ACTIVITY COUNSELING TRIAL MANUAL OF PROCEDURES

NOVEMBER, 1995

MANUAL OF PROCEDURES
ACTIVITY COUNSELING TRIAL (ACT)
Table of Contents
November 1995

Chapter 1	Introduction and ACT Protocol
Chapter 2	Recruitment and Prescreening
Chapter 3	Screening Visit 0 (SV0)
Chapter 4	Screening Visit 1 (SV1)
Chapter 5	Screening Visit 2 (SV2)
Chapter 6	Randomization
Chapter 7	Scheduled Follow-up Visits
Chapter 8	Safety Monitoring
Chapter 9	Promotion of Compliance with Data Collection
Chapter 10	Data Management
Chapter 11	Quality Control
Chapter 12	Appendices
Appendix A	Guidelines for Obtaining Informed Consent
Appendix B	Protocol For Graded Exercise Testing Protocol for Testing and Certification of Graded Exercise Testing Personnel
Appendix C	Procedures for 7-Day Recall
Appendix D	Procedures for Self-Administered Questionnaire
Appendix E	Procedures for Interviewing Participants
Appendix F	Measurement of Physical Parameters
Appendix G	Procedures for Blood Specimens
Appendix H	ACT Forms and Instructions

Appendix I	Cost Analysis Data Collection Procedures
Appendix J	Pulse Wave Velocity
Appendix K	List of ACT Personnel
Appendix L	References

Good/Bad Readings

CHAPTER 1
INTRODUCTION
MANUAL OF PROCEDURES (MOP)

1.1.1 Purpose 2

1.1.2 Organization 2

1.1.3 Revisions 3

1.1.4 Summary of ACT Procedures and Forms 4

Table 1. Schedule of Activities 5
Table 2. ACT Data Collection Forms Guide 6

CHAPTER 1
INTRODUCTION

DESCRIPTION OF THE MANUAL OF PROCEDURES (MOP)

1.1.1 Purpose

The ACT Manual of Procedures provides detailed descriptions for all ACT-related procedures and operations. It serves as a detailed extension of the ACT protocol. Whereas the protocol provides a general description of the design and operational aspects of the trial, the MOP offers a day-to-day guide on the execution of all aspects of the study. Another major difference between the protocol and the MOP is the frequent need for revisions to the MOP, as a result of inevitable changes that occur during the course of a trial. The MOP, in a sense, represents a "living document." One of the most important documentation activities occurring at each ACT site will be the meticulous and timely updating of the MOP.

All ACT study personnel should familiarize themselves with the study protocol. In addition, it is critical that ACT personnel become familiar with pertinent sections of the MOP. No one is expected to commit to memory the details of ACT. However, it is important that study personnel feel comfortable navigating through the sections of the MOP. As operational questions arise, ACT investigators and staff should consult the MOP to find the appropriate answer. Because no one document is all inclusive, there will be occasions when one cannot find the appropriate answer in the MOP. At this point, ACT personnel are encouraged to communicate their question(s) to the ACT Clinical Coordinating Center (CCC) preferably via e-mail or, if time is critical, by phone.

1.1.2 Organization

Efforts have been made to organize the MOP in a logical fashion, so that topics of interest can be identified quickly. Specific ACT forms and their corresponding instructions are found in varying chapters. For example, the "Demographics and Medical History" form and its instructions are located in the chapter devoted to Screening Visit 0 (when these data are collected). On the other hand, the 7-day Physical Activity Recall form and its instructions are located in an appendix of the MOP. An entire appendix section is devoted to this form because this instrument collects data on a primary endpoint for the study and because instructions for completion are more complex than for most ACT forms.

MOP chapters are initially organized chronologically, beginning with recruitment issues, followed by specifics about Screening Visits 0, 1 and 2 (including descriptions of procedures and corresponding forms to be administered at these visits), randomization, and scheduled follow-up visits (see MOP Table of Contents). Subsequent chapters focus on safety monitoring, adherence/retention, data management and quality control. The appendices contain detailed information on the informed consent process,

performance of specific study procedures and completion of the related forms, general instructions about forms completion, information related to collection of cost analysis data, the Ancillary Study on Arterial Stiffness, and a list of study personnel.

1.1.3 Revisions

As noted in section 1.1.1, periodic revisions to the MOP will occur. This is typical for most multicenter studies. Revisions may relate to alterations in blood processing or treadmill testing procedures, creation of new forms and corresponding instructions, clarification on any number of issues, revised recruitment plans, changes in training/certification procedures, additional safety issues, etc.

When revised pages are sent to the ACT Clinical Centers (CCs) from the Clinical Coordinating Center (CCC), it is strongly suggested that an appointed ACT staff member at each CC measurement site take on the responsibility of updating all the MOPs at that particular site. It is best to give this task to one individual, rather than assuming that everyone will take the initiative to update their own MOPs. All staff will soon be extremely busy as the trial progresses, and, unfortunately, updating the MOP often takes low priority. Out-of-date MOPs should never be relied upon; the only way to guarantee that all ACT MOPs at one location are current is for one person to ensure that all amendments and revisions are promptly incorporated. Updating the MOP entails:

1. Reviewing the accompanying cover memo from the CCC that describes the changes;
2. Removing outdated page(s) and replacing them with the corrected versions or;
3. Inserting new pages in the appropriate sections; and
4. Ensuring that all ACT staff and investigators are made aware of pertinent changes by copying and circulating the CCC cover memo.

Additionally, the person taking on the charge of updating the MOP should discuss pertinent MOP revisions during weekly staff/investigators meetings, when all ACT personnel are together. All revised MOP pages sent to the CCs will be identified by footers indicating the date of revision.

Most MOP changes need not be brought to the attention of your local Institutional Review Board (IRB). However, your IRB may want to know about changes related to select issues, perhaps having to do with altered recruitment strategies or matters concerning participant safety, such as alert values. Each site should check with their IRB at the beginning of ACT to determine what kinds of changes should be brought to the attention of the IRB. Any protocol changes should be discussed with your local IRB.

Each ACT Clinical Center (CC) will be issued a limited number of MOPs, which should be situated in key locations for easy access. The rationale for assigning a limited number of MOPs to each site is based on the fact that updating large numbers of MOPs at any one site can be very time-

consuming. Also, the more books to update, the greater is the likelihood that one may be overlooked and, therefore, be made out-of-date. During periodic site visits to each CC, one site visitor will review all MOPs to ensure that they are up-to-date.

