOUS DISEASES ARE CAUSED

by viruses. For example:

- AIDS is caused by a virus called HIV (Human Immunodeficiency Virus), which attacks the body's natural defense against disease.



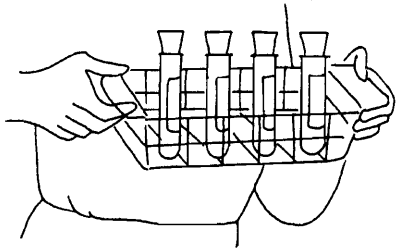
- Hepatitis B is caused by a virus called HBV (Hepatitis B Virus), which attacks the liver, and can result in severe illness – even death.



HIV, HBV AND SOME OTHER GERMS ARE SPREAD

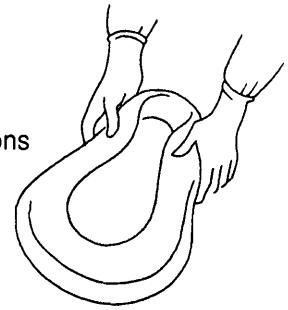
through certain body fluids, including:

- blood (or any fluid containing visible blood)
- semen
- vaginal secretions
- certain other fluids – amniotic, pericardial, peritoneal, pleural, synovial, and cerebrospinal.



Other body fluids may contain a small amount of HIV or HBV. But transmission of HIV or HBV has not been documented through any of these fluids, including:

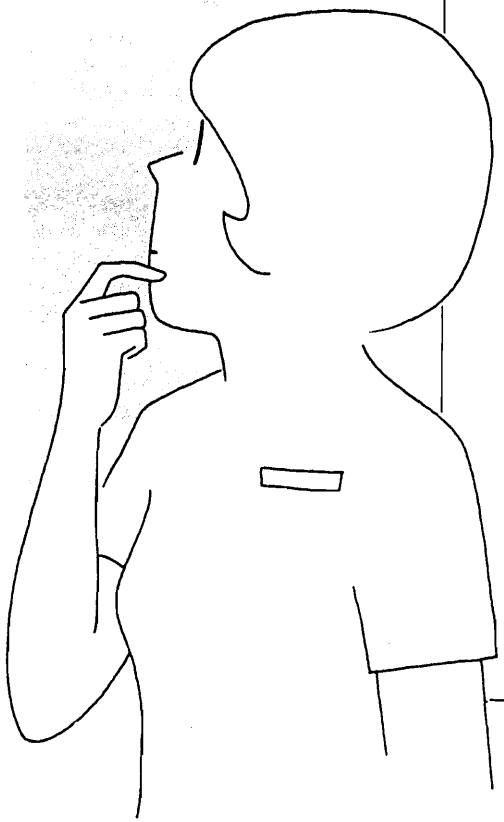
- tears
- saliva
- feces
- nasal secretions
- sputum
- sweat
- urine
- vomit.



HEALTH-CARE WORKERS AND STAFF CAN BECOME INFECTED

if infected blood or body fluids enter their body through:

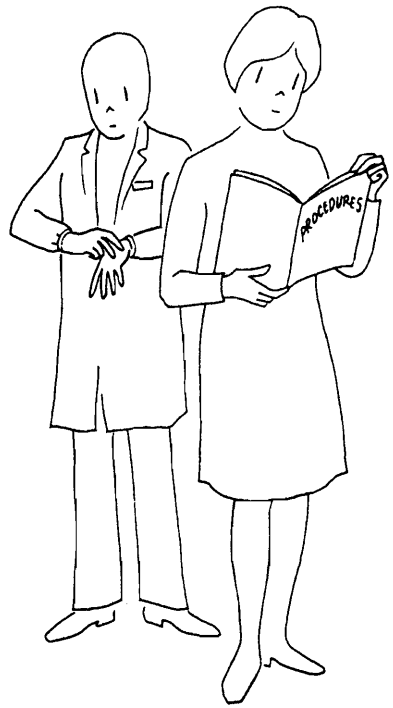
- a needlestick injury
- a cut or break in the skin
- mucous membranes (mouth, nose, eyes).



UNIVERSAL PRECAUTIONS HELP PREVENT INFECTION

through the use of:

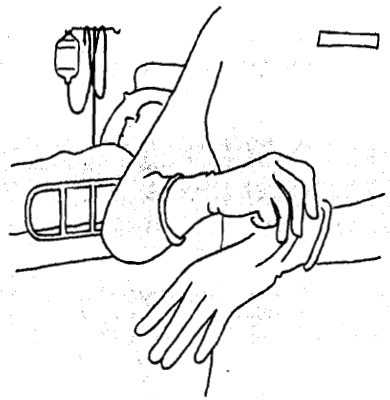
- protective barriers, such as gloves, gowns, masks, and protective goggles
- safe work practices, such as proper disposal of needles.



Learn more . . .

TAKE STEPS TO PROTECT YOURSELF

The effectiveness of universal precautions depends on you!



WEAR GLOVES

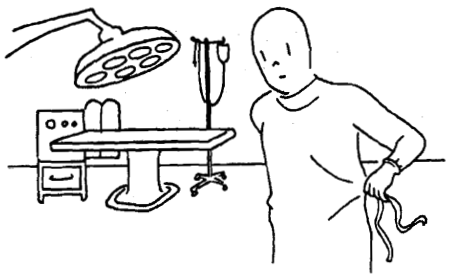
any time contact with blood or other infectious body fluids may occur. For example:

- when touching any mucous membranes or broken skin
- when handling items or surfaces soiled with blood or other infectious body fluids
- when doing venipuncture (unless your supervisor allows otherwise in some situations).

Change gloves if they're torn, and after contact with each patient. Do not reuse disposable gloves.

USE MASKS AND EYE PROTECTION

or protective face shields if there's any chance that blood or other infectious fluids may splash into your mouth, nose or eyes.



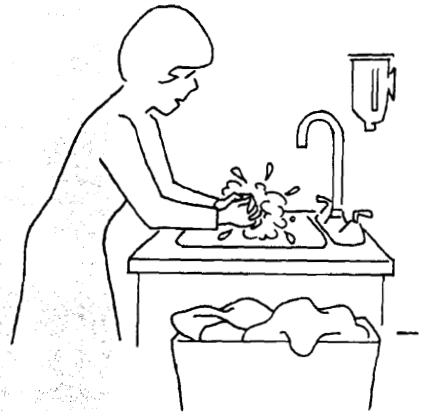
WEAR A GOWN

or apron if splashing of blood or other infectious fluids is likely.

WASH YOUR HANDS

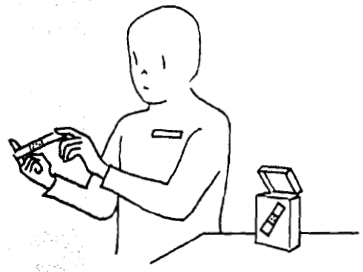
and other skin surfaces immediately after:

- direct contact with blood or other body fluids (without gloves, mask, etc.)
- removing gloves, gown or other protective clothing.
- handling potentially contaminated items.



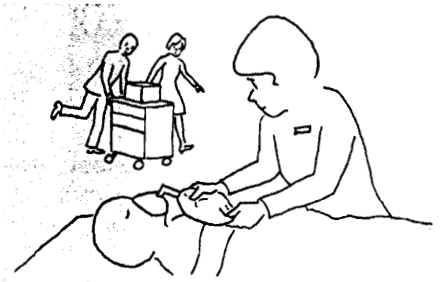
COVER OPEN WOUNDS

and broken skin. Also, refrain from all direct patient care and from handling patient-care equipment, if you have weeping dermatitis or sores with a discharge (unless you wear gloves and have your supervisor's OK).



USE RESUSCITATION BAGS,

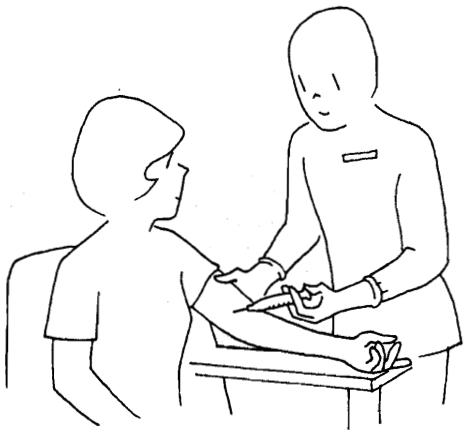
mouthpieces, or other devices, whenever possible, for mouth-to-mouth breathing.

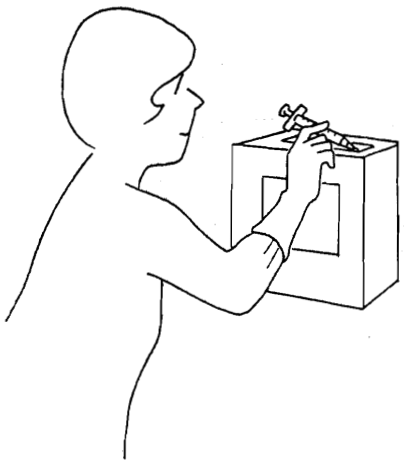


MORE STEPS TO PROTECT YOURSELF

USE SHARPS SAFELY

Stay alert, and always follow proper procedures when handling, using or disposing of sharps. Remember, gloves do not protect against injuries from sharps.





DISPOSE OF SHARPS PROPERLY

Do not recap, bend or break needles after use. Deposit a used sharp in a puncture-resistant container immediately after use. Report any container that is full.

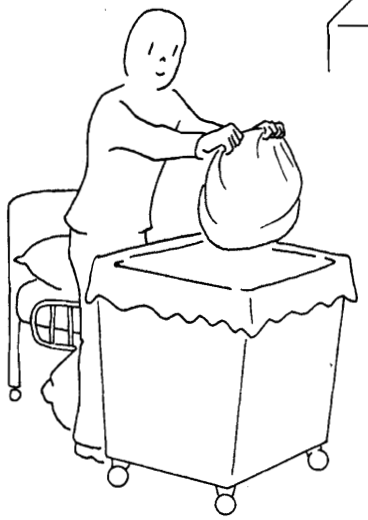
USE DISPOSABLE EQUIPMENT WHENEVER POSSIBLE

Use needles, syringes and other equipment designed to be discarded after one use.

If equipment is to be reused, sterilize or disinfect it (or label it properly) according to your facility's procedures.

CLEAN UP SPILLS PROMPTLY

Always use an approved disinfectant. Also, clean your work surface anytime it's contaminated with blood or body fluids, and after you've completed your work.



TAKE CARE OF SOILED LINEN

Follow your facility's procedures for processing soiled linen. Bag soiled linen, keeping it at arm's length, where it was used. Don't sort or rinse linen in patient-care areas.

DISPOSE OF INFECTIOUS WASTE CAREFULLY

Always follow your facility's recommended procedures.

OTHER SAFEGUARDS

DON'T REACH BLINDLY

into a waste container. If you must look through the trash, dump it out and search with your eyes. Handle laundry with care – it could contain a sharp instrument dropped by mistake.

HANDLE, LABEL AND PACKAGE SPECIMENS CAREFULLY

according to procedures recommended at your facility. Use an approved disinfectant for any spills. Treat every specimen of blood or body fluids as infectious.

GET HELP WITH UNCOOPERATIVE PATIENTS

to prevent accidents. It only takes a slight movement to endanger yourself or the patient.

ASK QUESTIONS

if there's anything you don't understand, and always follow safety procedures. They're designed for your protection!

WHAT TO DO IF YOU'RE EXPOSED

to blood or other infectious fluids

WASH THE EXPOSED AREA IMMEDIATELY

Save any sharps or other items involved for possible testing.

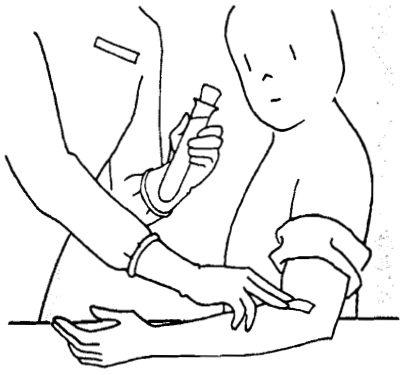
REPORT THE INCIDENT

Be sure to report:

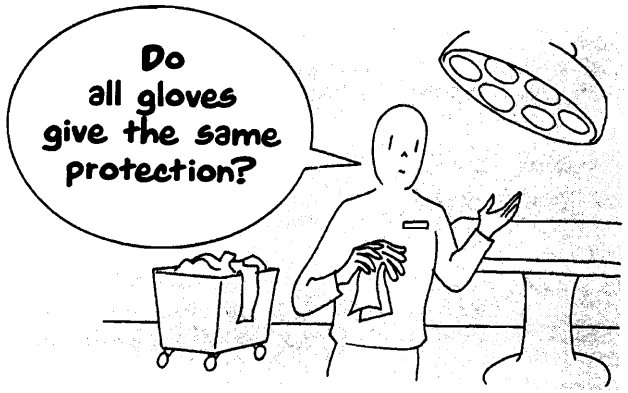
- a needlestick injury or other cut or puncture
- splashing of blood or other body fluids into your mouth, eyes or nose
- direct contact with a large amount of blood or other infectious fluids
- prolonged contact with blood or other infectious fluids.

FOLLOW PROCEDURES FOR TESTING AND TREATMENT

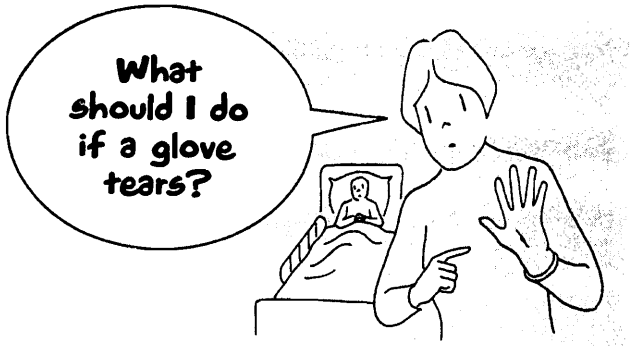
If you've been exposed to HBV, you may be given immune globulin and/or hepatitis B vaccine to help prevent infection.



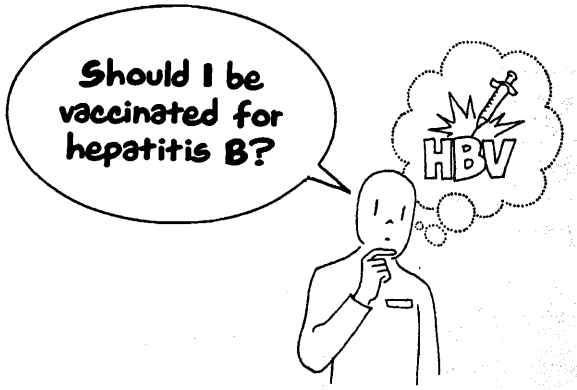
SOME QUESTIONS AND ANSWERS



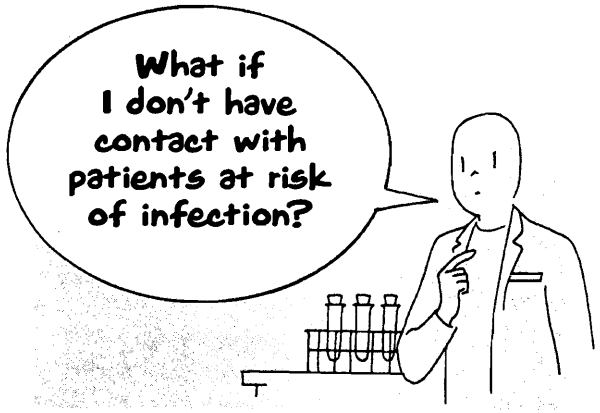
Surgical and examination gloves of vinyl and latex offer the same protection. Use heavier, utility gloves for housekeeping or other chores.



Remove the glove, wash your hands, and replace the glove with a new one as soon as patient safety permits.



Yes, if your job regularly involves exposure to blood or body fluids covered by universal precautions.



All patients are considered possibly infected. If you have any contact with blood or other infectious fluids, use universal precautions.

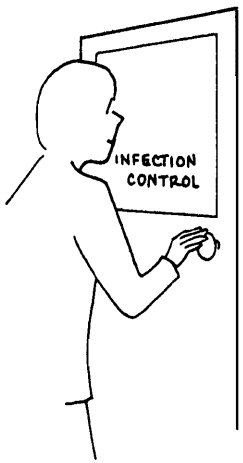
Always take time to protect yourself before providing patient care. In most instances, you can predict possible exposure to blood and other body fluids.

Gloves should be used to prevent contact with blood, saliva, and gingival fluid of all patients. Masks and eyewear or face shields should be used if splashing or spattering is likely.

FOR MORE INFORMATION, contact:

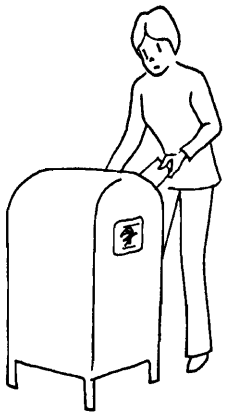
YOUR FACILITY INFECTION CONTROL DEPARTMENT

– ask your supervisor for the phone or room number.



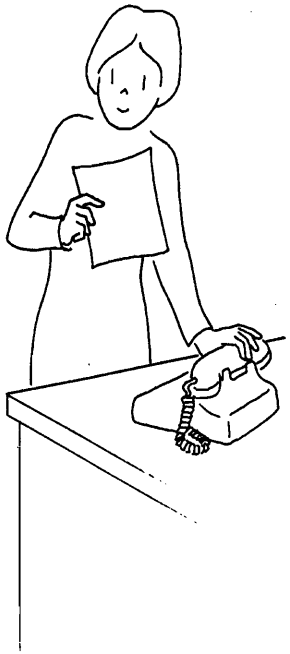
THE OCCUPATIONAL SAFETY AND HEALTH ADMINISTRATION (OSHA)

– check your phone book for the nearest regional or state office. Or, write to:
Occupational Safety and Health Administration
Dept. of Labor
200 Constitution Ave., N.W.
Washington, DC 20210



THE U.S. PUBLIC HEALTH SERVICE NATIONAL AIDS HOTLINE

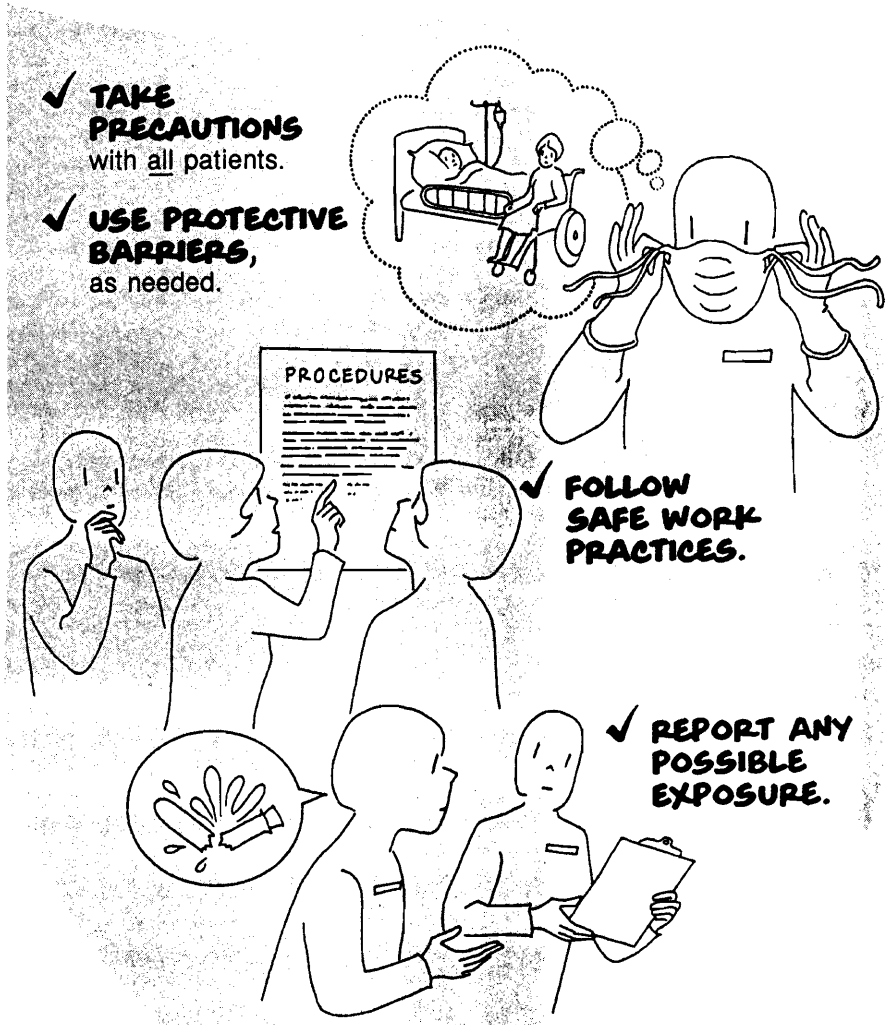
– 1-800-342-AIDS.



It pays to be informed. You can relax and concentrate on doing your job well if you're taking steps to protect yourself and others.

Soo--

UNIVERSAL PRECAUTIONS HELP PREVENT DISEASE!



Take the time to protect yourself -- your health depends on it!

APPENDIX E

DRUG CODES

CODE	NAME
AEJ	2-G®
CBA	5-FU®
XDA	7-Dehydrocholesterol, Activated
QAG	A-hydroCort®
QEA	A.P.L.®
KAJ	Abbokinase®
■ GGH	Acebutolol
FCA	Acenocoumarol
HCC	Acetaminophen
HCE	Acetaminophen-Diphenhydramine
HAP	Acetaminophen-Oxycodone
MFA	Acetazolamide
MSA	Acetic Acid & Sodium Acetate Ointment
JIA	Acetic Acid Irrigation Solution
MMA	Acetic Acid Lotion
QFA	Acetohexamide
■ HFA	Acetophenazine
MIA	Acetylcholine
AEA	Acetylcysteine
GAA	Acetyldigitoxin
BHG	Achromycin V® (Oral, Injection)
MAG	Achromycin® (Topical, Ophthalmic)
BCE	Achrostatin V®
NEC	Acidulin®
MCA	Acrisorcin
QKQ	Acthar®
QKQ	ACTH®
AAS	Actidil®
ABA	Actifed®
KAK	Activase®
BKC	Acyclovir (Injection)
BKO	Acyclovir (Oral)
MBD	Acyclovir (Topical)
■ HED	Adapin®
YAA	Adenosine
DBA	Adiphenine
DDD	Adrenalin®
CCC	Adriamycin®
HBB	Advil®
MGC	Afrin®
MCO	Aftate®
NDJ	Agoral®
DBF	Akineton®
BKK	AL-721
BII	Albamycin®
EAA	Albumin, Normal Human Serum
DDA	Albuterol
MHI	Alcaine®
IJA	Alcohol [Gastric Function]
■ JHV	Aldactazide®
■ JHP	Aldactone®
■ GCJ	Aldomet®
AES	Alevaire®
NAK	Alginic Acid/Sodium Bicarbonate/Magnesium Trisilicate
NAO	Alka-Seltzer®
MKA	Alkaline Aromatic Solution (Baking Powder/H2O Gargle)
CAH	Alkeran®
XBL	Allbee with C®
ABB	Allerest®
JJC	Allopurinol
MLA	Alpha Chymar®
MRI	Alpha-Keri Bath Oil
QAF	Alphadrol®
HAA	Alphaprodine
HGU	Alprazolam

CODE	NAME
KAK	Alteplase Recombinant
NAA	Alternagel®
NAA	Alucaps®
MMB	Aluminum Acetate & Subacetate
NAA	Aluminum Hydroxide
NAP	Aluminum Hydroxide-Magnesium Carbonate
MSB	Aluminum Paste
NAB	Aluminum Phosphate Suspension
DDJ	Alupent®
DBB	Alverine
BKA	Amantadine
DAA	Ambenonium
MES	Amcinonide
BGU	Amdinocillin
MHB	Americaine®
FEA	Amicar®
HJZ	Amidate®
BIA	Amikacin
BIA	Amikin®
■ JHZ	Amiloride
■ JHX	Amiloride & HCTZ
JIB	Aminoacetic Acid
FEA	Aminocaproic Acid
DDQ	Aminophylline
BJA	Aminosalicylic Acid
GHA	Amiodarone
■ HEA	Amitriptyline
■ GII	Amlodipine
HIA	Ammonia, Aromatic Spirit
JAA	Ammonium Chloride
HJA	Amobarbital
■ HEN	Amoxapine
BGA	Amoxicillin
BGS	Amoxicillin/Clavulanate
BGA	Amoxil®
■ HIB	Amphetamine
NAA	Amphojel®
BCA	Amphotericin B (Injection)
MCB	Amphotericin B (Topical)
BGR	Ampicillin (Injection)
BGB	Ampicillin (Oral)
BGV	Ampicillin/Sulbactam
BKR	Ampligen
GAI	Amrinone
■ GDP	Amyl Nitrate
KAA	Amylase, Alpha
HJA	Amytal®
HCA	Anacin
QBI	Anadrol®
HBE	Anaprox®
QBH	Anavar®
MHB	Anbesol®
BDA	Ancef®
BCB	Ancobon®
QBF	Android®
DFP	Anectine®
■ JHE	Anhydron®
FCB	Anisindione
DBC	Anisotropine
KAL	Anistreplase
HBG	Ansaid®
BKI	Ansamycin
BDG	Anspor®
YHA	Antabuse®
BBD	Antepar®

CODE	NAME
MUA	Anthralin
FEB	Antihemophilic Factor, Human
DAD	Antilirium®
BBE	Antiminth®
UAA	Antirabies Serum
MKB	Antiseptic Solution
UAB	Antivenin, Spider-Bite
NFG	Antivert®
DBU	Antrenyl®
JJB	Anturane®
NIA	Anusol
NIE	Anusol-HC
HCB	APC®
NFA	Apomorphine
HGB	Apoxide®
■ GCU	Apresoline® (Injection)
KAL	APSAC
■ GCH	Apresoline® (Oral)
HJB	Aprobarbital
XFB	Aqua-Mephyton®
MSV	Aquaphor
XAA	Aquasol A®
XEA	Aquasol E®
BLB	Aralen®
GFF	Aramine®
■ GCR	Arfonad®
IUA	Arginine [Pituitary Function]
QAM	Aristocort® (Oral, Injection)
MEI	Aristocort® (Topical)
GDH	Arlidin®
DCC	Artane®
HCD	Arthropan
MLE	Artificial Tears
HAO	Ascodeen®
XCA	Ascorbic Acid
HCA	Ascriptin
■ HEN	Asendin®
HCA	Aspirin
HCA	Aspirin, Buffered
HCB	Aspirin/Salicylamide/Caffeine
AAF	Astemizole
BBG	Atabrine®
HGS	Atarax®
■ GGA	Atenolol
HGE	Ativan®
DFS	Atracurium Besylate
GBC	Atromid S®
DBD	Atropine (Injection, Inhalation)
MJA	Atropine (Ophthalmic)
DCD	Atrovent®
BGS	Augmentin®
OAB	Auranofin
BHH	Aureomycin®
■ HEG	Aventyl®
BNA	Avlosulfon®
NHG	Axid®
MWA	Axsain®
BIW	Azactam®
AAT	Azatadine
CDA	Azathioprine
BGN	Azlin®
BGN	Azlocillin
QAM	Azmacort®
BKD	AZT
BIW	Aztreonam

CODE	NAME
BMN	Azulfidine®
HCB	B C Powder®
NBD	Bacid®
BIB	Bacitracin (Injection)
MAA	Bacitracin (Ophthalmic, Topical)
DFR	Baclofen
BRC	Bactrim®
MAM	Bactroban Ointment®
PBA	BAL®
DBQ	Banthine®
IVA	Barium Sulfate
NAA	Basaljel®
ADA	Bayer Decongestant®
UCA	BCG Vaccine
QAN	Beclomethasone (Inhalation)
MER	Beclomethasone (Nasal)
QAN	Beclovent®
DBD	Belladonna Alkaloids
■ HEB	Benactyzine/Meprobamate
AAI	Benadryl®
■ JHA	Bendroflumethiazide
JJA	Benemid®
MHA	Benoxinate
MSC	Bentonite Topical
DBI	Bentyl®
AAI	Benylin®
MDA	Benzalkonium Chloride
MPA	Benzene Hexachloride, Gamma
■ GJC	Benzepril HCl
MHB	Benzocaine
MCC	Benzoic Acid/Salicylic Acids
MSD	Benzoin
AEC	Benzonatate
MTG	Benzoyl Peroxide
HIC	Benzphetamine
NFB	Benzquinamide
■ JHB	Benzthiazide
DBE	Benztropine
MPB	Benzyl Benzoate
IHA	Benzylpenicilloyl-Polylysine [Drug Hypersensitivity]
■ GIF	Bepridil
XBM	Berocca®
DDF	Berotec®
MSE	Beta-Carotene
MDU	Betadine Preparations
■ MLK	Betagan®
XBJ	Betalin®
QAA	Betamethasone (Oral, Injection)
MEB	Betamethasone (Topical)
QAH	Betapar®
■ MLI	Betaxolol (Ophthalmic)
■ GGL	Betaxolol (Oral)
UB	Betazole [Gastric Function]
DAB	Bethanechol®
■ MLI	Betoptic®
BFB	Biaxin®
JBB	Bicitra®
CAC	BiCNU®
IYA	Bilazo Reagent - [Bilirubin]
DBF	Biperiden
NDA	Bisacodyl
NBA	Bismuth Subcarbonate
DDS	Bitolterol
CCA	Blenoxane®
CCA	Bleomycin

CODE	NAME
■ GGC	Blocadren®
NFG	Bonine®
MDB	Boric Acid
ABD	Breacol®
DDP	Brethine®
GHF	Bretylium Tosylate
GHF	Bretylol®
■ GGI	Brevibloc®
HJM	Brevital®
DDP	Bricanyl®
KAB	Bromelain
HDA	Bromides
HLA	Bromocriptine
AAG	Bromodiphenhydramine HCl
IYC	Bromophenol Blue Reagent [Protein]
AAA	Brompheniramine
DDQ	Brondecon®
DDE	Bronkephrine®
DDG	Bronkometer®
DDG	Bronkosol®
■ HFB	Buclizine
■ JLA	Bumetanide
■ JLA	Bumex®
MHL	Bupivacaine
HMC	Buprenorphine
HMC	Buprenex®
■ HEQ	Bupropion
HGW	BuSpar®
HGW	Buspirone
CAA	Busulfan
HJC	Butabarbital
MHC	Butacaine
HCB	Butalbital/Aspirin/Caffeine
■ HFC	Butaperazine
HBH	Butazolidin®
HAZ	Butorphanol
MHC	Butyn®
DEA	Cafergot®
HID	Caffeine
MQA	Calamine
■ GIC	Calan®
XDA	Calciferol
QKA	Calcimar®
QKA	Calcitonin
XDB	Calcitriol
NAC	Calcium Carbonate
AED	Calcium Iodide
XBB	Calcium Panthothenate
JDA	Calcium Salts
CAB	Calusterone
MHP	Camphor/Menthol/Phenol
MCD	Candicidin
DBP	Cantil®
BJB	Capastat®
MDX	Capitrol®
■ GCB	Capoten®
BJB	Capreomycin
MWA	Capsaicin
■ GCB	Captopril
NAQ	Carafate®
MIB	Carbachol
■ HDB	Carbamazepine
BAA	Carbarsone
FEC	Carbazochrome
BGC	Carbenicillin

CODE	NAME
AEE	Carbetapentane
AAB	Carbinoxamine
MHM	Carbocaine®
MCE	Carbol-Fuchsin
MFC	Cardase®
■ GID	Cardene®
■ GIA	Cardizem®
■ GJA	Cardura®
DFA	Carisoprodol
CAC	Carmustine
■ HFD	Carphenazine
HBZ	Carprofen
■ GGJ	Carteolol
■ GGJ	Cartrol®
■ GGM	Carvedilol
NDB	Cascara
NDC	Castor Oil
■ GCC	Catapres®
KAC	Catarase®
CAF	CCNU®
BDK	Ceclor®
GAB	Cedilanid-D®
CAF	CeeNu®
BDK	Cefaclor
BDJ	Cefadroxil
BDF	Cefadyl®
BDI	Cefamandole
BDA	Cefazolin
BDV	Cefixime
BDR	Cefizox®
BDN	Cefobid®
BDT	Cefonicid
BDN	Cefoperazone
BDQ	Ceforanide
BDU	Cefotan®
BDL	Cefotaxime
BDU	Cefotetan
BDH	Cefoxitin
BDW	Cefprozil
BDP	Ceftazidime
BDO	Ceftin®
BDR	Ceftizoxime
BDS	Ceftriaxone
BDO	Cefuroxime
BDW	Cefzil®
QAA	Celestone®
FED	Cellulose, Oxidized
HDJ	Celontin®
HGV	Centrax®
MDI	Cepacol (Lozenges)
MKC	Cepacol (Mouthwash)
BDB	Cephalexin
BDC	Cephaloglycin
BDD	Cephaloridine
BDE	Cephalothin
BDF	Cephapirin
BDG	Cephradine
JCA	Cephulac®
GDI	Cerespan®
MLH	Cerumenex Drops
MDI	Cetylpyridinium (Lozenges)
MKC	Cetylpyridinium (Mouthwash)
XCA	Cevalin®
NAD	Charcoal, Activated
NAD	Charcocaps®

CODE	NAME
NAD	Charcodote®
IFC	Chemstrip bG Strips®
NHC	Chenix®
NHC	Chenodeoxycholic Acid
NHC	Chenodiol
AEG	Cheracol®
AEF	Chlopedianol
ABE	Chlor-Trimeton®
HJD	Chloral Hydrate
CAD	Chlorambucil
MAB	Chloramphenicol (Ophthalmic, Otic, Topical)
BIS	Chloramphenicol (Oral, Injection)
MHB	Chloraseptic
HGA	Chlorazepate
AAC	Chlorcyclizine
HGB	Chlordiazepoxide
HGL	Chlordiazepoxide/Clidinium
MDW	Chlorhexidine
MDJ	Chlorhydroxyquinolin/Diiodohydroxyquin/Iodochlorhydroxyquin
TAA	Chlormerodrin Hg 197
TAB	Chlormerodrin Hg 203
HGR	Chlormezanone
BIS	Chloromycetin® (Oral, Injection)
MNA	Chlorophyll Derivatives, Water Soluable
MHS	Chloroprocaine HCI
BLB	Chloroquine
■ JHC	Chlorothiazide
QDA	Chlorotrianisene
MDX	Chloroxine
DFB	Chlorphenesin
AAD	Chlorpheniramine/Dexchlorpheniramine
ABW	Chlorpheniramine/Phenylpropanolamine/Guaifenesin
DBG	Chlorphenoxamine
HIE	Chlorphentermine
■ HFG	Chlorpromazine
QFB	Chlorpropamide
■ HFF	Chlorprothixene
BHH	Chlortetracycline
■ JHD	Chlorthalidone
DFC	Chlorzoxazone
DDQ	Choledyl®
UCB	Cholera Vaccine
GBB	Cholestyramine
NGA	Choline
HCD	Choline/Magnesium Trisalicylate
HCD	Choline Salicylate
GBE	Choloxin®
QEA	Chorionic Gonadotropin/Menotropins
JCA	Chronulac®
MUB	Chrysarobin
KAC	Chymotrypsin
GHL	Cibenzoline
■ GCX	Cilazapril (Investigatonal)
NHA	Cimetidine
BQG	Cinobac®
BQG	Cinoxacin
BQI	Ciprofloxacin
BQI	Cipro®
CDO	Cisplatin
XBE	Citrovorum Factor
BDL	Claforan®
BFB	Clarithromycin
ABV	Clemastine fumarate/phenylpropanolamine HC1
BIC	Cleocin®
BIC	Clindamycin
HGL	Clindex®
HBU	Clinoril®
HGL	Clinoxide®
MDJ	Clioquinol
HGL	Clipoxide®
BNC	Clofazimine
GBC	Clofibrate
QDH	Clomid®
QDH	Clomiphene
HDC	Clonazepam
■ GCC	Clonidine
■ GCC	Clonidine-Chlorthalidone
HDC	Clonopin®
DDB	Clopane®
MCG	Clotrimazole
MCS	Clotrimazole/betamethasone
BGE	Cloxacillin
KAN	Co-enzyme 10
KAN	Co-Q 10®
ABH	Co-Tylenol®
BGU	Coactin®
MVA	Coal Tar Ointment
MVB	Coal Tar Solution
MHD	Cocaine
IIA	Coccidioidin [Fungi]
XAB	Cod Liver Oil
HAB	Codeine
DBE	Cogentin®
NDE	Colace®
JJD	Colchicine
GBD	Colestid®
GBD	Colestipol
BID	Colistin Sulfate
MWB	Collagenase
MRA	Collodion
BID	Coly-Mycin®
NFK	Combid
■ GCC	Combipres®
■ HFO	Compazine®
ABS	Comtrex®
QKL	Concentraid®
IBA	Congo Red [Amyloidosis]
MLG	Contact Lens Solutions
ABF	Contac®
MPC	Copper Oleate
MEP	Cordran®
■ GGF	Corgard®
ADB	Coricidin D®
ADB	Coricidin®
JFA	Corn Oil
QAM	Cortenema®
MEJ	Corticosteroid-Antibiotic
QKQ	Corticotropin
IAA	Corticotropin [Adrenocortical Insufficiency]
QAB	Cortisone (Oral, Injection)
MEA	Cortisone (Topical)
MEJ	Cortisporin®
QAB	Cortone®
IAB	Cortrosyn®
ACB	Cosanyl®
CCB	Cosmegen®
IAB	Cosyntropin [Adrenocortical Insufficiency]
NEG	Cotazym®
MRB	Cottonseed Oil
FCI	Coumadin®

CODE	NAME
FCC	Coumarin & Indandione Derivatives
YHE	Cromolyn Sodium
UAC	Crotaline Antivenin, Polyvalent
MPD	Crotamiton
FEJ	Cryoprecipitate
■ GCD	Cryptenamine
GAD	Crystodigin®
MCH	Cupric Sulfate
IYE	Cupric Sulfate Reagent - [Sugar]
PEA	Cuprimine®
XBA	Cyanocobalamin
TAC	Cyanocobalamin Co 57
GDB	Cyclandelate
NFC	Cyclizine
DFD	Cyclobenzaprine
MES	Cyclocort®
MJB	Cyclogyl®
DDB	Cyclopentamine
MJB	Cyclopentolate
CAE	Cyclophosphamide
BJC	Cycloserine
GDB	Cyclospasmol®
CDM	Cyclosporine
■ JHE	Cyclothiazide
DBH	Cycrimine
AAE	Cyproheptadine
CDB	Cytarabine
GBG	Cytellin®
QKD	Cytomel®
CDB	Cytosar®
NHE	Cytotec®
BKT	Cytovene®
CAE	Cytoxan®
IKA	D-Xylose [Intestinal Absorption]
CDC	Dacarbazine
MLJ	Dacriose®
DBV	Dactil®
CCB	Dactinomycin
MDV	Dakin's Solution
HGD	Dalmane®
QBA	Danazol [Antiandrogenic]
QBA	Danocrine®
NDD	Danthron
DFE	Dantrium®
DFE	Dantrolene
BNA	Dapsone
MFB	Daranide®
BRB	Daraprim®
DBO	Darbid®
DBT	Daricon®
HAP	Darvocet-N®
HAO	Darvon/ASA®
HAK	Darvon®
QFD	DBI®
QKL	DDAVP®
BKS	ddC®
BKQ	ddI®
HIG	Deaner®
HIG	Deanol
QBG	Deca-Durabolin®
QAD	Decadron® (Oral, Inhalation, Injection)
MEO	Decadron® (Topical, Ophthalmic)
DFF	Decamethonium
BHB	Declomycin®
PAA	Deferoxamine

CODE	NAME
NEA	Dehydrocholic Acid
QBK	Delatestryl®
QAK	Delta-Cortef®
QAL	Deltasone®
MIC	Demecarium
BHB	Demeclocycline
HAE	Demerol®
HDR	Depakene®
PEA	Depen®
■ HEB	Deprol®
QCC	Deralutin®
■ GCE	Deserpidine
PAA	Desferal®
■ HEC	Desipramine
GAB	Deslanoside
QKL	Desmopressin Acetate
MEV	Desonide
MEL	Desoximetasone
QAC	Desoxycorticosterone
■ HIM	Desoxyn®
MTG	Desquam®
■ HEK	Desyrel®
QCA	DES®
QAD	Dexamethasone (Oral, Inhalation, Injection)
MEO	Dexamethasone (Topical, Ophthalmic)
DDL	Dexatrim®
■ HIH	Dexedrine®
XBB	Dexpanthenol
JDB	Dextran 40
JDC	Dextran 70/Dextran 75
BKP	Dextran Sulfate
MNB	Dextro Pantothenyl Alcohol
■ HIH	Dextroamphetamine
AEH	Dextromethorphan
AEI	Dextromethorphan/Guaifenesin/Ipecac
JFB	Dextrose
GBE	Dextrothyroxine
BRF	DFMO
BKT	DHPG®
NAN	Di-Gel®
QFI	DiaBeta®
QFB	Diabinese®
MFA	Diamox®
QBE	Dianabol®
QKR	Diapid®
BNB	Diasone®
HGC	Diazepam
■ GFB	Diazoxide
■ DEB	Dibenzyline®
MHE	Dibucaine
DEA	Dichloralphenazone/Isometheptene Mucate/Acetaminophen
MFB	Dichlorphenamide
HBF	Diclofenac
BGF	Dicloxacillin
FCD	Dicumarol
DBI	Dicyclomine
BKQ	Didanosine
BKS	Dideoxycytidine
BKQ	Dideoxyinosine
HIC	Didrex®
XDC	Didronel
QDB	Dienestrol
DDL	Diet-Trim®
DDL	Dietac®
BBA	Diethylcarbamazine

CODE	NAME
HII	Diethylpropion
QCA	Diethylstilbestrol
BCH	Diflucan®
HBL	Diflunisal
GAC	Digitalis
GAD	Digitoxin
GAE	Digoxin
XDD	Dihydrotachysterol
NAE	Dihydroxyaluminum Aminoacetate
BAB	Diiodohydroxyquin
HDO	Dilantin®
HAC	Dilaudid®
■ GIA	Diltiazem
NFD	Dimenhydrinate
PBA	Dimercaprol
AAA	Dimetane®
ABI	Dimetapp®
AAH	Dimethindene
NDE	Dioctyl Sulfosuccinate Salts
GDC	Dioxyline
FCE	Dipaxin®
BMQ	Dipentum®
DBJ	Diphemanil
FCE	Diphenadione
AAI	Diphenhydramine
NFE	Diphenidol
NBB	Diphenoxylate
AAJ	Diphenylpyraline
UAD	Diphtheria Antitoxin
UBB	Diphtheria-Tetanus Toxoids
UBC	Diphtheria-Tetanus Toxoids-Pertussis Vaccine Combined
IGA	Diphtheria Toxin
UBA	Diphtheria Toxoid
MJJ	Dipivefrin
GDD	Dipyridamole
HCD	Disalcid®
GHB	Disopyramide
YHA	Disulfiram
DBS	Ditropan®
■ JHC	Diuril®
■ GCD	Diutensen®
JHQ	Doan's®
GFH	Dobutamine
GFH	Dobutrex®
NDE	Docusate Sodium
HBL	Dolobid®
HAS	Dolophine®
MDC	Domiphen
NEJ	Donnazyme®
GFA	Dopamine
HIJ	Dopram®
HJH	Doriden®
BHC	Doryx®
HIJ	Doxapram
■ GJA	Doxazosin
■ HED	Doxepin
NDE	Doxidan®
CCC	Doxorubicin
BHC	Doxycycline
HQA	Doxylamine
AFD	Doxylamine
UBC	DPT®
NFD	Dramamine®
ADC	Dristan®
ABT	Drixoral®