1.1.4 Summary of ACT procedures and forms

Enclosed in this section are two tables. Table 1 is taken from the ACT protocol. This summarizes all ACT procedures and visits during which the procedures are administered. Table 2 outlines when the various ACT forms are to be administered, in terms of which screening and follow-up visits. The order in which the forms are listed follows the overall suggested order for administering the forms.

TABLE 1.
SCHEDULE OF ACTIVITIES

	Clinic Chart Review	Phone Prescreen	SV0 Orient. Visit	SV1	SV2	Initial MD Visit	6mo FU Visit	12mo Phone Call	18 Month Ph Mail	24mo(a) FU Visit	24mo(b) FU Visit
Eligibility and Recruitment/Tracking											
Age and other eligibility data	X										
Telephone recruitment		X									
Informed Consent			X	X							
Demographics and Medical Hx and health habits			X								
7-Day Physical Activity Recall			X	X			X	X		X	X
Contact information; distribute at SV0				X							
Medications Inventory				X			X			X	
Physical exam				X							
Randomization						X					
Primary/Secondary Outcomes											
VO2max during GXT				X			X			X	
Submaximal Exercise Test (HR @ 50 & 75% V02max)					X		X				X
Heart Rate Variability				X			X			X	
Total Chol, HDL-C					X		X				X
Triglycerides, LDL-C (calculated)					X						X
Fibrinogen/clotting factors					X		X				X
Fasting insulin					X						X
SBP, DBP, resting HR				X	X		X			X	X
BMI					X		X				X
Anthropometrics (skinfolds, girths)					X						X
Diet Questionniare; distribute at SV1; mail for FU					X		X				X
Follow-up Health Habits							X	X		X	
HRQL/IOA; distribute at SV1; mail for FU					X		X				X
Initiate ACT Interventions						X					
Process Evaluation/Measures of Compliance	**collected regularly 0-24 mo.**										
Self report: Physical Activity Logs (IntGrpOnly)											
Documentation of Interventions Delivered (IntGrpOnly)											
Cost analysis data collection											
Safety and Adverse Effects											
Musculoskeletal, cardiovascular							X	X	X		X
Hospitalizations/deaths							X	X	X		X

TABLE 2
ACT Data Collection Forms Guide

MOP

Form Name	Visit	Admn By	Chapter/ Appendix
Preliminary Screening Contact[1]	Telephone Prescreen	Staff	2
Telephone Pre-screening	Telephone Prescreen	Staff	2
Contact Information[2,3]	SV0	Ppt[4]	3
Demographics & Medical History[3]	SV0	Ppt	D
Physical Activity Recall (PAR)	SV0,SV1,FU6,FU12, FU24a&b	Staff	C
Eligibility Disposition	SV0,SV1,SV2	Staff	3,4,5
Screening & Randomization Participation Consent	SV0,SV1	Staff	A
Medications Inventory[3]	SV1,FU6,FU24a	Staff	E
Clinical Measures (Blood Pressure)	SV1,SV2,FU6,FU24a,FU24b	Staff	F
Clinical Measures (Anthropometrics)	SV1,SV2,FU6,FU24a,FU24b	Staff	F
Physical Exam	SV1,FU6,FU24a	Staff	D
Graded Exercise Test (max)	SV1,FU6,FU24	Staff	B
Heart Rate Variability	SV1,FU6,FU24a	Staff	B
Graded Exercise Test (submax)	SV2,FU6,FU24a	Staff	B
Health Related Quality of Life/ Influences on Activity[5]	SV2,FU6,FU24b	Ppt	D
Diet Questionnaire[5]	SV2,FU6,FU24b	Ppt	D
Pulse Wave Velocity[6]	SV2,24b	Staff	J
Follow-up Health Habit	FU6,FU24a	Staff	7
Adverse Events	FU6,FU12,FU24a,*18moMailer	Staff	8

* Activities Inventory Questionnaire FU12, FU24B being developed *

1 - locally generated, optional form
2 - 1 part form; no entry into the database for this form
3 - take home at SV0; implies eligible for SV1
4 - Ppt = participant
5 - take home at SV1; implies for SV2
6 - protocol & form being developed

CHAPTER 2
RECRUITMENT AND PRESCREENING

2.1	Overview	2
2.2	Timeline	2
2.3	Strategy 1	3
2.4	Strategy 2	5
2.5	Telephone List	6
2.6	Telephone Interview	6
2.7	Pre-Screen Tracking Form	10
2.8	Telephone Pre-Screening Form	

CHAPTER 2
RECRUITMENT AND PRESCREENING

2.1 Overview

It is anticipated that as many as 70 to 80 patients may need to be screened each week to randomize an average of 6-7 patients per week over a 12-month recruitment period. Depending on the weekly patient volume seen by the participating primary care providers, the patients screened may comprise only a small subset of patients (e.g., only those seen on certain days of the week). If a subset is taken, the sampling method used should be capable of selecting an unbiased sample: for example, it should not differentially exclude initially eligible persons from screening by patient's sociodemographic characteristics.

Patients initially eligible for ACT are those who are age 35 to 75 years, with at least one prior primary care visit to a physician participating in ACT; those considered a patient of the physician participant; and those with a return clinic visit prescheduled at least 2 months in advance or those who are eligible for a return clinic visit at least 2 months in advance.

Prescreening will proceed through step-by-step process to eliminate those with readily and reliably identifiable ACT exclusions. To accommodate the different clinical environments, practices and resources, different methods may be used in the initial prescreening steps. The subsequent common pathway in prescreening is the ACT telephone interview. The centralized data collection and data entry begin with the telephone interview, once the participant has been contacted and agrees to the interview. Regardless of which initial prescreening strategy is used, in order to track recruitment and provide pertinent patient information for the subsequent prescreening steps, the clinics are encouraged to develop a local recruitment tracking system. A model tracking form is provided at the end of this section.

For the initial prescreening steps, two distinct recruitment strategies have been developed, each affording options and alternative steps. The **first** approach entails the following steps: compiling a Patient List of initially eligible patients; a record review to identify initial medical exclusions; and ending with the ACT Telephone Prescreening Interview. The **second** approach forgoes medical record review, and instead uses a brief office-based questionnaire to identify major medical history eligibility. It too, ends with the standard ACT Telephone Prescreening Interview. Each of these recruitment strategies, and options, is detailed below in sections 2.3 and 2.4.

2.2 Timeline

The timeline for completion of all recruitment prescreening steps including the date assigned

for the SV0 exam will vary according to the patient's next scheduled visit, ranging from a few weeks or less to several months. It is important that for patients with a "near-dated" next physician appointment (e.g., return visit scheduled 2 or 3 months beyond index clinic visit date) make every effort to expedite prescreening. This is because completion of the SV0, SV1 and SV2 phase will take a minimum of two to three weeks under the best circumstances. It is anticipated that some patients may need 45 days to 90 days and longer to complete the SVs allowing for patient's and ACT measurement site schedule availability (the maximum time period allowed for completing SV0, SV1 and SV2 is 3 months). For the other extreme, for patients with a next physician visit scheduled several months in advance (e.g., 6 to 12 months), there is considerable time to complete SV0 - SV2. In addition, because the total time between SV0 and the next clinic visit should not exceed 120 days (or four months) the patients SV0 visit may need to be delayed several weeks or months following selection from the Patient List or appointment logs.

2.3 Strategy 1

Initial Patient List. Recruitment staff will compile lists of patients from appointment logs or records of those who meet the age-eligibility criterion, and have a scheduled appointment within at least 2 months of the current (index) visit date. Additional screening can be performed at this stage depending on the information available for the office appointment logs or desk files: patients may be excluded from the Initial Patient List if the home residence is known to be greater than 50 miles from the medical center or clinic, if they have low or no proficiency in speaking the English language, if they do not have a home telephone, if they require a wheel chair or walker for mobility, if they have severe sensory impairment resulting in blindness or deafness. Thus, the Initial Patient List should include all persons considered initially eligible for ACT based on routinely available information in appointment logs and desk files.

The Patient List may be compiled each day prior to clinic, or during the day as patients are seen, and should span a sufficient number of days per week to meet anticipated randomization yields. In a 12-month recruitment period, potentially 52 weekly Patient Lists may be constructed. The Patient List should include at least: patient's name, telephone number, and DOB, name of the ACT participating primary care physician, date of next clinic visit, and medical record number. Patient sex, race, and home mailing address should be included if available. This information is typically available in printed reports, such as appointment logs, and may also be obtained from record systems normally used to initiate billing for services. The Patient Lists may be locally designed and produced as needed; these may also serve as recruitment tracking forms for local use.

Record Review to Identify Initial Medical Exclusions Once compiled, the Patient List should be obtained by the ACT recruiter or designated medical record reviewer at least on a weekly basis to begin the medical chart/data systems review. This second stage of prescreening will exclude patients with known medical diagnoses, procedures, or those on treatments consistent with active medical exclusions in ACT. This screening step is strongly encouraged as a relatively efficient way to exclude persons with ACT exclusion conditions that are often readily identifiable, thus avoiding the more resource-intensive telephone interview. Methods for excluding patients from the Patient Lists are variable: these could include marking out the lines of data on the List, or producing a new revised Patient List.

Two approaches to identifying medical exclusions may be used: a) a **medical chart review** (for an example, see the ACT Medical Chart Review Form developed for recruitment pilot testing); or b) a **computer search** of a patient database records system. As an additional step, with either approach, patient names retained on the Patient List may be reviewed by the treating primary care physician to identify persons with exclusions (e.g., mental illness, severe functional impairment, or trained athlete) which were not detected by the screening method. Note: as in any phase of prescreening, if this strategy is used it is important that exclusions are objectively ascertained using only the ACT inclusion or exclusion criteria.

a. **Patient Medical Chart Review**. This method for prescreening may be streamlined by using staff experienced in collecting information from medical charts. The patient medical record number is the starting point. At some locations, arrangements may be needed with Medical Records or Clinical staff for record retrieval, including time allocation for processing the record, and work space to maintain the files during processing and to abstract data. Medical exclusions which pertain to a patient's current status should be identified from the medical chart using the most recent visit. Exclusions pertaining to recent history of a particular condition (i.e., last 5 years) may be identified from entries or notes contained in earlier medical charts; however, it is not necessary that all medical charts recorded within a 5-year time frame be pulled. Every effort should be made to complete the medical chart reviews using a time period that spans no more than 2 or 3 previous visits. The reason for this limitation is that this stage of prescreening is considered only preliminary, not all encompassing, and because an ACT Pilot Study of medical chart abstraction revealed that notations regarding major medical exclusions are very likely to be included in the patient's recent medical charts/folders.

b. **Computerized Patient Information Systems**. Another prescreening strategy is to identify initial medical exclusions from computerized patient information systems. This data source may also be used to obtain complete demographic data, patient's address and telephone number. The type of information, its availability and usefulness as a screening method will vary by site. At some sites extensive patient data

are collected and stored, while others may have little information. Since many primary care clinics are components of medical centers, clinical patient databases may also be linked with hospital and intensive care databases to identify history of hospital admissions, emergency and major medical procedures.

Note that initially eligible patients will have had at least one prior office visit prior to the upcoming (index) appointment. Many patients will have had several previous kept appointments, some or all of which may be available in the Information Systems/Billings data. It is preferable to extract patient's address and telephone number from patient's last kept office visit to minimize obsolete addresses or telephone numbers. For clinics where hospital diagnostic and procedure codes are available, the search can include previous years, consistent with the eligibility criteria (i.e., MI within last x years/ months).

Introductory Letter. Following record review, but before the Telephone Interview, an Introductory Letter is an option which may bolster recruitment success. The purpose of the Introductory Letter is to inform potential participants about ACT in a non-intrusive manner and encourage them to learn more about the trial, if they are interested. This approach offers the advantage of giving the individual some time to think about the trial instead on making an 'on-the-spot' decision in response to a 'cold' telephone call. The letter, mailed on clinic stationery and signed by the physician, announces an upcoming telephone contact to inquire about joining ACT. It should also provide some means for the recipient to contact ACT staff to inform them of preferred times to call. One means to do this is a telephone number to call to speak with an ACT staff person, preferably the ACT recruiter. This safeguard will help insure that inquiries of comments about the study are routed to the ACT recruiter rather than to the clinic.