CODE	NAME
QBB	Dromostanolone
YAD	Dronabinol
■ HFE	Droperidol
CDC	DTIC Dome®
UBB	DT®
NDA	Dulcolax®
MWI	DuoDerm (Flexible Hydroactive dressing & granules)
MUL	Duofilm®
QCH	Duphaston®
QBG	Durabolin®
XDE	Duralutin
BDJ	Duricef®
MTA	Dusting Powder, Absorbable
DAB	Duvoid®
QDB	DV® Cream
■ JHU	Dyazide®
MHF	Dyclone®
MHF	Dyclonine
QCH	Dydrogesterone
QFA	Dymelor®
■ GIH	DynaCirc®
BGF	Dynapen®
DDQ	Dyphylline
■ JHR	Dyrenium®
MID	Echothiophate
MEH	Econopred®
HCA	Ecotrin®
■ JHF	Edecrin®
PCA	Edetate Calcium Disodium
PDA	Edetate Disodium
IPA	Edrophonium [Myasthenia Gravis]
PDA	EDTA®
BRF	Eflornithine HCl
MWC	Elase®
■ HEA	Elavil®
HLD	Eldepryl®
FDC	Embolex®
NFB	Emete-Con®
BAC	Emetine
KAL	Eminase®
HAO	Empirin #3®
■ GCW	Enalapril
GHG	Encainide
■ HEA	Endep®
■ JHL	Enduron®
JKE	Energol®
HNA	Enflurane
JKB	Ensure
ABR	Entex-LA®
DDC	Ephedrine
DDD	Epinephrine (Injection, Inhalation)
MGA	Epinephrine (Nasal)
MJC	Epinephrine (Ophthalmic)
FAE	EPO
FAE	Epoetin Alfa (Erythropoietin)
FAE	Epogen®
FAE	Eprex®
NDH	Epsom Salts®
HCB	Equagesic®
HJK	Equanil®
UAA	Equine®
XDE	Ergocalciferol
DEA	Ergoloid Mesylates (Oral/Sublingual)
DEA	Ergostat®
DEA	Ergot Alkaloids

CODE	NAME
MAC	Erythromycin (Ophthalmic, Topical)
BFA	Erythromycin (Oral, Injection)
■ JHH	Esidrex®
■ HHA	Eskalith®
■ GGI	Esmolol
MVB	Estar®
QDD	Estinyl®
QDD	Estrace®
QDD	Estradiol
QCB	Estrogen-Progestin Combinations
QDE	Estrogenic Substances, Conjugated
QDF	Estrone
■ JHF	Ethacrynic Acid
BJD	Ethambutol
MFC	Ethamide®
HJE	Ethchlorvynol
HJF	Ethinamate
BJE	Ethionamide
GHI	Ethmozine
DBK	Ethopropazine
HDD	Ethosuximide
HDE	Ethotoin
BQA	Ethoxazene
MFC	Ethoxzolamide
HNA	Ethrane®
MHG	Ethyl Aminobenzoate
MHQ	Ethyl Chloride
QBC	Ethylestrenol
DDE	Ethylnorepinephrine
HBR	Etodolac
HJZ	Etomidate
CDN	Etoposide
MSU	Eucerin Cream/Lotion
CEA	Eulexin®
MPD	Eurax®
QKE	Euthroid®
■ GCK	Eutonyl®
ICA	Evans Blue [Blood Volume]
NDP	EX-Lax®
HCE	Excedrin-P.M.®
MLJ	Eye-stream®
FEE	Factor IX Complex, Human
FEJ	Factor VIII
NHD	Famotidine
BRE	Fansidar®
HBK	Feldene®
■ GIG	Felodipine
QDD	Feminone®
HIK	Fenfluramine
HBA	Fenoprofen
DDF	Fenoterol
HAV	Fentanyl
XHD	Feosol®
XHD	Fergon®
ISA	Ferric Ammonium Sulfate Reageant [PKU]
ISB	Ferric Chloride Reagent [PKU]
XHD	Ferro-Sequels®
XHD	Ferrous Sulfate
NDK	Fiber Con®
EBA	Fibrinogen, Human
MWC	Fibrinolysin-Desoxyribonuclease
KAD	Fibrinolysin, Human
YAE	Filgrastim®
QBL	Finasteride
HCF	Fioricet®
HCB	Fiorinal®
YMB	Fish Oil
BIR	Flagyl®
DBL	Flavoxate
DFG	Flaxedil®
GHH	Flecainide
NDO	Fleets Phospho Soda®
DFD	Flexeril®
NEB	Florantyrone
QAE	Florinef®
MIE	Floropryl®
BQJ	Floxin®
CDD	Floxuridine
BCH	Fluconazole
BCB	Flucytosine
QAE	Fludrocortisone
MEQ	Flunisolide
MEM	Fluocinolone
MLB	Fluorescein
XHC	Fluoride
MED	Fluorometholone
CBA	Fluorouracil
HNC	Fluothane®
■ HEP	Fluoxetine
QBD	Fluoxymesterone
■ HFH	Fluphenazine
QAF	Fluprednisolone
MEP	Flurandrenolide
HGD	Flurazepam
HBG	Flurbiprofen
MET	Flurbiprofen Sodium 0.03% Soln
CEA	Flutamide
XBC	Folate
XBC	Folic Acid
XBC	Folvite®
HNB	Forane®
BDP	Fortaz®
BKG	Foscarnet
■ GJB	Fosinopril
IYF	Fouchet's Reagent [Bilirubin]
ADH	Four-Way Cold Tablets®
JFC	Fructose
CDD	FUDR®
BCC	Fulvicin®
BCA	Fungizone® (Injection)
MCB	Fungizone® (Topical)
MDP	Furacin®
BQE	Furadantin®
BRA	Furazolidone
■ JHG	Furosemide
BRA	Furoxone®
YAE	G-CSF
DFG	Gallamine
UAF	Gamastan®
BKT	Ganciclovir
BMJ	Gantanol®
MAH	Gantrisin® (Ophthalmic)
BMP	Gantrisin® (Oral, Injection)
BIE	Garamycin® (Injection)
MAD	Garamycin® (Ophthalmic, Topical)
YAB	Garlic Supplement
UAE	Gas Gangrene Antitoxin, Pentavalent
NCA	Gas-X®
NAK	Gaviscon®
MWD	Gelatin Film, Absorbable

CODE	NAME
MWD	Gelfoam®
NAN	Gelusil®
GBH	Gemfibrozil
HDI	Gemonil®
BIE	Gentamicin (Injection)
MAD	Gentamicin (Ophthalmic, Topical)
BBB	Gentian Violet
BGC	Geocillin®
BGC	Geopen®
XBN	Geritol®
BKJ	Germanin®
GAF	Gitalin
QFH	Glipizide
QFC	Glucagon
IFA	Glucose Oxidase Reagent [Diabetes]
IYG	Glucose Oxidase Reagent [Sugar]
IFC	Glucose [Blood Tests]
QFH	Glucotrol®
NEC	Glutamic Acid
HJH	Glutethimide
QFI	Glyburide
MQB	Glycerin Hand Lotions
MLC	Glycerin OTIC
NDF	Glycerin Suppositories
AEJ	Glyceryl Guaiacolate
JIC	Glycine [See Aminoacetic Acid]
DBM	Glycopyrrolate
YAG	GM-CSF
NDQ	Go Lytely®
TAD	Gold Au 198
OAA	Gold Salts
YAE	Granulocyte Colony Stimulating Factor
YAG	Granulocyte Macrophage-Colony Stimulating Factor
BCC	Grifulvin®
BCC	Gris-Peg®
BCC	Griseofulvin
IYH	Guaiac Reagent [Occult Blood]
AEJ	Guaifenesin
■ GCT	Guanabenz
■ GCV	Guanadrel
■ GCG	Guanethidine
■ GCY	Guanfacine
YAC	Habitrol®
MEN	Halcinonide
HGH	Halcion®
■ HFI	Haldol®
QAJ	Haldrone®
NDJ	Haley's MO®
MEN	Halog®
■ HFI	Haloperidol
MCI	Haloprogin
QBD	Halotestin®
MCI	Halotex®
HNC	Halothane
■ GCE	Harmonyl®
■ JHV	HCTZ & Sprionolactone
■ JHU	HCTZ & Triamterene
FDB	Heparin
FDC	Heparin Sodium-Dihydroergotamine Mesylate (DHE)
HMB	Heroin
MBA	Herplex®
JDD	Hespan®
BGG	Hetacillin
JDD	Hetastarch
BBA	Hetrazan®

CODE	NAME
MDK	Hexachlorophene
DFH	Hexafluorenium
HJI	Hexobarbital
DBN	Hexocyclium
MHO	Hexylcaine
AAF	Hismanal®
IJC	Histamine [Gastric Function]
ITA	Histamine [Pheochromocytoma]
ABU	Histaminic®
IIB	Histoplasmin [Fungi]
BKS	Hivid®
MEF	HMS®
MJE	Homatropine
BKH	HPA-23
BAD	Humatin®
AEJ	Humibid L.A.®
AEJ	Humibid Sprinkle®
KAE	Hyaluronidase
HMA	Hycodan®
DEA	Hydergine®
■ GCU	Hydralazine (Injection)
■ GCH	Hydralazine (Oral)
CDE	Hydrea®
NED	Hydrochloric Acid
■ JHH	Hydrochlorothiazide (HCTZ)
AEL	Hydrocodone
QAG	Hydrocortef®
QAG	Hydrocortisone (Oral, Rectal, Injection)
MEE	Hydrocortisone (Topical, Ophthalmic)
QAM	Hydrocortisone Enema
■ JHH	HydroDiuril®
■ JHI	Hydroflumethiazide
■ JHW	Hydroflumethiazide & Reserpine
MKD	Hydrogen Peroxide
AEK	Hydroidic Acid
HAC	Hydromorphone
■ JHO	Hydromox®
MQC	Hydrophilic Lotion
MSH	Hydrophilic Ointment
MSF	Hydrous Wool Fat & Castor Oil Ointment
MQD	Hydrous Wool Fat Lotion
XBD	Hydroxocobalamin
■ MJF	Hydroxyamphetamine
BLC	Hydroxychloroquine
QCC	Hydroxyprogesterone
CDE	Hydroxyurea
HGS	Hydroxyzine
■ JHD	Hygroton®
■ GCV	Hylorel®
UAL	Hyper Tet®
■ GFB	Hyperstat®
UAG	Hypertussis®
XDD	Hytakerol®
MEE	Hytone®
■ GCA	Hytrin®
HBB	Ibuprofen
MVC	Ichthammol
MVC	Icthyol®
MBA	Idoxuridine
XBB	Ilopan®
MAC	Ilotycin Ointment®
KAF	Ilozyme®
BIV	Imipenem - Cilastatin
■ HEE	Imipramine
UAF	Immune Serum Globulin

CODE	NAME
NBE	Imodium®
CDA	Imuran®
BKM	Imuthiol
■ HFE	Inapsine®
■ JHT	Indapamide
■ GGE	Inderal®
ILD	Indigotindisulfonate [Kidney Function]
HBC	Indocin-SR®
HBC	Indocin®
IDA	Indocyanine Green [Cardiac Function, Liver Function]
HBC	Indomethacin
UCC	Influenza Vaccine, Polyvalent
BJF	INH®
GAI	Inocor®
BKF	Inosiplex®
QFG	Insulin - All Types
YHE	Intal®
CDP	Interferon Alpha
CDQ	Interferon Gamma
YNA	Interleukin-2
GFA	Intropin®
ILA	Inulin [Kidney Function]
■ GCF	Inversine®
JFD	Invert Sugar
IVB	Iocetamic Acid
QKB	Iodide, Potassium
AEM	Iodinated Glycerol
TAE	Iodinated I 125 Serum Albumin
TAG	Iodinated I 131 Serum Albumin, Macroaggregated
TAF	Iodinated I 131 Serum Albumin
MDL	Iodine
TAH	Iodohippurate Sodium I 131
HIN	Ionamin®
IVC	Iopanoic Acid
IVD	Iophendylate
NFF	Ipecac
IVE	Ipodate Calcium/Ipodate Sodium
DCD	Ipratropium Bromide
XHD	Iron Preparations
■ GCG	Ismelin®
■ HEF	Isocarboxazid
DDG	Isoetharine
HNB	Isoflurane
MIE	Isoflurophate
DEA	Isometheptene mucate/Dichloralphenazone/Acetaminophen
BJF	Isoniazid
BKF	Isoprinosine
DBO	Isopropamide
DDH	Isoproterenol (Inhalation)
GFE	Isoproterenol (Injection, SL, Rectal)
■ GIC	Isoptin®
MJA	Isopto Atropine®
MIG	Isopto Carpine
MAH	Isopto Cetamide®
MIF	Isopto Eserine®
MJE	Isopto Homatropine®
MJH	Isopto Hyoscine®
MLE	Isopto Tears®
■ GDM	Isordil Chewable®
■ GDN	Isordil Oral®
■ GDM	Isordil SL®
■ GDM	Isosorbide Dinitrate
■ GDN	Isosorbide Dinitrate
GDE	Isoxsuprine
■ GIH	Isradipine

CODE	NAME
DDH	Isuprel® (Inhalation)
GFE	Isuprel® (Injection, SL, Rectal)
BCJ	Itraconazole
GDQ	Itramin
MVD	Juniper Tar
BDC	Kafocin®
BIF	Kanamycin
BIF	Kantrex®
NBC	Kaolin & Pectin
NBC	Kaopectate®
JCB	Kayexalate®
BDB	Keflex®
BDE	Keflin®
BDO	Kefurox®
BDA	Kefzol®
DBX	Kemadrin®
QAM	Kenalog® (Oral, Injection)
MEI	Kenalog® (Topical)
MRH	Keri Oil
■ GGL	Kerlone®
BCF	Ketoconazole
HBV	Ketoprofen
HBO	Ketorolac Tromethamine
HDC	Klonopin®
MPA	Kwell®
DBD	L-Hyoscyamine Sulfate
HAX	LAAM
■ GGB	Labetalol
LAH	Lachydrin 12%®
MLE	Lacri-lube®
LAH	Lactic Acid Lotion
NBD	Lactinex®
NBD	Lactobacillus Acidophilus
JCA	Lactulose
BNC	Lamprene®
GAB	Lanatoside C
ABW	Lanatuss®
GAE	Lanoxin®
HLB	Larodopa®
BGA	Larotid®
■ JHG	Lasix®
MOB	Lauryl Sulfoacetate
NDA	Laxatives & Cathartics
XHF	Lecithin
QKC	Letter®
YAG	Leucomax®
XBE	Leucovorin Calcium
CAD	Leukeran®
HAL	Levallorphan
BKN	Levamisole
■ GGK	Levatol®
HAD	Levo-Dromoran®
HAX	Levo-alpha-acetylmethadol
■ MLK	Levobunolol
HLB	Levodopa
HLC	Levodopa/Carbidopa
GFD	Levophed®
HJN	Levoprome®
AEN	Levopropoxyphene
HAD	Levorphanol
QKC	Levothyroxine
DBD	Levsin®
HGL	Librax®
HGB	Librium®
MEM	Lidex®

CODE	NAME
GHC	Lidocaine (Injection)
MHK	Lidocaine (Topical)
HGL	Lidox®
MUC	Lime Solution, Sulfurated
BIG	Lincocin®
BIG	Lincomycin
MPA	Lindane®
MTB	Linseed
DFR	Lioresal®
QKD	Liothyronine
QKE	Liotrix
QCG	Lipo-Lutin®
MLE	Liquifilm®
■ GCZ	Lisinopril
■ HHA	Lithium Carbonate
■ HHA	Lithobid®
HBR	Lodine®
BQK	Lomefloxacin
NBB	Lomotil®
CAF	Lomustine
■ GCI	Loniten®
NBE	Loperamide
GBH	Lopid®
■ GGD	Lopressor®
HGE	Lorazepam
GBF	Lorelco®
HAL	Lorfan®
BDD	Loridine®
NHF	Losec®
■ GJC	Lotensin®
MCG	Lotrimin®
MCS	Lotrisone®
GBI	Lovastatin
■ HFJ	Loxapine
■ HFJ	Loxitane®
■ JHT	Lozol®
MSW	Lubriderm®
■ HEM	Ludiomil®
XHC	Luride®
YMC	Lycolan®
INA	Lymphogranuloma Venereum Antigen
QKR	Lypressin
YMC	Lysine
CDG	Lysodren®
NAM	Maalox
BQE	Macrodantin®
MDM	Mafenide
NAF	Magaldrate
NDL	Magcyl®
NAG	Magnesia Magma
JID	Magnesium & Sodium Citrates
NAM	Magnesium-Aluminum Hydroxide
NAN	Magnesium-Aluminum Hydroxide-Simethicone
NAH	Magnesium Carbonate
JDN	Magnesium Chloride
NDG	Magnesium Citrate (Laxative)
NAI	Magnesium Oxide
JDK	Magnesium Salts, Gluconate/Sulfate
HDF	Magnesium Sulfate (Injection)
NDH	Magnesium Sulfate (Oral)
NAJ	Magnesium Trisilicate
BQB	Mandelamine®
BDI	Mandol®
■ JHJ	Mannitol
GDF	Mannitol Hexanitrate
ILB	Mannitol [Kidney Function]
DFB	Maolate®
■ HEM	Maprotiline
DDR	Marax®
MHL	Marcaine®
NFC	Marezine®
YAD	Marinol®
■ HEF	Marplan®
CDI	Matulane
DDT	Maxair®
BQK	Maxaquin®
QBC	Maxibolin®
ABP	Maximum Strength Tylenol Sinus®
MEO	Maxitrol®
■ JHU	Maxzide®
UCD	Measles Virus Vaccine, Live, Attenuated
HDH	Mebaral®
BBC	Mebendazole
■ GCF	Mecamylamine
CAG	Mechlorethamine
NFG	Meclizine
HBM	Meclofenamate
HBM	Meclomen®
QAI	Medrol® (Oral, Injection)
MEG	Medrol® (Topical)
QCD	Medroxyprogesterone
MEF	Medrysone
HBN	Mefenamic Acid
BDH	Mefoxin®
CDF	Megace®
CDF	Megestrol
IVF	Meglumine Diatrizoate
IVG	Meglumine Iodaipamide
IVH	Meglumine Iothalamate
■ HFR	Mellaril®
MSG	Meloxine®
CAH	Melphalan
XFA	Menadione/Menadiol Sodium Diphosphate
UCE	Meningococcal Polysaccharide Vaccine, Group C
UCE	Meningovax-C®
DBP	Mepenzolate
HAE	Meperidine
DFI	Mephenesin
DDI	Mephentermine
HDG	Mephenytoin
HDH	Mephobarbital
XFB	Mephyton®
MHM	Mepivacaine
QAH	Meprednisone
HJK	Meprobamate
MDN	Merbromin
■ JHK	Mercaptomerin
CBB	Mercaptopurine
MDO	Mercury, Ammoniated
■ HEO	Merital®
MDF	Merthiolate
UCN	Meruvax®
BND	Mesalamine
■ HFK	Mesoridazine
DAE	Mestinon®
NDM	Metamucil®
QBF	Metandren®
DDJ	Metaprel®
DDJ	Metaproterenol
GFF	Metaraminol

CODE	NAME
BHD	Methacycline
HAS	Methadone
QDG	Methallenestril
■ HIM	Methamphetamine
QBE	Methandrostenolone
DBQ	Methantheline
AAK	Methapyrilene
HJL	Methaqualone
HDI	Metharbital
MFD	Methazolamide
AAL	Methdilazine
BQB	Methenamine
BGH	Methicillin
QKF	Methimazole
NGB	Methionine
DBR	Methixene
DFK	Methocarbamol
DFL	Methocarbamol/Aspirin
HJM	Methohexital
CBC	Methotrexate
HJN	Methotrimeprazine
GFJ	Methoxamine
MSG	Methoxsalen
DDK	Methoxyphenamine
HDJ	Methsuximide
■ JHL	Methyclothiazide
IYJ	Methyl Red/Bromothymol Blue Reagent [pH]
MQE	Methyl Salicylate
NDI	Methylcellulose
■ GCJ	Methyldopa
BQC	Methylene Blue
MDD	Methylparaben & Propylparben
HIO	Methylphenidate
QAI	Methylprednisolone (Oral, Injection)
MEG	Methylprednisolone (Topical)
MCJ	Methylrosaniline Chloride
QBF	Methyltestosterone
QKG	Methylthiouracil
HJO	Methyprylon
NFL	Metoclopramide
■ JHM	Metolazone
■ GGD	Metoprolol
BIR	Metronidazole
MHH	Metycaine®
IUB	Metyrapone [Pituitary Function]
GBI	Mevacor®
CBC	Mexate®
GHK	Mexiletine
GHK	Mexitil®
BGO	Mezlin®
BGO	Mezlocillin
BCG	Miconazole
QFI	Micronase®
QCE	Micronor®
■ JHZ	Midamor®
HND	Midazolam
DEA	Midrin®
NAG	Milk ofMagnesia®
HDN	Milontin®
NDJ	Mineral Oil Emulsion
■ GCL	Minipress®
■ GDR	Minitran®
BHE	Minocin®
BHE	Minocycline
■ GCI	Minoxidil