2.4 Strategy 2

Office-Based Self-Administered Screening Questionnaire. The brief questionnaire should be designed to collect information on select medical exclusions, as well as patient's age, address, and telephone number, and next scheduled appointment in the brief office-based screen. Patients eligible for ACT based on their questionnaire responses will be contacted for an ACT Telephone Interview within 7 days. A simple patient log system should be implemented listing age-eligible patients receiving the questionnaire, including: patient's name, DOB (or age), and date of visit. This log system may be prepared each week, in advance, to flag age-eligible patients to receive the self-administered questionnaire as they come in, and to track recruitment locally. The self-administered questionnaire should be distributed to patients preferably by ACT personnel who are familiar with the study and with responsibility for recruitment. This approach will minimize regular clinic staff burden. Alternatively, an office receptionist or the physician during the clinical visit could distribute these questionnaires. A brief

written and/or oral description of ACT, instructions on where to return the questionnaire should be included. The patient should be told that if eligible he/she will be contacted by telephone within several days. To ensure a high return rate the completed questionnaire should be returned before the patient leaves the clinic. A drop box, or a designated staff person may be used to collect the questionnaires. Depending on staff or clinic resources available, patients found not eligible for ACT based on their questionnaire responses may be contacted and provided with this information.

Three methods for distributing the Office-Based Questionnaire have been proposed and described: 1) by an ACT staff person in the clinic; 2) By the physician. Prior to each of the ACT physician's scheduled clinic, a study staff person will attach a brief introductory letter from the patient's physician describing ACT along with the self-administered questionnaire to the patients medical chart. The physicians will be asked to give both the letter and the questionnaire to the identified patients scheduled during their clinic hours. 3) By the Office Staff/Receptionist. A brief invitation should be given to the patient to complete the form, along with the information about ACT describing that the patient's physician is participating in a national study to increase physical activity and exercise in primary care patients to improve health. Patients interested in learning more about the study should complete the questionnaire to determine their eligibility. Regular office staff should be adequately briefed about the study, should patients have questions. Study brochures and information packets may be useful, in addition.

2.5 Telephone List.

A Telephone List should be prepared listing all patients screened who remain eligible for the ACT Telephone Interview. Essentially, this list is the Initial Patient List, now refined by the removal of patient names and data with known ACT exclusions. The Telephone List is used locally for tracking purposes and documentation by the recruiter, and should include the following information: patient name, address, phone number, provider name, and date of next clinic visit. It should also include space to record the date and time of each call attempt (up to four attempts). See section below describing methods for the Telephone Interview.

2.6 The Telephone Interview. This final stage of prescreen is the telephone contact. This step is designed to ascertain whether an initially eligible patient is interested in participating in ACT, and if they meet the final prescreen eligibility criteria. A completed Telephone Interview culminates with a scheduled SV0 visit.

Planning the Telephone Contact. Each initially eligible patient on the Telephone List should be called as needed. Implementing a recruitment tracking system will be invaluable in determining the numbers of subjects necessary to call on average, per week. Priority in "time to telephone contact"

generally reflects the number of days until the patient's next scheduled appointment. Patients scheduled for a return office visit in 3 months or less will require an SV0 visit as soon as possible. There is considerably more flexibility in scheduling SV0 for those with later scheduled physician's office visits, but still constrained by the timeline for the SVs. For the latter, the time period recommended for completing all of SV0, SV1, and SV2 is 3 months or less. Thus, as an estimate, an average of approximately 1.5 months could occur between SV0 and SV1, and SV1 and SV2. One month has been targeted as the time period between SV2 and the patient's upcoming physician's office visit (baseline). Thus, some patient's may require an SV0 scheduled to occur several months after the date of the patient's index physicians office visit (shown on Initial Patient List) in order to adhere to the SV0 - Baseline Visit (next clinic visit) recommended timeline of 4 months.

Obtaining Valid Telephone Numbers. A secondary information source may be necessary from which project staff may obtain patient telephone numbers when information on the Patient List or office appointment log is incomplete or incorrect. Two major resources for this information are the patient's clinical or billing records, and local telephone directories.

Call Attempts. Multiple call attempts should be made until either the patient is contacted or the designated number of attempts is exhausted. Generally the number of call attempts varies from four to as many as ten, and is adjusted during the trial based on actual experience and recruitment yields. Experience with telephone recruitment has shown that it is often useful to create a time-of-day plan for call attempts to avoid calling back at the same time(s) when the individual is apparently not available. For example, if four call attempts are used, the first call could be placed during one of the designated blocks of optimal hours (e.g., 9:00 am to 1:00 pm, and 2:00 pm to 5:00 pm Monday through Friday); the second call could be placed during an unused block; the third call could be an evening call (e.g., 6:30 pm to 9:00 pm Monday through Friday), and the fourth and last attempt could be a weekend call during optimal hours. Once the final call attempt has been exhausted, the household would not be called again, even if a different individual listed with the phone number is later identified as initially eligible for ACT. A phone call to a targeted number is typically **not** counted as a call attempt if a busy signal is received. A call attempt is generally defined as an attempt to contact a designated person and has one of the following results: 1) no-one answers after 8 rings, 2) an answering machine answers, or 3) someone answers the telephone but the targeted person is not available to receive the call.

Beginning the Interview. After contact is made by speaking directly to the targeted person, the ACT recruiter should follow the script included on the first page of the Telephone Pre-screening Form. If an introductory letter was mailed, it may be useful to mention that such a letter was recently mailed, and that this a follow-up call.

Making this connection may more clearly legitimize the phone call and study from the patient's point of view. Recruiters should be prepared to answer more in-depth questions than provided by the material furnished in the telephone script. A small percentage of persons contacted may ask for more details about the intervention, whether their doctor has given his/her permission for the respondent to join, whether their doctor wants them to participate, any potential costs (time or money) to the participant, any risks involved, duration of the study, and who is sponsoring the study. To handle these occasions it is useful for each site to prepare a more in-depth description of ACT (see the ACT Information session in SV0 for key study features). Answers to such questions should be kept brief but informative, noting that a more in-depth description will be provided at a later screening visit.