CODE	NAME
BBH	Mintezol®
MIA	Miochol®
MIB	Miostat®
NHE	Misoprostol
CCD	Mithracin®
CCD	Mithramycin
CCE	Mitomycin
CDG	Mitotane
CDR	Mitoxanthrone HCl
■ HFL	Moban®
NDD	Modane®
■ GCN	Moderil®
■ JHX	Moduretic®
■ HFL	Molindone
MCK	Monistat®
BCG	Monistat®
BDT	Monocid®
YNB	Monoclonal Antibodies
■ GJB	Monopril®
HAG	Morphine
GEA	Morrhuate Sodium
HBB	Motrin®
BDM	Moxalactam
BDM	Moxam®
AEA	Mucomyst®
XHG	Multivitamin with Iron
XGA	Multivitamins
XGB	Multivitamins with Minerals
IOA	Mumps Skin Test Antigen
UCF	Mumps Virus Vaccine, Inactivated
UCG	Mumps Virus Vaccine, Live, Attenuated
MAM	Mupirocin
CAG	Mustargen®
CCE	Mutamycin®
BJD	Myambutol®
MCG	Mycelex®
BIH	Mycifradin®
BCD	Mycostatin® (Oral)
MCL	Mycostatin® (Topical)
MJI	Mydriacyl®
NAN	Mylanta®
DFH	Mylaxen®
CAA	Myleran®
NCA	Mylicon®
OAA	Myochrysine®
HDP	Mysoline®
DAA	Mytelase®
HBS	Nabumetone
■ GGF	Nadolol
QCI	Nafarelin Acetate Nasal Solution
BGI	Nafcillin
BGI	Nafcil®
MCR	Naftifine HCl
MCR	Naftin®
HAY	Nalbuphine [Studies after 189]
ABU	Naldecon®
HBA	Nalfon®
ABU	Nalgest®
BQD	Nalidixic Acid
HAM	Nalline®
HAM	Nalorphine
HAT	Naloxone
HAR	Naltrexone [Studies after 189]
QBG	Nandrolone
MGB	Naphazoline

CODE	NAME
HBE	Naprosyn®
HBE	Naproxen
■ JHS	Naqua®
HAT	Narcan®
HAP	Narcotic-Acetaminophen Combinations
HAO	Narcotic-Salicylate Combinations
■ HEH	Nardil®
QAM	Nasacort®
MEQ	Nasalide®
■ JHA	Naturetin®
■ HFS	Navane®
BIN	Nebcin®
BQD	NegGram®
HJQ	Nembutal®
MAL	Neo-Polycin Oint.®
GFG	Neo-Synephrine® (Injection, Inhalation)
MGD	Neo-Synephrine® (Ophthalmic)
MEJ	NeoDecadron®
BIH	Neomycin (Oral, Injection)
MAE	Neomycin (Topical)
MAL	Neomycin-Bacitracin-Polymyxin B Oint
MAJ	Neosporin
DAC	Neostigmine
MFD	Neptazane®
MHS	Nesacaine®
BIT	Netilmicin
BIT	Netromycin®
YAE	Neupogen®
JDM	Neutra-Phos-K®
JDM	Neutra-Phos®
XBG	Niacin
■ GID	Nicardipine
BBI	Niclocide®
BBI	Niclosamide
XBG	Nicobid®
YAC	Nicoderm®
YBA	Nicorette®
XBF	Nicotinamide
GBA	Nicotinate
YBA	Nicotine Gum
YAC	Nicotine Transdermal System
XBG	Nicotinic Acid
GDG	Nicotinyl Alcohol
■ GIB	Nifedipine
BCD	Nilstat® (Oral, Vaginal)
MCL	Nilstat® (Topical)
■ GIE	Nimodipine
■ GIE	Nimotop®
■ GCP	Nipride®
HAA	Nisentyl®
GDF	Nitranitol®
■ GDN	Nitrates Cardiac, Long Acting
■ GDM	Nitrates Cardiac, Short Acting
■ GDR	Nitrodisc®
BQE	Nitrofurantoin
MDP	Nitrofurazone
■ GDO	Nitroglycerin® (Injection)
■ GDM	Nitroglycerin® (Sublingual)
■ GDN	Nitroglycerin® (Sustained-release)
■ GDR	Nitroglycerin® (Transdermal)
■ GDN	Nitropaste®
■ GCP	Nitroprusside
■ GDO	Nitrostat IV®
NHG	Nizatidine
BCF	Nizoral®

CODE	NAME
HID	No Doz®
HJD	Noctec®
HJO	Noludar®
■ HEO	Nomifensine
DFJ	Norcuron®
GFD	Norepinephrine
QCE	Norethindrone
QCF	Norethynodrel
DFM	Norflex®
BQH	Norfloxacin
DFN	Norgesic Forte®
DFN	Norgesic®
QCE	Norlutin®
■ GGB	Normodyne®
BQH	Noroxin®
GHB	Norpace®
■ HEC	Norpramin®
■ HEG	Nortriptyline
■ GII	Norvasc®
AEO	Noscapine
ACE	Novafed®
AEG	Novahistine DH®
AEG	Novahistine Expectorant®
ABK	Novahistine®
CDR	Novantrone®
BII	Novobiocin
MHN	Novocaine®
HAY	Nubain® [Studies after 189]
HAI	Numorphan®
MHE	Nupercainal®
HBB	Nuprin®
GDH	Nylidrin
ABL	Nyquil®
BCD	Nystatin (Oral)
MCL	Nystatin (Topical)
BCE	Nystatin - TCNs (Oral)
MTC	Oatmeal
MET	Ocufen®
BQJ	Ofloxacin
MSH	Ointment, Hydrophilic
BIJ	Oleandomycin/Troleandomycin
BIO	Oleandomycin®
XAA	Oleovitamin A
MRE	Olive Oil
BMQ	Olsalazine
YMB	Omega-3
NHF	Omeprazole
CCG	Oncovin®
MLJ	Ophthalmic Irrigation Solutions
HAU	Opium & Opium Mixtures® [includes: B & O suppositories]
NBF	Opium Anti-Diarrheal Preparations
AAT	Optimine®
QAL	Orasone®
MFB	Oratrol®
ACA	Ordrine AT®
QBF	Oreton-Methyl®
QBK	Oreton®
IFB	Orinase Diagnostic®
QFF	Orinase®
ABM	Ornade®
ACF	Ornex®
BRF	Ornidyl®
DFM	Orphenadrine
DFN	Orphenadrine/ASA
QCB	Ortho-Novum®

CODE	NAME
IYM	Orthortolidine Reagent [Occult Blood]
DDK	Orthoxine®
HBV	Orudis®
XHA	Os-Cal
■ JHJ	Osmitrol®
MEU	Otic Tridesilon
MGH	Otrivin®
GAH	Ouabain
NEE	Ox Bile Extract
BGJ	Oxacillin
BBJ	Oxamniquine
QBH	Oxandrolone
HGF	Oxazepam
MCF	Oxiconazole Nitrate
MCF	Oxistat®
BQF	Oxolinic Acid
MSG	Oxsoralen®
DDQ	Oxtriphylline
DBS	Oxybutinin
HAH	Oxycodone
YAF	Oxygen
MED	Oxylone®
MGC	Oxymetazoline
QBI	Oxymetholone
HAI	Oxymorphone
HBD	Oxyphenbutazone
DBT	Oxyphencyclamine
DBU	Oxyphenonium
BHF	Oxytetracycline
IYK	p-Nitrobenzene Diazonium p-Toluene Sulfonate Reag. [Bilirub]
MSJ	PABA Topical (Pre-Sun)
■ HEG	Pamelor®
KAF	Pancrease Enzymes
KAF	Pancrease®
NEG	Pancrelipase
DFO	Pancuronium
XBB	Pantothenic Acid
KAG	Papain
GDI	Papaverine
MSJ	Para-Aminobenzoic Acid (Topical)
ILE	Para-Aminohippurate [Kidney Function]
DFC	Paraflex®
DFC	Parafon Forte®
DFC	Parafon®
HJP	Paraldehyde
HDK	Paramethadione
QAJ	Paramethasone
QKO	Parathyroid
■ MJF	Paredrine®
NBF	Paregoric®
■ GCK	Pargyline
HLA	Parlodel®
■ HEJ	Parnate®
BAD	Paromomycin
DBK	Parsidol®
BJA	PAS®
DCB	Pathilon®
GDI	Pavabid®
GDC	Paveril®
DFO	Pavulon®
MRF	Peanut Oil
HDE	Peganone®
BGK	Pen Vee K®
■ GGK	Penbutolol
PEA	Penicillamine

CODE	NAME
BGL	Penicillin (Injection)
BGK	Penicillin (Oral)
BGK	Penicillin V
BGK	Penicillin VK®
IJD	Pentagastrin [Gastric Function]
BIU	Pentam 300®
BIU	Pentamidine
HAJ	Pentazocine
HJQ	Pentobarbital
HJX	Pentothal®
FFA	Pentoxifylline
NHD	Pepcid®
NBA	Pepto-Bismol®
HAP	Percocet-5®
HAO	Percodan®
HCB	Percogesic®
QAC	Percorten®
NDE	Peri-Colace®
AAE	Periactin®
MDW	Peridex (Chlorhexidine)
JIF	Peritoneal Dialysis Solution
■ GDN	Peritrate®
■ HFH	Permitil®
■ HFM	Perphenazine
GDD	Persantine
GDD	Persantine®
■ HEC	Pertofrane®
AEH	Pertussin®
UAG	Pertussis Immune Human Serum
UCH	Pertussis Vaccine
MNC	Peruvian Balsam
MSK	Petrolatum
MSL	Petrolatum, Hydrophilic
BKG	PFA
NCA	Phazyme®
HDL	Phenacemide
IYO	Phenaphthazine Reagent [pH]
MHR	Phenazopyridine
■ HEH	Phenelzine
ABN	Phenergan Compound®
■ HJS	Phenergan®
QFD	Phenformin
FCG	Phenindione
AAM	Pheniramine
HDM	Phenobarbital
NDP	Phenolphthalein
ILC	Phenolsulfonphthalein [Kidney Function]
DBG	Phenoxene®
■ DEB	Phenoxybenzamine
FCH	Phenprocoumon
HDN	Phensuximide
HIN	Phentermine
■ DEC	Phentolamine
HBH	Phenylbutazone
GFG	Phenylephrine (Injection)
MGD	Phenylephrine (Nasal)
MJG	Phenylephrine (Ophthalmic)
DDL	Phenylpropanolamine
ACA	Phenylpropanolamine/Caramiphen
ABU	Phenylpropanolamine/phenylephrine/chlorpheniramine/phenyltol
HDO	Phenytoin
MDK	pHisoHex®
NAB	Phosphaljel®
JDM	Phosphate Salts
MID	Phospholine Iodide®

CODE	NAME
BKG	Phosphonoformate
BMB	Phthalylsulfathiazole
DAD	Physostigmine (Injection)
MIF	Physostigmine (Ophthalmic)
XFB	Phytonadione
MIG	Pilocarpine
■ GGG	Pindolol
■ HFN	Piperacetazine
BGM	Piperacillin
BBD	Piperazine
DBV	Piperidolate
MHH	Piperocaine
CDH	Pipobroman
BGM	Pipracil®
DDT	Pirbuterol
HBK	Piroxicam
QKT	Pitressin®
HJE	Placidyl®
UCI	Plague Vaccine
BLC	Plaquenil®
ECA	Plasma Antihemophilic, Human
EDA	Plasma Protein Fraction, Human
CDO	Platinol®
■ GIG	Plendil®
UCT	Pneumococcal Vaccine, Polyvalent
UCT	Pneumovax 23®
UCT	Pnu-Imune 23®
MUD	Podophyllum Resin
MWF	Poison Ivy Extract
DBW	Poldine
UCJ	Poliomyelitis Vaccine
UCK	Poliovirus Vaccine, Live, Oral
NDL	Poloxalkol
NDK	Polycarbophil
JBB	Polycitra®
MOC	Polyethanolamine Alkyl Sulfate
MSM	Polyethylene Glycols
BIK	Polymyxin B (Injection)
MAF	Polymyxin B (Ophthalmic)
MAK	Polymyxin B/Bacitracin
MAK	Polysporin®
JCB	Polystyrene Sulfonate, Sodium
■ JHN	Polythiazide
HIK	Pondimin®
HBN	Ponstel®
MHJ	Pontocaine®
YMA	Potaba
AEP	Potassium Iodide
QKB	Potassium Iodide, Saturated Solution
QKK	Potassium Perchlorate
MDQ	Potassium Permanganate
JDE	Potassium Supplements
BBF	Povan®
MDU	Povidone-Iodine
MHT	Pramoxine HCl
GBJ	Pravachol®
GBJ	Pravastatin Sodium
MHT	Prax®
HGV	Prazepam
■ GCL	Prazosin
IHA	Pre-Pen®
BDQ	Precef®
MEH	Pred-Forte®
MEH	Prednisolone (Ophthalmic)
QAK	Prednisolone (Oral, Injection)
QAL	Prednisone
QDE	Premarin®
DDO	Prempar®
NIB	Preparation H
NHF	Prilosec®
BLD	Primaquine
BIV	Primaxin®
HDP	Primidone
■ GCZ	Prinivil®
GDJ	Priscoline®
DBY	Probanthine®
JJA	Probenecid
GBF	Probucol
GHD	Procainamide
MHN	Procaine
GHD	Procan®
CDI	Procarbazine
■ GIB	Procardia®
■ HFO	Prochlorperazine
DBX	Procyclidine
QCG	Progesterone
■ GFB	Proglycem®
DDL	Prolamine®
■ HFH	Prolixin®
QKI	Proloid®
BRD	Prololprim®
■ HFP	Promazine
YMB	Promega®
■ HJS	Promethazine
GHD	Pronestyl®
DBY	Propantheline
MHI	Proparacaine
MJJ	Propine®
HJT	Propiomazine
MCM	Propionate Compound
HAK	Propoxyphene, All Salt & Combinations
■ GGE	Propranolol
MGE	Propylhexedrine
QKH	Propylthiouracil
QBL	Proscar®
BGJ	Prostaphlin®
YAC	ProStep®
DAC	Prostigmine®
FEH	Protamine Sulfate
JFE	Protein Hydrolysate
DDM	Protokylol
■ HEI	Protriptyline
DDA	Proventil®
QCD	Provera®
■ HEP	Prozac®
DDN	Pseudoephedrine
ABP	Pseudoephedrine/Acetaminophen
MVB	Psorigel®
NDM	Psyllium Hydrophilic Mucilloid
QKH	PTU
CBB	Purinethol®
GAD	Purodigin®
BBE	Pyrantel
BJG	Pyrazinamide
AAR	Pyribenzamine®
MHR	Pyridium®
DAE	Pyridostigmine
XBH	Pyridoxine
BRB	Pyrimethamine
BRE	Pyrimethamine/Sulfadoxine

CODE	NAME
AAO	Pyrrobutamine
ADE	Pyrroxate®
BBF	Pyrvinium
HJL	Quaalude®
DFP	Quelicin®
GBB	Questran®
DDR	Quibron®
■ HFN	Quide®
BBG	Quinacrine
BLE	Quinamm®
■ JHO	Quinethazone
GHE	Quinidex®
GHE	Quinidine
BLE	Quinine®
UAH	Rabies Immune Globulin, Human
UCL	Rabies Vaccine
NHB	Ranitidine
■ GCM	Rauwolfia Serpentina
■ DEC	Regitine®
NFL	Reglan®
DAE	Regonal®
HBS	Relafen®
■ JHN	Renese®
BME	Renoquid®
■ GCN	Rescinnamine
■ GCO	Reserpine
MUE	Resorcinol
HGG	Restoril®
MNE	Retin A®
BKD	Retrovir®
UAI	Rho GAM®
UAI	Rho Immune Globulin, Human
BKE	Ribavirin
XBI	Riboflavin
OAB	Ridaura®
BJH	Rifadin®
BJH	Rifampin
BJH	Rimactane®
HBZ	Rimadyl®
BKL	Rimantadine
JDF	Ringer's Injection
JDG	Ringer's Injection, Lactated
NAF	Riopan®
HIO	Ritalin®
DDO	Ritodrine
DFK	Robaxin®
DFL	Robaxisal®
DBM	Robinul®
AEG	Robitussin AC®
AEJ	Robitussin®
XDB	Rocaltrol®
BDS	Rocephin®
UCM	Rocky Mountain Spotted Fever Vaccine
NAE	Rolaids®
BHD	Rondomycin®
GDG	Roniacol®
TAI	Rose Bengal Sodium I 131
MSN	Rose Water Ointment
AAP	Rotoxamine
BND	Rowasa®
HAP	Roxicet®
UCN	Rubella Virus Vaccine, Live
HBB	Rufen®
JGA	Saccharin
DDA	Salbutamol®

CODE	NAME
HCB	Salicylate/Analgesic & Other Combinations
HCA	Salicylates, Acetylated
HCD	Salicylates, Non-Acetylated
MUF	Salicylic Acid (Topical)
MUL	Salicylic Acid/Lactic Acid/Flexible Collodion
HCZ	Salpine (Aspirin - CSP #199)
HCD	Salsalate®
■ JHI	Saluron®
■ JHW	Salutensin®
CDM	Sandimmune®
DEA	Sansert®
MWB	Santyl®
MND	Scarlet Red
DBD	Scopolamine (Injection)
MJH	Scopolamine (Ophthalmic, Transdermal)
MUK	Sebulex Shampoo
HJU	Secobarbital
HJU	Seconal®
IRA	Secretin [Pancreatic Function]
■ GGH	Sectral®
AAU	Seldane®
HLD	Selegiline
XHE	Selenium
MDR	Selenium Sulfide
MDR	Selsun®
NDN	Senna
NDN	Senokot®
BRC	Septra®
■ GCS	Ser-Ap-Es
HGF	Serax®
BQA	Serenium®
■ HFK	Serentil®
BJC	Seromycin®
■ GCO	Serpasil®
■ HER	Sertraline
NDN	Shaklee's Herb Laxative
JBB	Shohl's Solution
AEH	Silence is Golden®
MSO	Silicone (Topical)
MDT	Silvadene®
MDE	Silver Nitrate Ophthalmic Solution
MUG	Silver Nitrate Sticks
MUG	Silver Nitrate, Toughened
MDS	Silver Protein
NCA	Simethicone
GBK	Simvastatin
ACH	Sinacet®
ADF	Sine-Off®
ABP	Sine-Aid®
HLC	Sinemet®
■ HED	Sinequan®
ACG	Sinutab II®
ABQ	Sinutab®
GBG	Sitosterols
JDN	Slow Mag®
UCO	Smallpox Vaccine
MOD	Soap, Medicinal Soft
IVI	Sodium Acetrizoate
NAO	Sodium Bicarbonate/Citric Acid/Potassium Bicarbonate
JBA	Sodium Bicarbonate [Alkalinizing Agent]
NAL	Sodium Bicarbonate [Antacids]
MKE	Sodium Borate Solution
JDH	Sodium Chloride
JIF	Sodium Chloride Irrigation Solution
TAJ	Sodium Chromate Cr 51

CODE	NAME
JBB	Sodium Citrate/Citric Acid Solution
JBB	Sodium Citrate [Alkalinizing Agent]
IEA	Sodium Dehydrocholate [Circulation Time]
IVJ	Sodium Diatrizoate
JGB	Sodium-Free Salt
MDV	Sodium Hypochlorite
IVK	Sodium Iodide
TAK	Sodium Iodide I 125
TAL	Sodium Iodide I 131
IVL	Sodium Iothalamate
JBC	Sodium Lactate [Alkalinizing Agent]
MOE	Sodium Lauryl Sulfate
IYQ	Sodium Nitroprusside Reagent [Ketones]
MKF	Sodium Perborate Solution
TAM	Sodium Pertechnetate Tc 99m
TAN	Sodium Phosphate P 32
NDO	Sodium Phosphate [Laxative]
JDI	Sodium/Potassium/Ammonium Chlorides
JDJ	Sodium/Potassium Chlorides & Sodium Lactate
BNB	Sodium Sulfoxone
GEB	Sodium Tetradecyl Sulfate
IVM	Sodium Tyropanoate
MHB	Solarcaine®
OAA	Solganal®
QAG	Solu-Cortef®
QAI	Solu-Medrol®
QKS	Somatropin
DFA	Soma®
JGC	Sorbitol
AEI	Sorbutuss®
GEB	Sotradecol®
DBB	Spacolin®
■ HFP	Sparine®
BIL	Spectinomycin
■ JHP	Spironolactone
FEF	Sponge, Absorbable Gelatin
BCJ	Sporanox®
QKB	SSKI
AEP	SSKI®
HAZ	Stadol®
QBJ	Stanozolol
BGH	Staphcillin®
MTD	Starch
■ HFV	Stelazine®
MBA	Stoxil®
FGA	Streptase®
FGA	Streptokinase
KAH	Streptokinase-Streptodornase
BIM	Streptomycin
XBL	Stresstabs
HAV	Sublimaze®
DFP	Succinylcholine
NAQ	Sucralfate
DDN	Sudafed®
HAW	Sufentanil Citrate
HAW	Sufenta®
MAH	Sulamyd®
BMC	Sulfacetamide
BMD	Sulfachlorpyridazine
BME	Sulfacytine
BMF	Sulfadiazine
MDT	Sulfadiazine Silver
BMG	Sulfamerazine
BMH	Sulfameter
BMI	Sulfamethizole

CODE	NAME
BMJ	Sulfamethoxazole
BRC	Sulfamethoxazole-Trimethoprim
BMK	Sulfamethoxypyridazine
MDM	Sulfamylon®
BML	Sulfaphenazole
BMM	Sulfapyridine
BMN	Sulfasalazine
MOF	Sulfate-Octadecanoic & Stearic Acids
JJB	Sulfinpyrazone
BMO	Sulfisomidine
BMP	Sulfisoxazole
IMB	Sulfobromophthalein [Liver Function]
BMA	Sulfonamide - Sulfonamide Combinations
MAH	Sulfonamides (Ophthalmic)
MAI	Sulfonamides (Topical)
IYS	Sulfosalicylic Acid Reagent [Protein]
MUH	Sulfur
HBU	Sulindac
IYT	Sulkowitch's Reagent [Calcium]
MAI	Sultrin®
MWH	Suluybs & Coal Tar
ADG	Super Anahist®
MOG	Superfatted Soap
BDV	Suprax®
HBI	Suprofen
HBI	Suprol®
BKJ	Suramin
NDE	Surfak®
■ HEL	Surmontil®
JKA	Sustacal
MWG	Sutilains
BKA	Symmetrel®
MEM	Synalar®
QCI	Synarel® (Nasal Solution)
XFA	Synkayvite®
MVA	Syntar®
QKC	Synthroid®
■ GCQ	Syrosingopine
KAK	t-PA
QDA	Tace®
NHA	Tagamet®
HJV	Talbutal
MTE	Talc
HAJ	Talwin®
GHH	Tambocor®
HBD	Tandearil®
MMD	Tannic Acid
BIJ	TAO®
QKF	Tapazole®
ABV	Tavist-D®
MLE	Tears®
TAO	Technetium Sulfide Tc 99m
DDR	Tedral®
BGE	Tegopen®
■ HDB	Tegretol®
AAQ	Temaril®
HGG	Temazepam
■ GCY	Tenex®
■ GGA	Tenormin®
HII	Tenuate®
BCI	Terazol 7®
■ GCA	Terazosin
DDP	Terbutaline
BCI	Terconazole
AAU	Terfenadine

CODE	NAME
AEQ	Terpin Hydrate
BHF	Terramycin®
IFA	Tes-Tape®
CDK	Teslac®
AEC	Tessalon Perles®
CDK	Testolactone
QBK	Testosterone
UAK	Tetanus & Gas Gangrene Antitoxins
UAJ	Tetanus Antitoxin
UAL	Tetanus Immune Globulin, Human
UBD	Tetanus Toxoid
MHJ	Tetracaine
BHG	Tetracycline (Oral, Injection)
MAG	Tetracycline (Topical, Ophthalmic)
MGF	Tetrahydrozoline
BCE	Tetrastatin®
DDQ	Theodur®
DDR	Theophylline Salt Combinations
DDQ	Theophylline Salts
BBH	Thiabendazole
XBJ	Thiamine
HJW	Thiamylal
■ HFT	Thiethylperazine
MDF	Thimerosal
CDL	Thio-Tepa
CBD	Thioguanine
■ JHK	Thiomerin®
HJX	Thiopental
■ HFQ	Thiopropazate
■ HFR	Thioridazine
MCN	Thiosulfate, Sodium
BMI	Thiosulfil®
■ HFS	Thiothixene
DBZ	Thiphenamil
■ HFG	Thorazine®
FEG	Thrombin
FEG	Thrombostat®
QKI	Thyroglobulin
QKJ	Thyroid
QKE	Thyrolar®
IQA	Thyrotropin [Myxedema]
BGQ	Ticarcillin
BGT	Ticarcillin/Clavulanate
BGQ	Ticar®
FAA	Ticlid®
FAA	Ticlopidine HCl
NFJ	Tigan®
BGT	Timentin®
■ MLD	Timolol (Ophthalmic)
■ GGC	Timolol (Oral)
■ MLD	Timoptic (Ophthalmic)
MCO	Tinactin®
MSD	Tincture of Benzoin, Compound
■ HFA	Tindal®
MSP	Titanium Dioxide
NAC	Titralac®
BIN	Tobramycin
GHJ	Tocainide
■ HEE	Tofranil®
QFE	Tolazamide
GDJ	Tolazoline
QFF	Tolbutamide
IFB	Tolbutamide Sodium [Diabetes]
HBP	Tolectin®
QFE	Tolinase®

CODE	NAME
HBP	Tolmetin
MCO	Tolnaftate
GHJ	Tonocard®
MEL	Topicort®
HBO	Toradol®
■ HFT	Torecan®
DDS	Tornalate®
MDJ	Torofor®
DFS	Tracrium®
DBN	Tral®
HGR	Trancopal®
■ GGB	Trandate®
■ GDR	Transderm/Nitro®
HGA	Tranxene®
■ HEJ	Tranylcypromine
NFD	Trav-Arex®
MWG	Travase®
■ HEK	Trazodone
BJE	Trecator®
FFA	Trental®
DBR	Trest®
MNE	Tretinoin
HAR	Trexan® [Studies after 189]
MCP	Triacetin
QAM	Triamcinolone Acetonide Spray
QAM	Triamcinolone (Oral, Injection, Inhalation)
MEI	Triamcinolone (Topical)
ABR	Triaminic (Phenylpropanolamine/Guaifenesin)
ABR	Triaminicin®
■ JHR	Triamterene
HGH	Triazolam
IOB	Trichinella Extract [Trichinosis]
■ JHS	Trichlormethiazide
MUI	Trichloroacetic Acid
HJY	Triclofos
HJY	Triclos®
MEV	Tridesilon®
DCB	Tridihexethyl
■ GDO	Tridil®
HDQ	Tridione®
■ HFV	Trifluoperazine
■ HFU	Triflupromazine
MBC	Trifluridine
DCC	Trihexyphenidyl
■ HFM	Trilafon®
HCD	Trilisate®
AAQ	Trimeprazine
HDQ	Trimethadione
■ GCR	Trimethaphan
NFJ	Trimethobenzamide
BRD	Trimethoprim
■ HEL	Trimipramine
ACI	Trind®
XHG	Trinsicon®
MSQ	Trioxsalen
AAR	Tripelennamine
MAI	Triple Sulfa®
AAS	Triprolidine
BIL	Trobicin®
DBZ	Trocinate®
BIO	Troleandomycin
JBD	Tromethamine [Alkalinizing Agent]
MHT	Tronothane HCl®
MJI	Tropicamide
KAI	Trypsin, Crystallized

CODE	NAME
IOC	Tuberculin
DFQ	Tubocurarine
NAC	Tums®
AEJ	Tusscidin®
AEL	Tussionex®
HGT	Tybamate
HAP	Tylenol #3®
HCC	Tylenol®
AES	Tyloxapol
HAP	Tylox®
UCQ	Typhoid & Paratyphoid Vaccine
UCP	Typhoid Vaccine
UCR	Typhus Vaccine
MGF	Tyzine®
BDJ	Ultracef®
BGV	Unasyn®
BGI	Unipen®
HQA	Unisom®
AFD	Unisom®
MSI	Unna's Boot®
CAI	Uracil Mustard
MNF	Urea
MDG	Urea Peroxide
DAB	Urecholine®
DBL	Urispas®
KAJ	Urokinase
BQC	Urolene®
NHZ	Ursodeoxycholic Acid
NHZ	Ursodiol®
BQF	Utibid®
UAM	Vaccinia Immune Globulin, Human
MEB	Valisone®
HGC	Valium®
QDG	Vallestril®
HJF	Valmid®
DBC	Valpin®
HDR	Valproic Acid
MER	Vancenase®
QAN	Vanceril®
BIP	Vancocin®
BIP	Vancomycin
BBJ	Vansil®
KAH	Varidase®
■ GIF	Vascor®
MGB	Vasoclear®
GDE	Vasodilan®
QKT	Vasopressin
■ GCW	Vasotec®
GFJ	Vasoxyl®
DFJ	Vecuronium Bromide
CCF	Velban®
BDG	Velosef®
DDM	Ventaire®
DDA	Ventolin®
CDN	Vepesid®
■ GIC	Verapamil
CDH	Vercyte®
BBD	Vermizine®
BBC	Vermox®
BGG	Versapen®
HND	Versed®
PCA	Versenate Disodium®
NFG	Vertrol®
■ HFU	Vesprin®
BHC	Vibramycin®
MGD	Vicks®
BKB	Vidarabine (Ophthalmic)
MBB	Vidarabine (Topical)
BKQ	Videx®
CCF	Vinblastine
CCG	Vincristine
MDJ	Vioform®
KAF	Viokase®
BIQ	Viomycin
BKB	Vira-A® (Ophthalmic)
MBB	Vira-A® (Topical)
BKE	Virazole®
MBC	Viroptic®
IFC	Visidex II Reagent Strips®
MGF	Visine®
■ GGG	Visken®
HGS	Vistaril®
XAB	Vitamin A & D Combinations
XBM	Vitamin B Complex
XBL	Vitamin B Complex w/C
XBG	Vitamin B3
XBA	Vitamin B12
XCA	Vitamin C
XDE	Vitamin D
XEA	Vitamin E Products
MNG	Vitamins A & D (Topical)
■ HEI	Vivactyl®
HID	Vivarin®
JKC	Vivonex
HBF	Voltaren®
NFE	Vontrol®
MLF	VoSol (Otic)
MEU	VoSol HC (Otic)
CDN	VP-16®
FCI	Warfarin Sodium
JIG	Water, Purified
■ HEQ	Wellbutrin®
NEH	Whiskey
MUJ	White Lotion
DEA	Wigraine®
NEI	Wine
NAM	Wingel®
QBJ	Winstrol®
MQE	Wintergreen, Oil of
MSR	Wool Fat, Hydrous (Lanolin)
DDI	Wyamine®
NIC	Wyanoid
■ GCT	Wytensin®
NDN	X-Prep®
HGU	Xanax®
JHQ	Xanthine Products
MHK	Xylocaine Viscous®
GHC	Xylocaine®
MGH	Xylometazoline
UCS	Yellow Fever Vaccine
DED	Yocon®
BAB	Yodoxin®
DED	Yohimbine HCL
BKS	Zalcitabine
NEB	Zanchol®
NHB	Zantac®
HDD	Zarontin®
■ JHM	Zaroxolyn®
HGL	Zebrax®
■ GCZ	Zestril®

CODE	NAME
BKD	Zidovudine
BDO	Zinacef®
MKG	Zinc Chloride Solution
MSI	Zinc Gelatin
MSS	Zinc Gelatin Topical
MQF	Zinc Oxide & Talc Lotions
MST	Zinc Oxide Topical
MTF	Zinc Stearate
XHB	Zinc Sulfate
MDH	Zinc Sulfate/Zinc Peroxide
MCQ	Zinc Undecylenate Topical
XHB	Zincate®
MGD	Zincfrin®
GBK	Zocor®
■ HER	Zoloft®
HBJ	Zomax®
HBJ	Zomepirac
MWA	Zostrix®
BKC	Zovirax® (Injection)
BKO	Zovirax® (Oral)
MBD	Zovirax® (Topical)
JJC	Zyloprim®

APPENDIX F

SAMPLE GUIDE TO MEDICAL QUESTIONS, FORM 5

Medical History	Have you ever been told you have or had...
Cirrhosis Alcoholic Hepatitis	elevated liver lab tests,"fatty liver",jaundice (yellow skin),enlarged liver or abdomen (ascites)
Pancreatitis	inflammation of the pancreas with severe (requiring pain meds)right-sided abdomenal pain
Alcohol related Upper Gastric Bleeding Varices	vomiting excessive amounts of blood (requiring transfusion),frequent "black" stools distended veins in esophagus,lighted scope down esophagus
Peripheral Neuropathy	weakness/loss of function of one or more extremities,tingling/numbness in hands or feet due to diabetes or other neurological problem
Cerebellar Dysfunction Encephalopathy Significant Cognitive Deficits	problems perceiving,recognizing,judging, reasoning,stupor,vertigo(dizziness),inability to coordinate muscle movement,frequent "forgetfulness",convulsions,coma
Major Psychotic, Affective,Anxiety, Personality Disorder	psychiatric history:depression,suicidal tendencies,note consistancy of answering questions,any psych admissions,medication for "nerves"
Malignancy (active)	any active cancer or history of (get a few details to determine if past ca history is likely to cause problems)
Seizure Disorder	epilepsy:on dilantin,tegretol,phenobarb,etc.
Clotting/Bleeding Disorders	anticoagulant Rx:coumadin,heparin,ASA,etc., any hospital admissions for blood clots in the deep veins of legs/lungs,history of abnormal clotting tests
Stroke (CVA)	impaired blood flow to brain due to hemorrhage/clots, causing paralysis,amnesia, inability to speak
Cerebral or Subarachnoid Hemorrhage	bleeding into brain tissue,may cause damage, esp. cognitive or motor
Myocardial Infarction	heart attack due to decrease blood flow to heart muscle and tissue dies (infarcts) if answer is yes,ask when

Medical History	Have you ever been told you have or had...
Symptomatic Ischemic Heart Disease	obstruction of the blood flow to the heart, (mainly arterial narrowing),decrease blood flow to coronary arteries = angina (chest pain)
Congestive Heart Failure	pulmonary edema (excessive fluid in lungs) excessive swelling of extremities, is pt. on digoxin or diuretics eg lasix?
Atrial Fibrillation Dysrythmia	defective rythm,abnormal rate,regularity,or sequence of cardiac activity,evident by EKG changes
Retinopathy	upon physical exam of eyes,shows scattered small hemorrhages,arteriole constriction, possible edema of optic disk
Surgically Curable or Secondary Hypertension	history of renal/kidney disease or disease process that causes HTN, but has surgical cure

APPENDIX G

STUDY DATA COLLECTION FORMS

DVA COOPERATIVE STUDY #996
PATHS

BRIEF SCREENING INSTRUMENT

The Department of Veterans Affairs is currently looking for veterans who might be eligible to participate in a research study we are conducting on risk factors for heart disease. Individuals who are eligible to participate are not easy to find. We would like you to answer the questions on this form so that we can determine if you might be eligible. Completion of this form is voluntary. Your responses will be kept confidential. If we think you might be eligible, we would like to contact you and tell you a little more about the study. If you are eligible, you will be asked if you are willing to participate. If you do not want to participate in the study it will have no effect on any of your DVA benefits. If you agree to participate, you will retain the right to withdraw from the study at any time.

1. ARE YOU A VETERAN? (CIRCLE ONE) **YES** **NO**

2. HOW OLD ARE YOU? ___ ___

3. SEX (CIRCLE ONE): **MALE** **FEMALE**

4. DO YOU DRINK COFFEE, TEA, OR COLA (COKE, PEPSI, ETC.) WITH CAFFEINE ALMOST EVERY DAY? (CIRCLE ONE)

   YES **NO**

5. ON DAYS WHEN YOU DRINK COFFEE, TEA, OR OTHER BEVERAGES CONTAINING CAFFEINE, ABOUT HOW MANY **TOTAL** CUPS AND/OR GLASSES OF THESE DO YOU DRINK?

   1 2 3 4 5 6 7 8 9 10 or more

6. DO YOU ADD SALT TO YOUR FOOD: (CIRCLE YES FOR ANY THAT APPLY TO YOU)

WHILE COOKING?	**YES**	**NO**
FOR TASTE AT THE TABLE?	**YES**	**NO**
BEFORE TASTING?	**YES**	**NO**

7. HOW MANY PACKS OF CIGARETTES DO YOU SMOKE EACH DAY? (CIRCLE ONE)

   DON'T SMOKE 1 2 3 **4 or more**

8. HAVE YOU EVER BEEN TOLD THAT YOU HAVE HIGH BLOOD PRESSURE? (CIRCLE ONE)

   YES **NO**

(SEE BACK)

DVA COOPERATIVE STUDY #996
PATHS

BRIEF SCREENING INSTRUMENT

The Department of Veterans Affairs is currently looking for veterans who might be eligible to participate in a research study we are conducting on risk factors for heart disease. Individuals who are eligible to participate are not easy to find. We would like you to answer the questions on this form so that we can determine if you might be eligible. Completion of this form is voluntary. Your responses will be kept confidential. If we think you might be eligible, we would like to contact you and tell you a little more about the study. If you are eligible, you will be asked if you are willing to participate. If you do not want to participate in the study it will have no effect on any of your DVA benefits. If you agree to participate, you will retain the right to withdraw from the study at any time.

1. ARE YOU A VETERAN? (CIRCLE ONE) **YES** **NO**

2. HOW OLD ARE YOU? ___ ___

3. SEX (CIRCLE ONE): **MALE** **FEMALE**

4. DO YOU DRINK COFFEE, TEA, OR COLA (COKE, PEPSI, ETC.) WITH CAFFEINE ALMOST EVERY DAY? (CIRCLE ONE)

   YES **NO**

5. ON DAYS WHEN YOU DRINK COFFEE, TEA, OR OTHER BEVERAGES CONTAINING CAFFEINE, ABOUT HOW MANY **TOTAL** CUPS AND/OR GLASSES OF THESE DO YOU DRINK?

   1 2 3 4 5 6 7 8 9 10 or more

6. DO YOU ADD SALT TO YOUR FOOD: (CIRCLE YES FOR ANY THAT APPLY TO YOU)

WHILE COOKING?	**YES**	**NO**
FOR TASTE AT THE TABLE?	**YES**	**NO**
BEFORE TASTING?	**YES**	**NO**

7. HOW MANY PACKS OF CIGARETTES DO YOU SMOKE EACH DAY? (CIRCLE ONE)

   DON'T SMOKE **1** **2** **3** **4 or more**

8. HOW MANY DAYS EACH WEEK DO YOU **USUALLY** EAT BACON, SAUSAGE, HAM, LUNCHEON MEATS, OR FRIED FOOD?

   0 1 2 3 4 5 6 7

(SEE BACK)

9. DO YOU USUALLY DRINK ALCOHOLIC BEVERAGES, INCLUDING BEER, WINE, AND LIQUOR, AT LEAST ONCE EVERY WEEK? (CIRCLE ONE ANSWER BELOW)

YES **NO** (If you answered NO, please skip to Question 12.)

IN THE FOLLOWING QUESTION, ONE DRINK = *ONE GLASS OF WINE*
= *ONE CAN, GLASS OR BOTTLE OF BEER*
= *ONE MIXED DRINK*
= *ONE SHOT OF LIQUOR*

10. ON DAYS WHEN YOU DRINK, HOW MANY DRINKS DO YOU USUALLY HAVE? (CIRCLE ONE)

1 2 3 4 5 6 7 8 9 10 or more

11. OVER THE PAST SIX MONTHS, HOW MANY DAYS PER WEEK DID YOU TYPICALLY DRINK LIKE THIS? (CIRCLE ONE)

1 2 3 4 5 6 7

12. HOW MANY DAYS PER WEEK DO YOU PERFORM EXERCISE THAT WORKS UP A SWEAT AND INCREASES YOUR BREATHING AND HEART RATE FOR AT LEAST 15 MINUTES? (CIRCLE ONE)

0 1 2 3 4 5 6 7

IN ORDER TO CONTACT YOU ABOUT POSSIBLE PARTICIPATION IN THIS STUDY, WE WOULD LIKE TO HAVE THE FOLLOWING INFORMATION:

NAME: _____

MAILING ADDRESS: _____

_____

HOME TELEPHONE: AREA CODE _____ NUMBER _____

SOCIAL SECURITY NUMBER: __ __ __ - __ __ - __ __ __ __

THANK YOU VERY MUCH FOR COMPLETING THIS QUESTIONNAIRE.