If the respondent agrees to a telephone interview, verify the person's name and address. Record any corrections. The recruiter should proceed to collect the prescreening information on the Telephone Prescreen Form. Note that the centralized data collecting begins at this point, when the respondent has agreed to proceed with the interview. If a respondent abruptly refuses to continue an interview, this should be coded as a refusal. If for some reason a respondent cannot complete the interview and asks for a call-back, the recruiter should start over the interview at a mutually agreed upon time and date.

Determining Eligibility. If a respondent affirms any response highlighted by a shaded box he/she is ineligible to participate in ACT. If no shaded-box responses are checked, the individual qualifies for an SV0 visit. In this step, the participant should be congratulated for passing all of the screening questions and informed that, based on their responses, they are eligible to attend the ACT clinic screening visits. The recruiter should describe the purpose of the SVs generally as: "at these visits participants will receive free medical tests and complete questionnaires to verify that they do not have any other medical conditions that may prevent them from joining an exercise study, and that they are not already too physically active to benefit from the study. You will also be given an in-depth description of the study and what you will be required to do if you decide join."

Scheduling SV0. To avoid making the respondent feel pressured into joining before a complete description of the study has been provided, the recruiter may offer: "you do not have to decide whether you want to join the study right now, you may want to wait until you've attended one of our screening visits." At this time the recruiter should attempt to schedule an SV0 visit using a locally developed scheduling protocol. Please note that the target time-period for the participant to complete all screening visits **and** attend the next scheduled physicians visit is four months or sooner. For many respondents, less than four months time may be available before the patient's next scheduled physicians appointment. These cases will need to be scheduled for an SV0 to occur as soon as possible in order to maximize the time remaining to complete SV1 and SV2.

Ineligibles. When a respondent is found to be ineligible the interview should close, without completing the remaining items. The recruiter should politely indicate that the ACT study requires that participants not have the specific exclusion criterion identified, and should close the conversation by thanking the respondent for his/her time, and suggesting that they may want to discuss the health advantages of physical activity and forms of safe exercises with their primary care physician.

Answering Machines. If the recruiter reaches the household's answering machine, and the message includes times that the person named on the Telephone List may be reached, the recruiter should arrange to call back at that time. A decision with answering machines is whether or not to leave a message. It is recommended that if used, a message should paraphrase the Telephone Screening Script " Hello, this is _____, I am calling you on behalf of your physician Dr. _____, who is taking part in a national study to help patients increase their physical exercise. We are contacting you to see if you are interested in participating in this study (called the ACT study), and to see if you are eligible. I will try calling you back in a few days, hopefully, when you are in. Thank you." If the household's recorded message does not refer to when to call back, the recruiter may want to add: "You can reach me at _ _____ if you would like to suggest a convenient time for me to call back or if you have any questions. Thank you."

Disconnected Numbers. Temporarily disconnected numbers, or numbers not in service should be recycled for a future telephone call attempts, since experience has shown that many of these numbers will be working several days later.

Call Backs. If the household is successfully contacted but the target person is not available the recruiter should inquire for a better time to reach this person. Persons who are ill or away for an indeterminate or unknown period of time should be recontacted, for the next call attempt, one to two weeks later. This will avoid exhausting call attempts during a period when the target person is physically unable to receive a telephone call.

ACT PRESCREEN REPORT FORM

Record for Month ☐☐ Clinic _____

Beginning Date ☐☐/☐☐/☐☐ (MO DAY YR) Ending Date ☐☐/☐☐/☐☐ (MO DAY YR)

Staff Code ☐☐

Please record the following data for the <u>two-week</u> period recorded above, as applicable.

(A)	Number of patients in period identified from appointment logs (optional)	☐☐☐
(B)	Number of patients in period prescreened with medical chart review or office-based questionnaire	☐☐☐
(C)	Number of patients in (B) identified as eligible for ACT	☐☐☐
(D)	Number of questionnaires not returned, or medical charts not found	☐☐☐
(E)	Number of patients telephoned for screening (initial call attempt)	☐☐☐
(F)	Number of patients not reachable (call attempts exhausted)	☐☐☐
(G)	Number of patients refused interview	☐☐☐

Data entry code ☐☐

ACTIVITY COUNSELING TRIAL
TELEPHONE PRE-SCREENING

INTERVIEWER: **Please do not complete any information on this form until the potential participant has agreed to be interviewed.**

"Hello, this is *<interviewer name>*, and I'm calling you on behalf of your physician, Dr. *<physician name>*, who is taking part in a national study to help patients increase their physical activity.

Participating in regular physical activity, such as walking or moderate exercise, can be good for people of all ages. It can reduce your chances of developing heart disease. Since you are a patient of Dr. *<physician name>*, you have the opportunity to join the study, if you qualify. Do you think you might be interested?"

IF NO: **"Thank you for your time."**

IF YES: **" I would like to ask you a few questions to find out if you can take part in the study. Answering these questions will take about ten minutes. If you are not eligible for the study, I'll let you know right away. Your answers will be kept confidential. You can refuse to answer any question or stop me at any time. Are you ready to begin?"**

Phone number called: ☐☐☐ - ☐☐☐ - ☐☐☐☐

"What is your full name?"

(First)	(Middle or Maiden)	(Last)

"What is your address?"

(Street name and number or P.O. Box)		
(City)	(State)	(ZIP code)

Data Entry Use

ID Number ☐☐☐☐☐☐ Acrostic ☐☐☐☐☐☐

Acrostic: ☐☐☐☐☐☐

Date of Interview ☐☐/☐☐/☐☐ (Mon Day Year) Interviewer ☐☐ (staff code)

Physician Visit Information

Date and time of scheduled appointment:
Date ☐☐/☐☐/☐☐ (Mon Day Year) Time ☐☐:☐☐ ☐ am ☐ pm

Physician ID ☐☐☐

PART I

1. "What is your date of birth?" ☐☐/☐☐/☐☐ (Mon Day Year)
2. "What is your age?" ☐☐ years
3. "Are you a woman or a man?" 1☐ Female 2☐ Male
4. "Are you of Spanish or Hispanic origin or descent?" 1☐ Yes 2☐ No

"What race do you consider yourself to be?"