SOURCE __ __

ID __ __ __ __ __

DVA COOPERATIVE STUDY #996 - PATHS

FORM 1 - BRIEF SCREENING INSTRUMENT LOG

Medical Center Name ______________________________ Medical Center No. ___ ___ ___

Form Completed By ______________________________ Date Completed ___ ___ (Mo) ___ ___ (Day) ___ ___ (Yr)

Participant Number	Q.1 Veteran 1=Yes, 2=No	Q.2 Age	Q.3 Sex 1=Male 2=Female	Alcohol Use: Q.9 1=Yes 2=No	Alcohol Use: Q.10 (Enter No.)	Alcohol Use: Q.11 (Enter No.)	Race 1=Black 2=Nonblack	Source (Code)	Eligible 1=Yes 2=No
_ _ _ _ _	_	_ _	_	_	_ _	_	_	_ _	_
_ _ _ _ _	_	_ _	_	_	_ _	_	_	_ _	_
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_ _ _ _ _	_	_ _	_	_	_ _	_	_	_ _	_

PI's Signature ______________________________

DVA COOPERATIVE STUDY #996
PATHS

FORM 2
DATA COLLECTION FORM

Medical Center Name _____ Medical Center No. __ __ __

Participant Name _____ Participant No. __ __ __ __ __

Form Completed By _____ Date Completed __ __ __ __ __ __
Mo Day Yr

CODE APPROPRIATE RATING PERIOD ..... __ __

SCREENING: S1=91 S2=92 S3=93 FOLLOW-UP MONTH: 01 02 03 04 05 06 09 12 15 18 21 24

IF INTERIM VISIT, ENTER INTERIM VISIT NUMBER ..... __ __

1. DID PARTICIPANT COME IN FOR THIS VISIT? (1=Yes, 2=No) ..... ____

IF NO, EXPLAIN _____

2. PREPARATION FOR BLOOD PRESSURE MEASUREMENTS

a. Time of day ..... __ __:__ __ AM / PM

WAIT FIVE MINUTES

b. Room temperature ..... __ __ °F

c. Arm circumference .. (Code: 1=Right arm, 2=Left arm) ..... __ __ cm ____

d. Cuff size (code) ..... _____
1=Small adult (<25 cm) 3=Large adult (33-41 cm)
2=Adult (25-32 cm) 4=Thigh (>41 cm)

e. Resting 30-second heart rate ..... __ __ / 30 sec.

f. Resting one-minute heart rate (2 x e) ..... __ __ __ / 1 min.

g. Pulse obliteration pressure (using standard mercury manometer) .... __ __ __ mm Hg

+ 3 0

h. Maximum zero ..... + __ __ mm Hg

i. Random zero peak inflation level ..... __ __ __ mm Hg

j. Certification number of random zero device ..... __ __ __ __

3. FIRST RANDOM ZERO SITTING BLOOD PRESSURE SBP / DBP

a. Reading ..... __ __ __ / __ __ __ mm Hg

b. Zero value ..... __ __ / __ __

c. Corrected value (a - b) ..... __ __ __ / __ __ __ mm Hg

WAIT 30 SECONDS

4. SECOND RANDOM ZERO SITTING BLOOD PRESSURE SBP / DBP

a. Reading ..... __ __ __ / __ __ __ mm Hg

b. Zero value ..... __ __ / __ __

c. Corrected value (a - b) ..... __ __ __ / __ __ __ mm Hg

STAND PARTICIPANT AND WAIT 60 SECONDS

5. RANDOM ZERO STANDING BLOOD PRESSURE SBP / DBP

a. Reading ..... __ __ __ / __ __ __ mm Hg

b. Zero value ..... __ __ / __ __

c. Corrected value (a - b) ..... __ __ __ / __ __ __ mm Hg

 Medical Center No. __ __ __ Participant No. __ __ __ __ __

6. SUM OF 2 SITTING BLOOD PRESSURES (3c + 4c) ..... __ __ __ / __ __ __ mm Hg

7. MEAN BLOOD PRESSURES (item 6 ÷ 2) ..... __ __ __ / __ __ __ mm Hg

8. IF SCREENING VISIT, Does participant meet blood pressure inclusion criteria? (1=Yes, 2=No) ..... ____

9. HEIGHT (Screening Visit 3 ONLY) ..... __ __ inches

10. WEIGHT ..... __ __ __ lbs.

CONCURRENT MEDICATION:

Drug Name	A. Drug Code	B. Daily Dose (mg/day)
11. _____	__ __ __	__ __ __ __
12. _____	__ __ __	__ __ __ __
13. _____	__ __ __	__ __ __ __
14. _____	__ __ __	__ __ __ __
15. _____	__ __ __	__ __ __ __
16. _____	__ __ __	__ __ __ __

INTERCURRENT ILLNESS:

17. Has participant been ill, had any medical or psychiatric treatment initiated, or been hospitalized since last visit? (1=Yes, 2=No) ..... ___

IF YES, complete Form 19.

18. DATE OF NEXT VISIT ..... Mo __ __ Day __ __ Yr __ __

_____
Participating Investigator's Signature

DVA COOPERATIVE STUDY #996 **FORM 3**
PATHS **DEMOGRAPHIC CHARACTERISTICS**

Medical Center Name _____ Medical Center No. __ __ __

Participant Name _____ Participant No. __ __ __ __ __

Form Completed By _____ Date Completed __ __ __ __ __ __
Mo Day Yr

1. Please tell me your date of birth, starting with the month, the day, and then the year ..... Mo __ __ Day __ __ Yr __ __

2. Which of the following best describes your racial/ethnic background? ..... ___
   1=White, not of hispanic origin
   2=Black, African American
   3=Hispanic or Latino
   4=Asian
   5=American Indian
   6=Other, specify _____

3. Marital status ..... ___
   1=Married and living with spouse
   2=Not married, living with another
   3=Separated
   4=Widowed
   5=Divorced
   6=Never married, not living with someone

4. Including yourself, how many persons are now living in your household?
   a. Adults (18 and older) ..... ___
   b. Children (17 and younger) ..... ___

5. Are you currently self-employed or employed outside the home? (1=Yes, 2=No) ..... ___

   IF YES, ANSWER QUESTIONS 6 AND 7 AND GO TO QUESTION 11.
   IF NO, SKIP TO QUESTION 8.

6. How many hours do you work each week? ..... ___
   1=35 hrs or more 3=Less than 10 hrs
   2=10-34 hrs 4=Variable

7. What kind of work are you doing now?

   _____

8. IF NOT EMPLOYED, code main reason ..... ___
   1=Retired
   2=Permanently disabled (but not hospitalized)
   3=Temporarily disabled (but not hospitalized)
   4=Temporarily laid off
   5=Looking for a job but none available
   6=Doesn't want to work
   7=Other, specify _____

Medical Center No. __ __ __

Participant No. __ __ __ __ __

9. When was the last time you were employed? ..... Mo __ __ Yr __ __

10. What kind of work did you do then? _____

11. In some households, it is difficult to pay for basic expenses like food, transportation, and heating. How hard would you say it is for you to find money for these basics? ..... ___
    1=Very hard
    2=Somewhat hard
    3=Not very hard at all

12. How many years of education have you finished? ..... __ __

13. Do you have a high school diploma? (1=Yes, 2=No) ..... ___

14. Do you have a GED? (1=Yes, 2=No) ..... ___

15. Do you have an associate's degree, a bachelor's degree or study beyond a bachelor's degree? ..... ___
    1=No
    2=Associate's degree
    3=Bachelor's degree
    4=Beyond bachelor's degree
    Specify _____

16. Have you moved residence in the past year? (1=Yes, 2=No) ..... ___

17. Do you expect to move within the next six months? (1=Yes, 2=No) ..... ___

INTERVIEWER SHOULD NOTE EASE OF LANGUAGE ABILITY AND ANY POSSIBLE LITERACY PROBLEMS:

_____

_____

_____

_____
Participating Investigator's Signature

DVA COOPERATIVE STUDY #996
PATHS

FORM 4
ALCOHOL USE QUESTIONNAIRE (ADS-10)

Medical Center Name _____ Medical Center No. __ __ __

Participant Name _____ Participant No. __ __ __ __ __

Form Completed By _____ Date Completed __ __ __ __ __ __
Mo Day Yr

1. HAVE YOU HAD "SHAKES" WHEN SOBERING UP (HANDS TREMBLE, SHAKE INSIDE) AS A RESULT OF DRINKING? ..... _____
   0 = No
   1 = Yes, sometimes
   2 = Yes, almost every time I drink

2. DO YOU GET PHYSICALLY SICK (E.G., VOMIT, STOMACH CRAMPS) AS A RESULT OF DRINKING? ..... _____
   0 = No
   1 = Sometimes
   2 = Almost everytime I drink

3. DO YOU PANIC BECAUSE YOU FEAR YOU MAY NOT HAVE A DRINK WHEN YOU NEED IT? ..... _____
   0 = No 1 = Yes

4. HAVE YOU HAD BLACKOUTS ("LOSS OF MEMORY" WITHOUT PASSING OUT) AS A RESULT OF DRINKING? ..... _____
   0 = No, never 2 = Often
   1 = Sometimes 3 = Almost every time I drink

5. DO YOU CARRY A BOTTLE WITH YOU OR KEEP ONE CLOSE AT HAND? ..... _____
   0 = No
   1 = Some of the time
   2 = Most of the time

6. HAVE YOU PASSED OUT AS A RESULT OF DRINKING? ..... _____
   0 = No
   1 = Sometimes
   2 = Almost every time

7. AS A RESULT OF BEING DRUNK, HAS YOUR THINKING BEEN FUZZY OR UNCLEAR? ..... _____
   0 = No 2 = Yes, for one or two days
   1 = Yes, but only for a few hours 3 = Yes, for many days

8. CAN YOU DRINK MORE THAN YOU USED TO BEFORE GETTING DRUNK? ..... _____
   0 = No 1 = Yes

9. HAVE YOU HAD WEIRD AND FRIGHTENING SENSATIONS WHEN DRINKING? ..... _____
   0 = No
   1 = Yes, perhaps once or twice
   2 = Yes, often

10. AFTER TAKING ONE OR TWO DRINKS, CAN YOU USUALLY STOP? ..... _____
    0 = Yes 1 = No

_____
Participating Investigator's Signature

VA FORM 10-29010(NR)d
AUGUST 1990

DVA COOPERATIVE STUDY #996
PATHS

FORM 5
MEDICAL HISTORY

Medical Center Name _____ Medical Center No. __ __ __

Participant Name _____ Participant No. __ __ __ __ __

Form Completed By _____ Date Completed __ __ / __ __ / __ __ (Mo / Day / Yr)

1. HAVE SCREENING CONSENT AND VA 10-1086 BEEN SIGNED? (1 = Yes, 2 = No) ..... ___

2. PARTICIPANT'S SOCIAL SECURITY NUMBER ..... __ __ __ __ __ __ __ __ __

MEDICAL HISTORY IS THERE A HISTORY OF:	CODE: 1=YES 2=NO	COMMENTS
3. Cirrhosis	___	_____
4. Alcoholic hepatitis	___	_____
5. Pancreatitis	___	_____
6. Alcohol-related UGI bleeding	___	_____
7. Varices	___	_____
8. Peripheral neuropathy	___	_____
9. Cerebellar dysfunction	___	_____
10. Encephalopathy	___	_____
11. Significant cognitive deficits	___	_____
12. Psychoactive substance dependence	___	_____
13. Major psychotic disorder	___	_____
14. Major affective disorder	___	_____
15. Severe anxiety disorder	___	_____
16. Major personality disorder	___	_____
17. Malignancy (active)	___	_____
18. Seizure disorder	___	_____
19. Clotting or bleeding disorder	___	_____
20. Stroke	___	_____
21. Cerebral or subarachnoid hemorrhage	___	_____
22. Myocardial infarction	___	_____
23. Symptomatic ischemic heart disease	___	_____
24. Congestive heart failure	___	_____
25. Atrial fibrillation or other dysrhythmia	___	_____
26. Retinopathy (grade III-IV: hypertensive hemorrhages and/or exudates with or without papilledema)	___	_____
27. Surgically curable or secondary hypertension	___	_____

28. Are there any reasons for excluding the participant? (1=Yes, 2=No) ..... ___

IF YES:

a. Summary of significant medical/psychiatric diagnoses and findings that would exclude participant: _____

_____

_____

IF YES, STOP HERE. PARTICIPANT NOT ELIGIBLE FOR THE STUDY. COMPLETE FORM 20.

 Medical Center No. __ __ __ Participant No. __ __ __ __ __

HYPERTENSION TREATMENT HISTORY

29. Has the participant been previously diagnosed as having hypertension? (1=Yes, 2=No) ..... ___

IF YES:

A. How long ago was participant's hypertension first detected? (years) ..... __ __

B. How long ago was participant first treated for hypertension? (years) ..... __ __

C. When screened, was participant currently being treated for hypertension? (1=Yes, 2=No) ..... ___

LIST ALL MEDICATIONS USED FOR HYPERTENSION AT TIME OF INITIAL SCREENING.

Drug Name	A. Drug Code	B. Daily Dose (mg/day)	C. Duration 1=<1 mo 2=1 mo-6 mo 3=>6 mo <1 yr 4=>1 yr
30. _____	__ __ __	__ __ __ __	____
31. _____	__ __ __	__ __ __ __	____
32. _____	__ __ __	__ __ __ __	____
33. _____	__ __ __	__ __ __ __	____
34. _____	__ __ __	__ __ __ __	____
35. _____	__ __ __	__ __ __ __	____
36. _____	__ __ __	__ __ __ __	____
37. _____	__ __ __	__ __ __ __	____

_____
Participating Investigator's Signature

DVA COOPERATIVE STUDY #996 - PATHS **FORM 6 - LIFETIME DRINKING HISTORY**

MEDICAL CENTER NAME _____ MEDICAL CENTER NO. ____ PARTICIPANT NAME _____ PARTICIPANT NO. _____

FORM COMPLETED BY _____ DATE COMPLETED Mo ___ Day ___ Yr ___ TOTAL NUMBER OF PHASES ___

PHASE	FREQUENCY	QUANTITY Drinks/Day	TYPE (%)	STYLE (Circle One)	LIFE EVENT OR CHANGES Code: 1=Positive, 2=Negative	CONTEXT (%)	TIME (%)
PAST WEEK From Date ____ To Date ____	____ Days/Wk.	Average ___ Maximum ___	Beer ___ Liquor ___ Wine ___	1 Occasional 2 Weekend 3 Binge 4 Frequent	___ 1 Family ___ 7 Financial ___ 2 Work ___ 8 Peer Group ___ 3 School ___ 9 Drug Use ___ 4 Medical ___10 Treatment ___ 5 Residence ___11 Death ___ 6 Legal-Jail ___12 Emotional	Alone ___ With Others ___	Morning ___ Afternoon ___ Evening ___
PAST SIX MO. From Date ____ To Date ____	____ Days/Mo.	Average ___ Maximum ___	Beer ___ Liquor ___ Wine ___	1 Occasional 2 Weekend 3 Binge 4 Frequent	___ 1 Family ___ 7 Financial ___ 2 Work ___ 8 Peer Group ___ 3 School ___ 9 Drug Use ___ 4 Medical ___10 Treatment ___ 5 Residence ___11 Death ___ 6 Legal-Jail ___12 Emotional	Alone ___ With Others ___	Morning ___ Afternoon ___ Evening ___

1 Drink (approx.) = 12 oz. beer
1-1/2 oz. liquor
5 oz. wine
3 oz. fortified wine
13.6 g absolute alcohol

Liquor: 1 mickey (12 oz.) = 8 drinks
1 bottle (25 oz.) = 17 drinks

Wine: 1 bottle (25 oz.) = 5 drinks
1 bottle fortified = 8 drinks

To Calculate Drinks/Week: FREQUENCY (___ Days/Mo.) x Average QUANTITY (___ Drinks/Day) ÷ 4.3 = _____.__ Drinks/Week

PARTICIPANT MEETS ALCOHOL CONSUMPTION INCLUSION CRITERION? (CIRCLE ONE) YES NO

IF YES, COMPLETE DRINKING HISTORY. IF NO, STOP.

DVA COOPERATIVE STUDY #996 - PATHS

FORM 6 (Cont.) - LIFETIME DRINKING HISTORY

MEDICAL CENTER NAME ________ MEDICAL CENTER NO. ____ PARTICIPANT NAME ________ PARTICIPANT NO. ______

FORM COMPLETED BY ____________ DATE COMPLETED Mo ___ Day ___ Yr ___

PHASE	FREQUENCY Days/Month	QUANTITY Drinks/Day	TYPE (%)	STYLE (Circle One)	LIFE EVENT OR CHANGES Code: 1=Positive, 2=Negative	CONTEXT (%)	TIME (%)
PHASE ___ From ___ Younger Age To ___ Older Age	___	Average __ Maximum __	Beer ___ Liquor ___ Wine ___	1 Occasional 2 Weekend 3 Binge 4 Frequent	__ 1 Family __ 7 Financial __ 2 Work __ 8 Peer Group __ 3 School __ 9 Drug Use __ 4 Medical __10 Treatment __ 5 Residence __11 Death __ 6 Legal-Jail __12 Emotional	Alone ___ With Others ___	Morning ___ Afternoon ___ Evening ___
PHASE ___ From ___ Younger Age To ___ Older Age	___	Average __ Maximum __	Beer ___ Liquor ___ Wine ___	1 Occasional 2 Weekend 3 Binge 4 Frequent	__ 1 Family __ 7 Financial __ 2 Work __ 8 Peer Group __ 3 School __ 9 Drug Use __ 4 Medical __10 Treatment __ 5 Residence __11 Death __ 6 Legal-Jail __12 Emotional	Alone ___ With Others ___	Morning ___ Afternoon ___ Evening ___
PHASE ___ From ___ Younger Age To ___ Older Age	___	Average __ Maximum __	Beer ___ Liquor ___ Wine ___	1 Occasional 2 Weekend 3 Binge 4 Frequent	__ 1 Family __ 7 Financial __ 2 Work __ 8 Peer Group __ 3 School __ 9 Drug Use __ 4 Medical __10 Treatment __ 5 Residence __11 Death __ 6 Legal-Jail __12 Emotional	Alone ___ With Others ___	Morning ___ Afternoon ___ Evening ___
PHASE ___ From ___ Younger Age To ___ Older Age	___	Average __ Maximum __	Beer ___ Liquor ___ Wine ___	1 Occasional 2 Weekend 3 Binge 4 Frequent	__ 1 Family __ 7 Financial __ 2 Work __ 8 Peer Group __ 3 School __ 9 Drug Use __ 4 Medical __10 Treatment __ 5 Residence __11 Death __ 6 Legal-Jail __12 Emotional	Alone ___ With Others ___	Morning ___ Afternoon ___ Evening ___

1 Drink (approx.) = 12 oz. beer
1-1/2 oz. liquor
5 oz. wine
3 oz. fortified wine
13.6 g absolute alcohol

Liquor: 1 mickey (12 oz.) = 8 drinks
1 bottle (25 oz.) = 17 drinks

Wine: 1 bottle (25 oz.) = 5 drinks
1 bottle fortified = 8 drinks

____
Participating Investigator's Signature

VA FORM 10-29010(NR)f
AUGUST 1990

DVA COOPERATIVE STUDY #996 - PATHS

FORM 7 - PHYSICAL ACTIVITY

MEDICAL CENTER NAME _____ MEDICAL CENTER NO. __ __ __

PARTICIPANT NAME _____ PARTICIPANT NO. __ __ __ __ __

FORM COMPLETED BY _____ DATE COMPLETED Mo __ __ Day __ __ Yr __ __

CODE APPROPRIATE RATING PERIOD (MONTH) 00 (PRE) 06 12 18 24 ..... __ __

READ TO PARTICIPANT: These questions are about physical exercise. In the PAST SEVEN DAYS, have you done any of the following exercises, sports, or physically active hobbies?

	CODE: 1 = YES 2 = NO	A. How many TIMES in the past week did you (play/go/do) this activity? CODE: TIMES	B. On the average, about how many MINUTES did you actually spend on this activity on each occasion? CODE: MINUTES	C. What usually happened to your heart rate or breathing when you did this activity? Did you have a small, moderate, or large increase, or no increase at all in your heart rate or breathing? CODE: 1 = SMALL 2 = MODERATE 3 = LARGE 4 = NONE
1. WALKING FOR EXERCISE ...	____	1A. __ __	1B. __ __ __	1C. ____
2. JOGGING/RUNNING	____	2A. __ __	2B. __ __ __	2C. ____
3. HIKING	____	3A. __ __	3B. __ __ __	3C. ____
4. GARDENING/YARD WORK	____	4A. __ __	4B. __ __ __	4C. ____
5. AEROBICS/AEROBIC DANCING	____	5A. __ __	5B. __ __ __	5C. ____
6. OTHER DANCING	____	6A. __ __	6B. __ __ __	6C. ____
7. CALISTHENICS OR GENERAL EXERCISE	____	7A. __ __	7B. __ __ __	7C. ____
8. GOLF	____	8A. __ __	8B. __ __ __	8C. ____
9. TENNIS	____	9A. __ __	9B. __ __ __	9C. ____
10. BOWLING	____	10A. __ __	10B. __ __ __	10C. ____
11. BIKING	____	11A. __ __	11B. __ __ __	11C. ____
12. SWIMMING/WATER EXERCISES	____	12A. __ __	12B. __ __ __	12C. ____
13. YOGA	____	13A. __ __	13B. __ __ __	13C. ____
14. WEIGHT LIFTING/TRAINING	____	14A. __ __	14B. __ __ __	14C. ____
15. BASKETBALL	____	15A. __ __	15B. __ __ __	15C. ____
16. BASEBALL/SOFTBALL	____	16A. __ __	16B. __ __ __	16C. ____
17. FOOTBALL	____	17A. __ __	17B. __ __ __	17C. ____
18. SOCCER	____	18A. __ __	18B. __ __ __	18C. ____
19. VOLLEYBALL	____	19A. __ __	19B. __ __ __	19C. ____
20. HANDBALL, RACQUETBALL, OR SQUASH	____	20A. __ __	20B. __ __ __	20C. ____
21. SKATING	____	21A. __ __	21B. __ __ __	21C. ____
22. SKIING	____	22A. __ __	22B. __ __ __	22C. ____

Have you done any (other) exercises, sports or physically active hobbies in the past week (that I haven't mentioned)? (1=Yes, 2=No)

23. Anything else?	____ (IF YES, DESCRIBE BELOW)			
24. _____	24A. __ __	24B. __ __ __	24C. ____	
25. _____	25A. __ __	25B. __ __ __	25C. ____	

Signature of Participating Investigator _____

VA FORM 10-29010(NR)g

AUGUST 1990

Medical Center Name _____ Medical Center No. __ __ __

Participant Name _____ Participant No. __ __ __ __ __

Form Completed By _____ Date Completed __ __ __ __ __ __
Mo Day Yr

CODE APPROPRIATE RATING PERIOD (MONTH) ..... __ __

CODE: 00 (PRE) 06 12 18 24

1. How would you rate your general state of health during the past six months? ..... ___
   1=Excellent 4=Fair
   2=Very good 5=Poor
   3=Good

SMOKE HABITS

2. Have you ever smoked? (1=Yes, 2=No) ..... ___
   IF NO, skip to Q. 10.

3. Do you currently smoke cigarettes? (1=Yes, 2=No) ..... ___
   a. IF NO, when did you stop smoking? ..... Mo __ __ Yr __ __
   (SKIP TO Q. 10)

4. How many cigarettes do you smoke each day? ..... __ __ __

5. Do you inhale? (1=Never, 2=Sometimes, 3=Always) ..... ___

6. Do you smoke more during the morning than during the rest of the day? (1=Yes, 2=No) ..... ___

7. How soon after you wake up do you smoke your first cigarette? ..... ___
   1=Less than 15 minutes 3=Within 2 hours
   2=Within 1 hour 4=Greater than 2 hours

8. Do you find it difficult to refrain from smoking in places where it is forbidden (work, cinema, airplanes, etc.)? (1=Yes, 2=No) ..... ___

9. Do you smoke if you are so ill that you are in bed most of the day? (1=No, 2=Yes, but lesser amount, 3=Yes, the same) ..... ___

10. Do you use chewing tobacco, snuff or other smokeless tobacco? (1=Yes, 2=No) ..... ___
    a. How often each day? ..... __ __

CAFFEINE

11. On a typical day, how many cups of regular coffee do you drink? ..... __ __
    1=One or two 4=Seven +
    2=Three or four 5=None
    3=Five or six

12. On a typical day, how many cups of tea do you drink? ..... __ __
    1=One or two 4=Seven +
    2=Three or four 5=None
    3=Five or six

13. On a typical day, how many glasses of cola or caffeine-containing soft drinks do you drink? ..... __ __
    1=One or two
    2=Three or four
    3=Five or six
    4=Seven +
    5=None (GO TO Q.15)

14. How often did you drink this much coffee/tea/cola per day in the last six months? ..... ___
    1=Every day or almost every day
    2=About once a week
    3=About once a month
    4=Several times in the last six months

EXERCISE

15. What kind of exercise do you get during a typical day AT WORK? ..... ___
    1=Do not work
    2=Usually sit during the day and do not walk very much
    3=Stand or walk about quite a lot but do not lift or carry things very often
    4=Usually lift or carry light loads or have to climb stairs or hills often
    5=Often lift or carry heavy loads

16. What kind of exercise do you get during a typical day when you are not at work or if you are not working now? ..... ___
    1=Usually sit during the day and do not walk very much
    2=Stand or walk about quite a lot but do not lift or carry things very often
    3=Usually lift or carry light loads or have to climb stairs or hills often

17. About how many flights of stairs do you climb each day? ..... __ __

18. How many times per week do you engage in any regular physical activity such as brisk walking, jogging, bicycling, etc. long enough to work up a sweat? ..... __ __

19. Compared to other men your age, how would you rate your physical activity? ..... ___
    1=Not very active
    2=Moderately active
    3=Very active

20. Has your physical activity changed during the past three months? ..... ___
    1=No, remains the same
    2=Less active, explain _____
    3=More active, explain _____

MEDICATIONS

During the past six months, how often have you used any of the following medications or drugs: USE CODES BELOW

(0=Never, 1=Less than monthly, 2=Monthly, 3=Weekly, 4=Daily or almost daily)

21. Allergy pills ..... ___
22. Amphetamines (uppers) ..... ___
23. Antibiotics ..... ___
24. Antidepressants ..... ___
25. Aspirin ..... ___
26. Diet pills ..... ___
27. Laxatives ..... ___
28. Pain killers ..... ___
29. Sleeping pills ..... ___
30. Medicine for indigestion ..... ___
31. Tranquilizers ..... ___
32. Vitamins ..... ___
33. Marijuana ..... ___
34. Cocaine ..... ___

STRESS

35. Some people live a calm, predictable life. Others find themselves facing unexpected changes, frequent interruptions, inconveniences, or "things going wrong." How often are you faced with these minor (or major) annoyances or frustrations? ..... ___
    1=Once a month or less
    2=Once a week
    3=A few times a week
    4=About once a day
    5=Several times a day

36. When you are under pressure or stress, what do you usually do? ..... ___
    1=Do something about it immediately
    2=Plan carefully before taking any action
    3=Do nothing at all

37. Some people easily get angry with others around them because of problems or just because they are not feeling happy. During the past six months, how often have you gotten into an argument with a fellow worker, friend, or family member that ended in yelling or loud shouting? ..... ___
    1=Once a month or less
    2=Once a week
    3=A few times a week
    4=About once a day
    5=Several times a day

38. During the past six months, about how often have you been in an argument or disagreement in which you or another person hit, slapped or shoved? ..... ___
    1=Once a month or less
    2=Once a week
    3=A few times a week
    4=About once a day
    5=Several times a day

SOCIAL NETWORKS

39. About how many friends do you have, people you know more than just casually? ..... __ __

40. How many close friends do you have, people you feel at ease with and can talk with about personal problems? ..... __ __

41. How many people do you know from whom you can expect real help in times of trouble? (include family and friends) ..... __ __

42. Is there a member of your family, other than those in your household, who lives less than 1 hour's travel (car, bus) from you? (1=Yes, 2=No) ..... __

43. How many clubs and organizations (e.g., church group, VFW, PTA, bowling team, etc.) do you belong to? ..... __ __

44. In the last month, how often did you attend religious services? ..... __ __

45. In the last month, how often did you read a book, magazine, or newspaper? ..... __ __

46. During the last month, how many times did you get together with one or more friends? ..... __ __

47. During the last month, how many times did you visit with relatives? ..... __ __

COPING FUNCTION AND ALCOHOL

Here are some different reasons people have for drinking alcohol. Thinking of yourself and your reasons, how true are each of these reasons for you personally? (Choices are very true, true, not true.)

1=Very True 2=True 3=Not True

48. A drink helps me relax ..... __
49. I drink to be sociable ..... __
50. A drink helps me to forget my worries ..... __
51. A drink helps me gain self-confidence ..... __
52. A drink helps cheer me up when I am in a bad mood ..... __
53. A drink helps me when I am lonesome ..... __
54. I like the way a drink tastes ..... __
55. I drink when I am bored ..... __
56. I am used to drinking often ..... __

SLEEP

In the past six months:

57. On the average, how many hours of sleep have you gotten each night? ..... __ __

58. Do you have difficulty falling asleep? (1=Yes, 2=No) ..... ___

59. Do you find yourself waking up during the night? (1=Yes, 2=No) ..... ___

60. Do you snore? (1=Never, 2=Rarely, 3=Sometimes, 4=Often) ..... ___

SEXUAL FUNCTION

61. Thinking of your current sex life, how would you describe it? ..... ___

1=Could not be better	6=Somewhat inadequate
2=Excellent	7=Poor
3=Good	8=Highly inadequate
4=Above average	9=Could not be worse
5=Adequate	

62. How often do you have sexual intercourse now? ..... ___

1=Not at all	5=More than once a week
2=Less than once per week	6=Once a day
3=Once or twice a month	7=More than once a day
4=Once a week	

63. How often would you like to have sexual intercourse now? ..... ___

1=Not at all	5=More than once a week
2=Less than once per week	6=Once a day
3=Once or twice a month	7=More than once a day
4=Once a week	

Participating Investigator's Signature

DVA COOPERATIVE STUDY #996
PATHS

FORM 10
LOCAL LABORATORY DATA

Medical Center Name _____ Medical Center No. __ __ __

Participant Name _____ Participant No. __ __ __ __ __

Form Completed By _____ Date Completed __ __ __ __ __ __
Mo Day Yr

CODE APPROPRIATE RATING PERIOD (MONTH) ..... __ __

CODE: 00 (PRE) 06 12 18 24

1. Hemoglobin (g) ..... __ __.__
2. Hematocrit (%) ..... __ __.__
3. WBC (total neutrophils, lymphocytes) ($x10^3$ cells/mm^3) ..... __ __.__
4. Platelets ($x10^3/mm^3$) ..... __ __ __ __
5. Mean cell volume (MCV) (μ^3) ..... __ __ __
6. Mean cell hemoglobin (MCH) ($\mu\mu g$) ..... __ __
7. Mean cell hemoglobin concentration (MCHC) (%) ..... __ __

8. Creatinine (mg %) ..... __ __.__
9. Urea nitrogen (BUN) (mg %) ..... __ __ __
10. Sodium (mEq/L) ..... __ __ __
11. Potassium (mEq/L) ..... __ __.__
12. Bicarbonate (HCO_3 or CO_2) (mEq/L) ..... __ __.__
13. Chloride (mEq/L) ..... __ __ __
14. Glucose (mg %) ..... __ __ __
15. Cholesterol (mg %) ..... __ __ __
16. Uric acid (mg %) ..... __ __.__
17. Calcium (mg %) ..... __ __.__
18. Phosphorus (mg%) ..... __ __.__
19. Magnesium (mg %) ..... __ __.__
20. AST (SGOT) (U/L) ..... __ __ __
21. Alkaline phosphatase (U/L) ..... __ __ __ __
22. LDH (U/L) ..... __ __ __ __
23. Albumin (g %) ..... __ __.__
24. Bilirubin (mg %) ..... __ __.__
25. Prothrombin time (sec.) ..... __ __.__ / __ __.__
(patient) (control)

VA FORM 10-29010(NR)j
AUGUST 1990

Medical Center No. __ __ __

Participant No. __ __ __ __ __

Urinalysis:

26. Glucose (1=None, 2=Trace, 3=1+, 4=2+, 5=3+, 6=4+) ..... ___

27. Protein (1=None, 2=Trace, 3=1+, 4=2+, 5=3+, 6=4+) ..... ___

COMMENT ON ANY SIGNIFICANT ABNORMALITIES: _____

_____

_____

Overnight Urine:

28. Date of specimen ..... Mo __ __ Day __ __ Yr __ __

29. Time begun/time completed ..... __ __:__ __ am/pm TO __ __:__ __ am/pm

30. Urine volume (ml) ..... __ __ __ __

31. Urine creatinine concentration (mg/dl) ..... __ __ __

32. Urine sodium concentration (mEq/L) ..... __ __ __

33. Urine potassium concentration (mEq/L) ..... __ __ __

34. Urine magnesium concentration (mEq/L) ..... __ __.__

Urine Drug Screen: (CODE: 1=Positive, 2=Negative)

35. Marijuana ..... ___

36. Cocaine ..... ___

37. Opiates ..... ___

38. Amphetamines ..... ___

39. Barbiturates ..... ___

40. Benzodiazepines ..... ___

Electrocardiogram: (NOT TO BE DONE AT 18-MONTH FOLLOW-UP VISIT)

41. Date obtained ..... Mo __ __ Day __ __ Yr __ __

42. ECG (1=Normal, 2=Abnormal) ..... ___

43. Mechanism ..... ___

1=Sinus 2=Other, specify _____

44. ST-T wave abnormalities (1=Absent, 2=Present) ..... ___

a. If present, specify _____

45. Old MI (1=Absent, 2=Present) ..... ___

a. If present, specify _____

46. LVH (1=Absent, 2=Present) ..... ___

47. SV_1 (mV) ..... __.__

48. $RV_{5 \text{ or } 6}$ (mV) ..... __.__

49. Strain (1=Yes, 2=No) ..... ___

50. Other abnormality? (1=Yes, 2=No) ..... ___

a. If yes, specify _____

_____

Participating Investigator's Signature

DVA CSP #996 - PATHS

FORM 10A - QUALITY CONTROL SAMPLES - OVERNIGHT URINES

MEDICAL CENTER NO. __ __ __

DATE SENT: MO __ __ DAY __ __ YR __ __

		CONCENTRATIONS			
PARTICIPANT NO.	RATING PERIOD	CREATININE (mg/dl)	SODIUM (mEq/L)	POTASSIUM (mEq/L)	MAGNESIUM (mEq/L)
__ __ __ __ __	__ __	__ __ __	__ __ __	__ __ __	__ __.__
__ __ __ __ __	__ __	__ __ __	__ __ __	__ __ __	__ __.__
__ __ __ __ __	__ __	__ __ __	__ __ __	__ __ __	__ __.__
__ __ __ __ __	__ __	__ __ __	__ __ __	__ __ __	__ __.__
__ __ __ __ __	__ __	__ __ __	__ __ __	__ __ __	__ __.__
__ __ __ __ __	__ __	__ __ __	__ __ __	__ __ __	__ __.__
__ __ __ __ __	__ __	__ __ __	__ __ __	__ __ __	__ __.__
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__ __ __ __ __	__ __	__ __ __	__ __ __	__ __ __	__ __.__
__ __ __ __ __	__ __	__ __ __	__ __ __	__ __ __	__ __.__

VA FORM 10-29010(NR)j(a)
AUGUST 1990

DVA COOPERATIVE STUDY #996
PATHS

FORM 11
PHYSICAL EXAMINATION

Medical Center Name _____ Medical Center No. __ __ __

Participant Name _____ Participant No. __ __ __ __ __

Form Completed By _____ Date Completed __ __ __ __ __ __
Mo Day Yr

1. Review of medical history with participant, including medications, nonalcohol substance use. Record relevant data and any reason(s) for exclusion:

_____

_____

PHYSICAL FINDINGS. Indicate within normal limits (1=WNL or absent) or abnormal findings (2=Abnormal). Please comment on abnormal findings below.

2. Head, ears, nose, throat, eyes (including optic fundi) (1=WNL, 2=Abnormal) ..... ___
3. Neck (1=WNL, 2=Abnormal) ..... ___
4. Lungs (1=WNL, 2=Abnormal) ..... ___
5. Heart:
   a. Rhythm (1=Regular, 2=Other) ..... ___
   b. Murmur (1=None, 2=Systolic, 3=Diastolic, 4=Both) ..... ___
   c. Gallop (1=None, 2=S_3 only, 3=S_4 only, 4=S_3 and S_4) ..... ___
6. Abdomen (1=WNL, 2=Abnormal) ..... ___
   a. Record liver span (cm) in mid-clavicular line ..... __ __
7. Rectal, prostate (if indicated) (1=WNL, 2=Abnormal, 3=Not Done) ..... ___
8. Extremities (1=WNL, 2=Abnormal) ..... ___
   a. Edema (1=Present, 2=Absent) ..... ___
   b. Peripheral pulses (1=WNL, 2=Abnormal) ..... ___
9. Lymphatics (1=WNL, 2=Abnormal) ..... ___
10. Neurological (1=WNL, 2=Abnormal) ..... ___
11. Skin (1=WNL, 2=Abnormal) ..... ___
12. Mental status (1=WNL, 2=Abnormal) ..... ___
13. Chest x-ray (1=Normal, 2=Abnormal) ..... ___
14. Date of chest x-ray ..... Mo __ __ Day __ __ Yr __ __

COMMENTS: _____

_____

_____

_____

15. Have study consent and VA Form 10-1086 been signed? (1=Yes, 2=No) ..... ___
16. Are there any reasons for excluding the participant? (1=Yes, 2=No) ..... ___

IF YES:

a. Summarize significant medical/psychiatric diagnoses and findings that would exclude participant: _____

_____

_____

COMPLETE FORM 20 FOR ALL EXCLUDED PARTICIPANTS.

_____
Participating Investigator's Signature

DVA COOPERATIVE STUDY #996 - PATHS

FORM 12 - DIET QUESTIONNAIRE

Medical Center Name ______________________ Medical Center No. __ __ __

Participant Name ______________________ Participant No. __ __ __ __ __

Form Completed By ______________________ Date Completed __ __ __ __ __ __ (Mo Day Yr)

CODE APPROPRIATE RATING PERIOD (MONTH) 00 (PRE) 03 06 12 18 24 __ __

This form asks you a variety of questions about your background, environment, and habits, which may affect or be related to your health. The information you provide will help scientists to understand more about the causes of disease. This questionnaire will take about 12-15 minutes to complete. Please fill in the information requested, or place a check in the appropriate space. If you are not sure about an answer, please estimate.

THIS SPACE FOR OFFICE USE

TODAY'S DATE: [Month] - [Day] - [Year] (11–16)

Please PRINT YOUR NAME (name of study participant)

17 LAST 31 FIRST 40 MIDDLE 48

A __ (79 80)

1-10*

ADDRESS: 11 STREET 34

35 CITY 49 STATE 52 ZIP 61

62 __ __ State Code

TELEPHONE: (64) - - 73

B __ (79 80)

11

1. When were you born? ___/___/___ Month Day Year

2. How old are you? ____ years — 18 __ __

3. Sex: 1 ___ Male 2 ___ Female — 20 __

4. Race or ethnic background:
   - 1 ___ White, not of Hispanic origin
   - 2 ___ Black, not of Hispanic origin
   - 3 ___ Hispanic
   - 4 ___ American Indian/Alaskan native
   - 5 ___ Asian
   - 6 ___ Pacific Islander

21 __

5. Please circle the highest grade in school you have completed:
   1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17+

22 __ __

6. How tall are you? ____ feet ____ inches 7. How much do you weigh? _____ pounds

24

8. Do you smoke cigarettes now? 1 ___ No 2 ___ Yes — 30 __

IF YES: On the average, about how many cigarettes a day do you smoke now? ____ cigarettes — 31 __ __

9. During the past year, have you taken any vitamins or minerals?
1 __ No 2 __ Yes, fairly regularly 3 __ Yes, but not regularly If Yes, → 33 __

What do you take fairly regularly?	# of PILLS per DAY, WEEK, etc.		
Multiple Vitamins			
One-a-day type	_____ pills per _____		34 ___
Stress-tabs type	_____ pills per _____		37 ___
Therapeutic, Theragran type	_____ pills per _____	How many milligrams or IUs per pill?	40 ___
Other Vitamins			
Vitamin A	_____ pills per _____	_____ IU per pill	43 ___
Vitamin C	_____ pills per _____	_____ mg per pill	47 ___
Vitamin E	_____ pills per _____	_____ IU per pill	51 ___
Calcium or dolomite	_____ pills per _____	_____ mg per pill	55 ___

Other (What?) 1 __ Yeast 2 __ Selenium 3 __ Zinc 4 __ Iron 5 __ Beta-carotene
6 __ Cod liver oil 7 __ Other _____ 59 __

Please list the brand of multiple vitamin/mineral you usually take: _____

C
79 80

10. This section is about your *usual* eating habits. Thinking back over the past year, how often do you usually eat the foods listed on the next page?

First, check (✓) whether your usual serving size is small, medium or large. (A small portion is about one-half the medium serving size shown, or less; a large portion is about one-and-a-half times as much, or more.)

Then, put a *NUMBER* in the most appropriate column to indicate *HOW OFTEN*, on the average, you eat the food. You may eat bananas *twice a week* (put a *2 in the "week"* column). If you never eat the food, check "Rarely/Never." Please DO NOT SKIP foods. And please BE CAREFUL which column you put your answer in. It will make a big difference if you say "Hamburger once a day" when you mean "Hamburger once a week"!

One item says "in season." Indicate how often you eat this just in the 2-3 month time when that food is in season. (Be careful about overestimating here.)
Please look at the *example* below. This person
1) eats a medium serving of cantaloupe once a week, in season.
2) has ½ grapefruit about twice a month.
3) has a small serving of sweet potatoes about 3 times a year.
4) has a large hamburger or cheeseburger or meat loaf about four times a week.
5) never eats liver.

EXAMPLE:

	Medium Serving	Your Serving Size			How often?				
		S	M	L	Day	Week	Month	Year	Rarely/ Never
Cantaloupe (in season)	¼ medium		✓			1			
Grapefruit	(½)		✓				2		
Sweet potatoes, yams	½ cup	✓						3	
Hamburger, cheeseburger, meat loaf	1 medium			✓		4			
Liver	4 oz.								✓

FOR OFFICE USE
Q 9, mg or IU: 1 = 50-100 2 = 200-250 3 = 400-500 4 = 1000 5 = 5000 6 = 10,000 7 = 20,000-25,000 8 = 50,000 9 = Unk.

On the following two pages, code the four characters for each food as follows:

__ S-1 M-2 L-3 NS-9

__ __ No. Times NS-99

__ Da-1 Wk-2 Mo-3 Yr-4 Nev-5 NS-9

If respondent places a checkmark in the "How often" columns, **do not** impute "01", once. Instead, code "99", Not Stated. If respondent does not check a portion size, **do not** impute medium, but code "9".