1☐ White or Caucasian
2☐ Black or African American
3☐ American Indian or Native American
4☐ Native Alaskan
5☐ Aleutian
6☐ Asian or Pacific Islander
7☐ Other race _____
(specify)

PART II

"The next questions are about your health habits and medical history."

6. "Do you currently and regularly participate in any physical activity such as walking, running, aerobic dance, swimming, or playing sports at least three times per week for 30 minutes or longer each time?" 1☐ Yes 2☐ No
7. "If you have a job, does your job require you to do heavy manual labor or vigorous physical exercise for most of your shift?" 1☐ Yes 2☐ No

Acrostic ☐☐☐☐☐☐

8. "Has a doctor ever told you that you have heart problems?"

1☐ Yes — "Please specify the type of problem you have:" _____

2☐ No

9. "Has a doctor ever told you that you have had a stroke?" 1☒ Yes 2☐ No

10. "Have you ever been diagnosed or treated for skin cancer?"

1☐ Yes — "Was it melanoma?"
- 1☐ Yes — "Was this within the last 5 years?" 1☒ Yes 2☐ No
- 2☐ No

2☐ No

11. "Have you ever been diagnosed or treated for any types of cancer other than skin cancer?"

1☐ Yes — "What kind of cancer?" _____
"Was this within the last 5 years?" 1☒ Yes 2☐ No

2☐ No

12. "Do you have diabetes that requires you to take insulin?" 1☒ Yes 2☐ No

13. "Has a doctor ever told you that you have asthma?"

1☐ Yes — "Do you currently take medications for your asthma on a daily basis?" 1☒ Yes 2☐ No

2☐ No

14. ***WOMEN ONLY:*** "Are you pregnant, breast feeding, or currently trying to get pregnant?" 1☒ Yes 2☐ No

15. "Are you able to walk one-quarter of a mile (about 3 blocks) or climb ten stairs without difficulty?" 1☐ Yes 2☒ No

16. "Are you willing to increase your level of physical activity?" 1☐ Yes 2☒ No

Acrostic: ☐☐☐☐☐☐☐

17. "Are you currently participating in another medical research study?"

1☐ Yes → "As part of this study are you receiving any medical treatments, taking any medications, or being asked to change your usual health habits?"
1☒ Yes 2☐ No

2☐ No

18. "Are any members of your household already participating in the Activity Counseling Trial?" 1☒ Yes 2☐ No

19. "Do you live within 50 miles of your doctor's office?" 1☐ Yes 2☒ No

20. "Do you plan to stay in this area for the next two years?" 1☐ Yes 2☒ No

Eligibility status:

1☐ **Possibly eligible**

"Would you be interested in learning more about the study?"
1☐ Yes → Complete scheduling information below.
2☒ No → End of questionnaire.

2☒ **Ineligible**

Give primary reason for exclusion:

_____

_____

Scheduling Information

Date and time of appointment:

Date ☐☐/☐☐/☐☐ (**Mo Day Yr**)

Time ☐☐:☐☐ ☐ **AM** ☐ **PM** (**Hour Minute**)

Date reviewed ☐☐☐☐☐☐ (Mon Day Year) Reviewed by ☐☐ (staff code)

CHAPTER 3
SCREENING VISIT 0 (SV0)

3.1 Overview 2

3.2 Information Session 2

3.3 Informed Consent 3

Table 3.1 SV0 Procedures and
Corresponding Data Collection Forms 3

3.4 Eligibility Determination 3

3.5 Mandatory order for SV0 Data Collection Activities 4

3.6 Suggested Order for Data Collection Activities 4
3.6.1 Medical History 4
3.6.2 Seven-Day Physical Activity Recall (PAR) 4

3.7 Scheduling 5

3.8 Data Entry and Forms Handling 5

3.9 Contact Information Form . . . . .

3.10 SV0 Disposition Form . . . . .

CHAPTER 3
SCREENING VISIT 0 (SV0)

3.1 Overview

Patients who remain eligible once completing telephone interview prescreen, and who express an interest in participating in ACT, should receive an SV0 appointment. Before the scheduled SV0 date, the clinic should provide the participant with directions to the ACT measurement site, pertinent instructions for transportation and parking, and a telephone number of an ACT staff person at the measurement site should the participant need further information. In addition, the site should contact the participant by mail or telephone to remind him/her of the date, time (to - from) and location of the appointment.

At SV0, the participant will receive detailed information about the study in an Information Session, and sign a brief consent form for attending the remaining of SV0. Participant information to be collected at SV0 includes: the Demographics/Medical History Form and Seven-Day Physical Activity Recall. This stage of the screening process is designed to eliminate an appreciable proportion of ineligible persons through paper and pencil testing, avoiding more costly expenditures of staff and study resources necessary for the physical and physiological tests in SV1 and SV2.

If a participant remains eligible for the trial throughout the visit, an SV1 appointment should be scheduled (see Chapter 4).

The procedures and corresponding data collection forms to be completed during SV0 are displayed in Table 3.1.

3.2 Information Session

At the beginning of SV0, participants will receive a 15 to 20 minute presentation on the ACT study. Each site should develop the presentation content and materials as appropriate for the demographic (e.g, ethnicity and SES) characteristics of the patient population served by the provider practices. The ACT logo should be used on printed material and visuals developed for this session. The material conveyed should include and expand on the following aspects:

1) that ACT is a national study operating through medical centers and health provider practices;
2) the goal is to help patients of all ages increase their physical activity to optimal levels as determined by medical research in promoting health and longevity;
3) that there are different methods for increasing physical activity being tested in ACT, such as educating patients about increasing exercise, newsletters, incentives, and actual training in exercises and physical activities. The intervention that a participant will receive will vary by group assignment made and determined randomly;

4) that the participant will receive several free medical tests, will complete some questionnaires, and must agree to attend each of three screening and follow-up visits; and

5) that their physician has given his/her approval for the participant to enroll in ACT if they pass the eligibility criteria.

The staff person should present the opportunity to participate in ACT as a positive and potentially enjoyable activity by discussing some of the "fun" aspects of the study such as the incentive programs and newsletters, and belonging to a national study. A clear and accurate picture of what ACT represents should be provided, yet, without sounding too formal and scientific. However, it should be stressed that since ACT is a study, it is important that the participant be committed to following the protocol and attend each of the scheduled ACT visits to the best of their ability. Persons who are enthusiastic, but who have not categorically agreed to seek participation in ACT can still proceed to complete SV0, but they should be encouraged to discuss this opportunity with their spouse and/or family. Participants who agree to complete SV0 should be told that, for safety reasons, prior to participating in ACT they will need be tested for possible health exclusions in two subsequent screening visits.