	Medium Serving	Your Serving Size			How often?					OFFICE USE
					Day	Week	Month	Year	Rarely/ Never	
FRUITS & VEGETABLES		S	M	L						
EXAMPLE – Apples, applesauce, pears	(1) or ½ cup		✓			4				
Apples, applesauce, pears	(1) or ½ cup									11
Cantaloupe (in season)	¼ medium									15
Oranges	1 medium									19
Orange juice or grapefruit juice	6 oz. glass									23
Grapefruit	(½)									27
Other fruit juices, fortified fruit drinks	6 oz. glass									31
Beans such as baked beans, pintos, kidney, limas, or in chili	¾ cup									35
Tomatoes, tomato juice	(1) or 6 oz.									39
Broccoli	½ cup									43
Spinach	½ cup									47
Mustard greens, turnip greens, collards	½ cup									51
Cole slaw, cabbage, sauerkraut	½ cup									55
Carrots, or mixed vegetables containing carrots	½ cup									59
Green salad	1 med. bowl									63
Salad dressing, mayonnaise (including on sandwiches)	2 Tblsp.									67
French fries and fried potatoes	¾ cup									71
Sweet potatoes, yams	½ cup									75 D 79 80
Other potatoes, incl. boiled, baked, potato salad, mashed	(1) or ½ cup									11
Rice	¾ cup									15
MEAT, MIXED DISHES, LUNCH ITEMS		S	M	L	Da	Wk	Mo	Yr	Nv	
Hamburgers, cheeseburgers, meat loaf	1 medium									19
Beef—steaks, roasts	4 oz.									23
Beef stew or pot pie with carrots, other vegetables	1 cup									27
Liver, including chicken livers	4 oz.									31
Pork, including chops, roasts	2 chops or 4 oz.									35
Fried chicken	2 sm. or 1 lg. piece									39
Chicken or turkey, roasted, stewed or broiled	2 sm. or 1 lg. piece									43
Fried fish or fish sandwich	4 oz. or 1 sand.									47
Other fish, broiled, baked	4 oz.									51
Spaghetti, lasagna, other pasta with tomato sauce	1 cup									55
Hot dogs	2 dogs									59
Ham, lunch meats	2 slices									63
Vegetable soup, vegetable beef, minestrone, tomato soup	1 med. bowl									67
BREADS / SALTY SNACKS / SPREADS		S	M	L	Da	Wk	Mo	Yr	Nv	
White bread (including sandwiches), bagels, etc., crackers	2 slices, 3 cracks									71
Dark bread, including whole wheat, rye, pumpernickel	2 slices									75 E 79 80
Corn bread, corn muffins, corn tortillas	1 med. piece									11
Salty snacks (such as chips, popcorn)	2 handfuls									15
Peanuts, peanut butter	2 Tblsp.									19
Margarine on bread or rolls	2 pats									23
Butter on bread or rolls	2 pats									27
BREAKFAST FOODS		S	M	L	Da	Wk	Mo	Yr	Nv	
High fiber, bran or granola cereals, shredded wheat	1 med. bowl									31
Highly fortified cereals, such as Product 19, Total, or Most	1 med. bowl									35
Other cold cereals, such as Corn Flakes, Rice Krispies	1 med. bowl									39
Cooked cereals	1 med. bowl									43
Eggs (1 egg = small, 2 eggs = medium)										47
Bacon	2 slices									51
Sausage	2 patties or links									55

	Medium Serving	Your Serving Size			How often?					OFFICE USE
SWEETS		S	M	L	Day	Week	Month	Year	Rarely/ Never	
Ice cream	1 scoop									59
Doughnuts, cookies, cakes, pastry	1 pc. or 3 cookies									63
Pies	1 med. slice									67
Chocolate candy	small bar, 1 oz.									71
DAIRY PRODUCTS, BEVERAGES		S	M	L	Da	Wk	Mo	Yr	Nv	
Cheeses and cheese spreads, not including cottage	2 slices or 2 oz.									75 F 79 80
Whole milk and bevs. with whole milk (not incl. on cereal)	8 oz. glass									11
2% milk and bevs. with 2% milk (not incl. on cereal)	8 oz. glass									15
Skim milk, 1% milk or buttermilk (not incl. on cereal)	8 oz. glass									19
Regular soft drinks (not diet)	12 oz. can or bottle									23
Beer	12 oz. can or bottle									27
Wine	1 med. glass									31
Liquor	1 shot									35
Milk or cream in coffee or tea	1 Tblsp.									39
Sugar in coffee or tea, or on cereal	2 teaspn.									43

	1 Seldom/Never	2 Sometimes	3 Often/Always	OFFICE USE
11. How often do you eat the skin on chicken?	_____	_____	_____	47 __
How often do you eat the fat on meat?	_____	_____	_____	48 __
How often do you add salt to your food?	_____	_____	_____	49 __
How often do you add pepper to your food?	_____	_____	_____	50 __

12. Not counting salad or potatoes, about how many servings of vegetables do you eat per day or per week? _____ vegetables per _____ day, week — OFFICE USE 51 ___

13. Not counting juices, how many servings of fruits do you usually eat per day or per week? _____ fruits per _____ day, week — OFFICE USE 54 ___

OFFICE USE G 79 80

THANK YOU VERY MUCH for taking the time to fill out this information.

Reviewed by _____

DVA COOPERATIVE STUDY #996 - PATHS

FORM 13 - CHRONOLOGICAL DRINKING RECORD

Medical Center Name _____ Medical Center No. __ __ __

Participant Name _____ Participant No. __ __ __ __ __

Form Completed By _____ Date Completed __ __ __ __ __ __
Mo Day Yr

CODE APPROPRIATE RATING PERIOD (MONTH) CODE: 00 (PRE) 03 06 12 18 24 __ __

1. WEEK (complete for Event 1 only) ..... BEGINNING: Mo _ _ Day _ _ ENDING: Mo _ _ Day _ _ Yr _ _

2. EVENT NUMBER ..... __ __

3. DAY OF WEEK (1=Sun., 2=Mon., 3=Tues., 4=Wed., 5=Thurs., 6=Fri., 7=Sat.) ..... ___

4. TIME OF DRINKING ..... FROM: _ _ : _ _ am/pm TO: _ _ : _ _ am/pm

5. WHERE WERE YOU DRINKING? (see codes) ..... __ __

6. WHAT WAS THE OCCASION? (see codes) ..... __ __

7. WHAT WERE YOU DRINKING? (List in order from first to last for event.)
CODE: 1=Beer 3=Table Wine 5=Cordial
2=Wine Cooler 4=Fortified Wine 6=Liquor

a. Type _____ ___
Size __ __.__ (oz.) Number __ __

b. Type _____ ___
Size __ __.__ (oz.) Number __ __

c. Type _____ ___
Size __ __.__ (oz.) Number __ __

d. Type _____ ___
Size __ __.__ (oz.) Number __ __

e. Type _____ ___
Size __ __.__ (oz.) Number __ __

f. Type _____ ___
Size __ __.__ (oz.) Number __ __

8. DID YOU EAT WHILE YOU WERE DRINKING? (1=Full meal, 2=Snacks only, 3=No food) ..... ___

a. If snacks only, specify _____

9. TIME OF LAST FULL MEAL ..... __ __ : __ __ am/pm

10. WERE YOU ALONE WHILE YOU WERE DRINKING? (1=Yes [Go to Q.15], 2=No) ..... ___

11. WHO WAS WITH YOU? (CODE: 1=Yes, 2=No)

a. My spouse/significant other ..... ___
b. Other relatives ..... ___
c. A date ..... ___
d. People from work ..... ___
e. Neighbors ..... ___
g. Other friends ..... ___
h. People I knew on sight, but didn't know very well ..... ___
i. People I met there ..... ___
j. Other ..... ___

12. HOW MANY PEOPLE WERE WITH YOU (don't count yourself)? ..... __ __

13. DID THESE OTHER PEOPLE DRINK? (1=Yes, 2=No) ..... ___

14. COMPARED TO THESE OTHER PEOPLE, HOW MUCH DID YOU DRINK? ..... ___
1=Drank more 2=Drank less 3=Drank the same 4-Don't know

15. TOTAL NUMBER OF EVENTS (complete if last event) ..... __ __

Participating Investigator's Signature _____

VA FORM 10-29010(NR)m
AUGUST 1990

DVA COOPERATIVE STUDY #996 **FORM 14**
PATHS CENTRAL LABORATORY DATA

Medical Center Name _____ Medical Center No. __ __ __

Participant Name _____ Participant No. __ __ __ __ __

Form Completed By _____ Date Completed __ __ __ __ __ __
Mo Day Yr

TO BE COMPLETED BY PARTICIPATING CLINIC

CODE APPROPRIATE RATING PERIOD (MONTH) ..... __ __

CODE MONTH: 00 (PRE) 03 06 12 18 24

1. DATE SPECIMEN COLLECTED ..... Mo __ __ Day __ __ Yr __ __

TO BE COMPLETED BY THE CENTRAL LABORATORY

2. DATE SPECIMEN ANALYZED ..... Mo __ __ Day __ __ Yr __ __
3. Total triglycerides (mg %) ..... __ __ __ __
4. Total cholesterol (mg %) ..... __ __ __
5. LDL cholesterol (mg %) ..... __ __ __
6. HDL cholesterol (mg %) ..... __ __
7. HDL_2 cholesterol (mg %) ..... __ __
8. HDL_3 cholesterol (mg %) ..... __ __
9. Apo - A_1 (mg %) ..... __ __ __
10. Apo - A_2 (mg %) ..... __ __ __
11. GGT (u/l) ..... __ __ __
12. CDT (mg/l) ..... __ __ __

COMMENTS: _____

_____

_____

_____

_____
Signature of Laboratory Director

VA FORM 10-29010(NR)n
AUGUST 1990

DVA COOPERATIVE STUDY #996
PATHS

FORM 15
ECHOCARDIOGRAM REPORT FORM

Medical Center Name _____ Medical Center No. __ __ __

Participant Name _____ Participant No. __ __ __ __ __

Form Completed By _____ Date of Reading __ __ __ __ __ __
Mo Day Yr

CODE APPROPRIATE RATING PERIOD: 00 (PRE) 06 (MONTH) ..... __ __

1. BLOOD PRESSURE ..... __ __ __ / __ __ __ mmHg
2. HEART RATE ..... __ __ __ BPM
3. STUDY QUALITY (Grade 0, 1, 2, 3, 4 [Excellent]) ..... ____

M-MODE MEASUREMENTS (ASE)	AVERAGE	S.D.
4. SEPTUM	__ __.__ mm	__.__
5. POSTERIOR WALL DIASTOLE	__ __.__ mm	__.__
6. POSTERIOR WALL SYSTOLE	__ __.__ mm	__.__
7. LEFT ATRIUM	__ __.__ mm	__.__
8. AORTIC DIMENSION	__ __.__ mm	__.__
9. LEFT VENTRICAL DIMENSION DIASTOLE (LVDD)	__ __.__ mm	__.__
10. LEFT VENTRICAL DIMENSION SYSTOLE (LVDS)	__ __.__ mm	__.__
11. RIGHT VENTRICLE WALL (ANTERIOR)	__ __.__ mm	__.__
12. RIGHT VENTRICLE WALL (EPICARDIAL)	__ __.__ mm	__.__

DIASTOLIC LEFT VENTRICULAR FUNCTION	AVERAGE	S.D.
13. MITRAL VALVE SLOPE	__ __ __.__ mm	__ __.__
14. E VELOCITY	__ __ __.__ cm/sec	__ __.__
15. A VELOCITY	__ __ __.__ cm/sec	__ __.__
16. Q-INFLOW	__ __ __.__ ms	__ __.__
17. Q-CC	__ __ __.__ ms	__ __.__

SYSTOLIC LEFT VENTRICULAR FUNCTION	AVERAGE	S.D.
18. EJECTION TIME (ET)	__ __.__ __ sec	__.__ __

19. REGIONAL LEFT VENTRICULAR WALL MOTION ..... ____
(CODE: 1=Normal, 2=Mildly Abnormal, 3=Markedly Abnormal)

COMMENTS: _____

_____

ECHO REPORT SUBMITTED BY (PRINT) _____

SIGNATURE _____

VA FORM 10-29010(NR)o
AUGUST 1990

DVA COOPERATIVE STUDY #996
PATHS

FORM 15A
ECHOCARDIOGRAM WORKSHEET

Medical Center Name _____ Medical Center No. __ __ __

Participant Name _____ Participant No. __ __ __ __ __

Form Completed By _____ Date of Echo __ __ __ __ __ __
Mo Day Yr

CODE APPROPRIATE RATING PERIOD: 00 (PRE) 06 (MONTH) ..... __ __

SEND TO ECHO CENTRAL LAB ONLY; RETAIN COPY AT HOSPITAL.

1. HEIGHT ..... __ __ inches
2. WEIGHT ..... __ __ __ lbs.
3. BLOOD PRESSURE (SUPINE) AFTER ECHO

   (Record two measurements, supine, taken at end of echo)

   Reading 1 __ __ __ / __ __ __

   Reading 2 __ __ __ / __ __ __

4. SONOGRAPHER'S NAME: _____
5. ECHO MACHINE MANUFACTURER: _____
6. SERIAL NUMBER: _____

M-MODE MEASUREMENTS (ASE):

7. LEFT VENTRICAL DIMENSION DIASTOLE (LVDD) ..... __ __ mm
8. LVDS ..... __ __ mm
9. POSTERIOR WALL ..... __ __ mm
10. SEPTUM ..... __ __ mm
11. LEFT ATRIUM ..... __ __ mm

DOPPLER MEASUREMENTS:

12. E VELOCITY ..... __ __ __ cm/sec
13. A VELOCITY ..... __ __ __ cm/sec

REGIONAL LEFT VENTRICULAR WALL MOTION:

14. CODE: 1=Normal, 2=Abnormal ..... ____

    Describe: _____

    _____

	2-DE	M-Mode	Doppler
15. ECHO QUALITY (code each item using codes below)	____	____	____

CODES: 1=Good-Excellent, 2=Fair, 3=Poor

VA FORM 10-29010(NR)p
AUGUST 1990

DVA COOPERATIVE STUDY #996
PATHS

FORM 16
ASSESSMENT OF INTERVENTION SESSIONS

Medical Center Name _____ Medical Center No. __ __ __

Participant Name _____ Participant No. __ __ __ __ __

Form Completed By _____ Date Completed __ __ __ __ __ __
Mo Day Yr

	SESSIONS					
	1	2	3	4	5	6
	CODING: 1=YES 2=SOME 3=NO					
1. DATE	__ __ __ Mo Day Yr	__ __ __ Mo Day Yr	__ __ __ Mo Day Yr	__ __ __ Mo Day Yr	__ __ __ Mo Day Yr	__ __ __ Mo Day Yr
2. APPOINTMENT KEPT	____	____	____	____	____	____
3. LENGTH OF VISIT[1]	__ __	__ __	__ __	__ __	__ __	__ __
4. COVERED ALLOCATED MATERIAL	____	____	____	____	____	____
5. PARTICIPANT GRASPED MATERIAL	____	____	____	____	____	____
6. PARTICIPANT COMPLETED ASSIGNMENTS	____	____	____	____	____	____
7. PARTICIPANT KEPT DDRs	____	____	____	____	____	____
8. PROGRESS MADE	____	____	____	____	____	____
9. GOAL STATUS	____	____	____	____	____	____
10. GOAL MODIFICATION[2]	____	____	____	____	____	____
11. INTERVENTION MODIFICATION[2]	____	____	____	____	____	____

[1]RECORD IN 15 MINUTE BLOCKS UP TO 90 MINUTES.

[2]WHERE THERE HAS BEEN MODIFICATION, SPECIFY EXACT TERMS ON A SEPARATE SHEET FOR EACH SESSION.

_____
Interventionist's Signature

VA FORM 10-29010(NR)q
AUGUST 1990

STUDY #996 - FORM 16 (Continuation) Medical Center No. __ __ __ Participant No. __ __ __ __ __

SESSION NO.	SESSION DATE (MO) (DAY) (YR)	GOAL/INTERVENTION MODIFICATION
____	__ __ - __ __ - __ __	
____	__ __ - __ __ - __ __	
____	__ __ - __ __ - __ __	
____	__ __ - __ __ - __ __	

DVA COOPERATIVE STUDY #996
PATHS

FORM 17

INTERVENTIONIST OR PARTICIPANT GLOBAL ASSESSMENT FORM

Medical Center Name _____ Medical Center No. __ __ __

Participant Name _____ Participant No. __ __ __ __ __

Form Completed By _____ Date Completed __ __ __ __ __ __
Mo Day Yr

PLEASE GIVE BRIEF AND SPECIFIC ANSWERS TO THE FOLLOWING QUESTIONS.

1. GOAL TO BE MAINTAINED:

	1	2	3	4	5
a. Satisfaction with Goal	Not at all Satisfied	Slightly Satisfied	Moderately Satisfied	Very Satisfied	Extremely Satisfied
b. Confidence in Maintaining Goal	Not at all Confident	Slightly Confident	Moderately Confident	Very Confident	Extremely Confident

2. RULES/GUIDELINES THAT WILL HELP YOU (PARTICIPANT) MAINTAIN THE GOAL:

A. _____

B. _____

C. _____

D. _____

3. AIDS TO MODERATE DRINKING (OR ABSTENTION):

A. _____

B. _____

C. _____

D. _____

4. IDENTIFY YOUR (PARTICIPANT'S) PROBLEM DRINKING RISKS:

INTERPERSONAL	SOCIAL PRESSURES: PEOPLE/PLACES/SITUATIONS	EMOTIONS
A. _____	A. _____	A. _____
B. _____	B. _____	B. _____
C. _____	C. _____	C. _____
D. _____	D. _____	D. _____

VA FORM 10-29010(NR)r
AUGUST 1990

Medical Center No. ___ ___ ___

Participant No. ___ ___ ___ ___ ___

5. GENERATE A LIST OF COPING STRATEGIES TO DEAL WITH:

A. UNEXPECTED URGES: _____

_____

B. SOCIAL PRESSURES: _____

_____

C. EMOTIONS: _____

_____

D. INTERPERSONAL PROBLEMS: _____

_____

6. FILL OUT THE FOLLOWING WEEKLY PLANNER, INCLUDE LEISURE ACTIVITIES:

_____

_____

_____

_____

_____

_____

_____

_____

_____

_____

_____

_____

_____

Interventionist's Signature

DVA COOPERATIVE STUDY #996
PATHS

FORM 18

ASSESSMENT OF FOLLOW-UP INTERVENTION SESSIONS

Medical Center Name _____ Medical Center No. _ _ _

Participant Name _____ Participant No. _ _ _ _ _

Form Completed By _____ Date Completed _ _ _ _ _ _
Mo Day Yr

	SESSION 1	SESSION 2	SESSION 3
	CODING: 1=YES 2=SOME 3=NO		
1. DATE (MO/DAY/YR)	_ _ _ _ _ _ Mo Day Yr	_ _ _ _ _ _ Mo Day Yr	_ _ _ _ _ _ Mo Day Yr
2. SESSION KEPT	_____	_____	_____
3. LENGTH OF SESSION[1]	_ _	_ _	_ _
4. PROGRESS MADE	_____	_____	_____
5. GOAL STATUS	_____	_____	_____
6. PROBLEMS[2]	_ _ _ _	_ _ _ _	_ _ _ _
7. LIFE CHANGES	_____	_____	_____
8. STRESSORS	_____	_____	_____
9. NEEDS MORE INTERVENTION	_____	_____	_____
10. NEEDS TREATMENT	_____	_____	_____
11. ALCOHOL PROBLEMS	_____	_____	_____

[1]RECORD IN 15 MINUTE BLOCKS UP TO 90 MINUTES

[2]CODE PROBLEMS: 1=GVEs
2=SOCIO-ECOLOGICAL
3=INTERPERSONAL
4=INTRAPERSONAL
5=OTHER, ONLY IF NECESSARY

Medical Center No. ___ ___ ___

Participant No. ___ ___ ___ ___ ___

12. LIST PROBLEMS (FROM QUESTION 6) AND HOW YOU PLAN TO DEAL (OR HAVE DEALT) WITH THEM.

_____

_____

_____

_____

_____

_____

_____

_____

_____

_____

_____
Interventionist's Signature

DVA COOPERATIVE STUDY #996
PATHS

FORM 19
INTERCURRENT ILLNESS

Medical Center Name _____ Medical Center No. __ __ __

Participant Name _____ Participant No. __ __ __ __ __

Form Completed By _____ Date Completed __ __ __ __ __ __
Mo Day Yr

	HAS THE PARTICIPANT DEVELOPED OR BEEN TREATED FOR:	CODE: 1=YES 2=NO	COMMENTS
1.	Alcohol dependence	___	
2.	Psychoactive substance dependence	___	
3.	Cirrhosis	___	
4.	Alcoholic hepatitis	___	
5.	Pancreatitis	___	
6.	Alcohol-related UGI bleeding	___	
7.	Varices	___	
8.	Peripheral neuropathy	___	
9.	Cerebellar dysfunction	___	
10.	Encephalopathy	___	
11.	Significant cognitive deficits	___	
12.	Psychoactive substance dependence	___	
13.	Major psychotic disorder	___	
14.	Major affective disorder	___	
15.	Severe anxiety disorder	___	
16.	Major personality disorder	___	
17.	Malignancy (active)	___	
18.	Seizure disorder	___	
19.	Clotting or bleeding disorder	___	
20.	Stroke	___	
21.	Cerebral or subarachnoid hemorrhage	___	
22.	Myocardial infarction	___	
23.	Symptomatic ischemic heart disease	___	
24.	Congestive heart failure	___	
25.	Atrial fibrillation or other dysrhythmia	___	
26.	Retinopathy (grade III-IV: hypertensive hemorrhages and/or exudates with or without papilledema)	___	
27.	Surgically curable or secondary hypertension	___	
28.	Other illness	___	
	a. Specify _____		
	b. Specify _____		
	c. Specify _____		

_____
Participating Investigator's Signature

DVA COOPERATIVE STUDY #996
PATHS

FORM 20
EXCLUSION/TERMINATION FORM

Medical Center Name _____ Medical Center No. __ __ __

Participant Name _____ Participant No. __ __ __ __ __

Form Completed By _____ Date Completed __ __ __ __ __ __
Mo Day Yr

EXCLUSION

1. Date excluded ..... Mo __ __ Day __ __ Yr __ __

2. Code up to 3 reasons for exclusion in order of importance, starting with the most important. ..... a. __ __ __
b. __ __ __
c. __ __ __

TERMINATION

3. Date terminated ..... Mo __ __ Day __ __ Yr __ __

Reasons for Termination — 1=YES 2=NO

4. Participant completed scheduled follow-up ..... ____

5. Participant moved or lost to follow-up ..... ____

6. Participant requests termination ..... ____

7. Death ..... ____
(Send copy of Death Certificate to Coordinating Center.)

8. Other, specify _____ ..... ____

COMMENTS: _____

_____

_____

_____

_____

_____

_____
Participating Investigator's Signature

VA FORM 10-29010(NR)u
AUGUST 1990