3.3 Informed consent. Refer to Appendix A, Guidelines for Obtaining Informed Consent, for detailed instructions about the informed consent process. The informed consent obtained at SV0 will pertain only to the activities performed during that visit. A more extensive informed consent will describe activities at SV1 and SV2.

The consent form must be signed before proceeding with SV0 data collection. The signed consent forms will be stored at the ACT measurement site.

Table 3.1 SV0 Procedures and Corresponding Data Collection Forms

Procedure	Form Name
Obtain locating information	Contact Information Form
Obtain informed consent	SV0 Informed Consent
Ascertainment of medical history	SV0 Medical History Form
Measurement of daily energy expenditure	7 Day Physical Activity Recall
Provision of eligibility status	SV0 Disposition Form

3.4 Eligibility Determination

As each participant proceeds through SV0, he/she must successfully pass through a series of eligibility checks. If a participant is declared ineligible, he/she will be offered an explanation of the exclusion criterion, thanked, and then excused from the remaining SV0 procedures. Ineligibility can arise by refusal to provide informed consent, presence of a medical exclusion on the Medical History Form, or deemed to be too physically active on the 7-Day Physical Activity Recall. The eligibility status of each

participant attending SV0 will be summarized on the SV0 Disposition Form.

3.5 Mandatory order for SV0 Data Collection Activities

The SV0 Informed Consent Form must be completed prior to collecting any participant information.

3.6 Suggested Order for Data Collection Activities

The ACT measurement sites may modify the non-mandatory elements as necessary. The following is a suggested sequence:

Information Session

Informed Consent (must occur prior to data collection)

Medical History/Demographics Form

3.6.1 Medical History

After obtaining informed consent the ACT Medical History and Demographics Forms may be presented. These questionnaires are self-administered, and completed in the clinic; however, a trained staff person should be nearby and available to answer questions participants may have about the eligibility, or on the content or meaning of items in the Medical History Form. Please refer to Appendix D for specific instructions for the Medical History and Demographics forms. If a participant of SV0 checks any of the boxes corresponding to a medical exclusion, he/she is no longer eligible for ACT. AT this point the SV0 exam is completed, and a SV0 Disposition Form should be completed. Please Refer to Appendix D for detailed instructions.

Some participants may be unsure of their past or present diagnoses. When this occurs, the reviewer should attempt to determine whether: a) the person is unsure because he/she has never heard of this condition or has had no prior knowledge of such a condition (in which case the item may be coded as 'no'); or b) the person has knowledge of having a condition similar to, or likely to related to, the specific exclusion factor cited. If the latter (b) is true, the interviewer may consult other resources to judge whether it is more likely than not that the exclusion factor is actually present. These sources may include: the patient's physician or primary care practice used, or the ACT manual of medical exclusions and terms in Appendix D.

3.6.2 Seven-Day Physical Activity Recall (PAR)

The PAR interview technique is used to estimate an individual's daily energy expenditure in physical activity, a primary endpoint. Energy expenditure is assessed by a structured interview in which the participant is asked to estimate the amount of time spent during the last seven days in various categories of daily activity. This interview format yields an estimate of daily kilocalorie/kg. Instructions for interviewer administration of the PAR are provided in Appendix C, Procedures for Seven-Day

Physical Activity Recall. Briefly, men and women with an estimated energy expenditure of > 35 Kcal/kg/day will be excluded from ACT.

3.7 Scheduling

All participants still eligible at the end of SV0 should be scheduled for SV1, to be held, as a target, 7 to 30- days post-SV0. The 7 day lower limit is necessary to avoid overlap in time recall periods between the SV0 and SV1 administrations of the Seven Day Physical Activity Recall.

3.8 Data Entry and Forms Handling

After all data collection forms and the disposition forms have been completed, the data coordinating staff will enter the data on site. This will serve as an additional check of the participant's eligibility status before proceeding to SV1. Please refer to Chapter 10, Data Management, concerning instructions for data entry operations.

Upon data entry, it is possible that the participant's eligibility status may be found to differ from what was determined by the staff member completing the SV0 forms. If so, the data coordinator should inform the study coordinator of this discrepancy and determine the source of error. If a previously eligible participant is determined to be truly ineligible, the participant should be notified of the change, and the appropriate action taken to cancel the SV1 schedule.

3.9 Contact Information Form (following pages)

3.10 SV0 Disposition Form (following pages)

ACT Contact Information Form

Clinic Use Only

ID ☐☐☐☐☐☐ Acrostic ☐☐☐☐☐☐

Date Distributed ☐☐-☐☐-☐☐ (Mon Day Year) Date Returned ☐☐-☐☐-☐☐ (Mon Day Year)

Full Name: _____
(First) (Middle or Maiden) (Last)

Name you prefer to be called: _____

Your Social Security Number: ☐☐☐-☐☐-☐☐☐☐

Your home address:

_____
(Number) (Street) (Apt Number)

_____
(City) (State) (ZIP Code)

Your mailing address (if different from above):

_____
(Number) (Street) (Apt Number)

_____
(City) (State) (ZIP Code)

Day time phone number: (___ ___ ___) ___ ___ ___ --- ___ ___ ___ ___
(Area Code)

Evening phone number: (___ ___ ___) ___ ___ ___ --- ___ ___ ___ ___
(Area Code)

Name phone is listed under: _____

What is the best time to call you? ☐ Morning ☐ Afternoon ☐ Evening

Acrostic ☐☐☐☐☐☐

If employed, what is the name of your employer?

_____

What is your employer's address?

_____
(Number) (Street)

_____
(City) (State) (ZIP Code)

May we call you at work? ☐ Yes ☐ No

Work phone number: (___ ___ ___) ___ ___ ___ --- ___ ___ ___ ___
(Area Code)

It will be very important for the study staff to stay in touch with you. Please provide us with the names, addresses and phone numbers of two friends or relatives **who do not live with you** that will always know where you live and whom we could contact if we were unable to reach you any other way.

Contact Person 1

Name: _____
(First) (M.I.) (Last)

Address: _____
(Number) (Street) (Apt Number)

_____
(City) (State) (ZIP Code)

Phone number: (___ ___ ___) ___ ___ ___ --- ___ ___ ___ ___
(Area Code)

Relationship to you: _____

Acrostic | | | | | | |

Contact Person 2

Name: _____
(First) (M.I.) (Last)

Address: _____
(Number) (Street) (Apt Number)

_____
(City) (State) (ZIP Code)

Phone number: (___ ___ ___) ___ ___ ___ --- ___ ___ ___ ___
(Area Code)

Relationship to you: _____

ACT SV0 Disposition Form

ID ☐☐☐☐☐☐ Acrostic ☐☐☐☐☐☐

Date of Visit ☐☐/☐☐/☐☐ (Mon / Day / Year)

Completed by ☐☐ (staff code)

Has informed consent been obtained for participation in SV0? ☐ Yes ☐ No

Eligibility Checklist

Please summarize the participant's eligibility status with respect to the items listed below.

Item	Participant Eligible?	
Medical History	☐ Yes ☐ No	Specify exclusion(s): _____ _____
7-day PAR energy expenditure	☐ Yes ☐ No	(≤35 kcal/kg/day)

Is this person still willing to participate in the trial? ☐ Yes ☐ No

In the opinion of the clinic staff, is this participant an appropriate candidate for ACT?

☐ Yes
☐ No — Specify why not: _____ _____

Was SV1 scheduled for this participant?

☐ Yes
☐ No

Date scheduled ☐☐/☐☐/☐☐ (Mon / Day / Year)

Time scheduled ☐☐ : ☐☐ ☐ am ☐ pm

CHAPTER 4
SCREENING VISIT 1 (SV1)

4.1 Overview 2

4.2 Signing of Screening and Randomization/Participation Consent 2

4.3 Eligibility Determination 3

4.4 Mandatory Order for Data Collection Activities 3

4.5 Suggested Order for Data Collection Activities 3

4.5.1 Completion of Baseline Medication Inventory 3

4.5.2 Measurement of Blood Pressure 4

4.5.3 Physical Examination 4

4.5.4 Seven-Day Physical Activity Recall (PAR) 5

4.5.5 Graded Exercise Test (GXT) 5

4.6 Distribution of Health-Related Quality of Life (HRQL) Form 5

and Diet Questionnaire 6

4.7 Scheduling SV2 6

4.8 Instructions for Completion of SV1 Disposition Form 6

4.9 Recycling of Temporarily Ineligible Participants at SV1 7

4.10 Data Entry and Forms Handling 7

Table 4.1 SV1 Procedures and Corresponding Data Collection Forms 8

Table 4.2 Exclusionary Medications by Class 9

4.11 Sample SV1 Disposition Form . . . . .

CHAPTER 4
Screening Visit 1 (SV1)

4.1 Overview

Those prospective participants still eligible for the trial after completing SV0 will return for SV1 within eight to thirty days. It is essential that at least eight days elapse between SV0 and SV1 so that two independent baseline measures for the seven-day physical activity recall (PAR) are obtained, corresponding to two distinct seven-day periods of time. It is recommended that no more than 30 days elapse between these two consecutive visits. However, a longer time span will be acceptable as long as the total time between SV0 and SV2 does not exceed 90 days. This should permit some additional flexibility in scheduling screening visits, in general, and rescheduling cancelled visits, in particular.

Before a scheduled SV1, clinics should contact the participant by phone or mail to remind him/her of the date and time of the visit. He/she should also be instructed to bring all medications currently being taken to the visit, and to wear lightweight, loose-fitting clothing for completion of the graded exercise test (GXT).

At this visit, the screenee will sign the consent form for attending the remaining screening visits and for full participation in the trial. After staff completion of the Baseline Medications Form, the potential participant will undergo a limited physical examination (including blood pressure measurement), will be administered the seven-day physical activity recall (PAR), and will perform the graded exercise test (GXT) under medical supervision.

If a participant remains eligible for the trial throughout the visit, two self-administered forms (Health-Related Quality of Life Questionnaire/Influences on Activity Questionnaire and Diet Questionnaire) will be distributed for completion at home and return at SV2.

It is estimated that this clinic visit will take approximately 2 to 2.5 hours to complete in full. The procedures and corresponding data collection forms to be completed during SV1 are displayed in Table 4.1.

4.2 Signing of Screening and Randomization/Participation Consent

At the beginning of Screening Visit 1, the study candidate will have an opportunity for an individual question-and-answer session with a Clinical Center staff member. During this discussion, every effort will be made to inform the prospective participant fully of all aspects of the trial, including randomization to intervention or control groups, potential risks and benefits, and the schedule for all baseline and follow-up procedures. The participant's full understanding of the overall trial is important for ethical considerations, as well as compliance with the study design. Refer to Appendix A, Guidelines for Obtaining Informed Consent, for detailed instructions about the informed consent process.

The consent form must be signed before proceeding with SV1 data collection activities. The signed consent forms will be stored at each Clinical Center.

4.3 Eligibility Determination

As each participant proceeds through SV1, he/she must successfully pass a series of eligibility checks before proceeding to the next procedure. Once a participant is declared ineligible, he/she will be offered an explanation of the exclusion criterion, thanked, and then excused from completing the remaining procedures. As a result, study resources and staff time can be more efficiently directed at screening participants who remain potentially eligible.

The eligibility status of each participant attending SV1 will be summarized on the SV1 Disposition Form. Detailed instructions for completing this form are presented in Section 4.8, and a copy of the form, in Section 4.11.

4.4 Mandatory Order for Data Collection Activities

Each clinical site will exercise local discretion in ordering many of the data collection activities to be completed during SV1, with a few exceptions noted below. For participant safety and in order to achieve reliable, standardized, and high-quality study data, **the following order should be strictly adhered to: 1) obtain blood pressure measurements before conducting the physical examination; and 2) perform the physical examination and administer the seven-day physical activity recall before the graded exercise test (GXT).**

4.5 Suggested Order for Data Collection Activities

This section describes a suggested sequence for conducting data collection procedures at SV1, incorporating the mandatory elements mentioned above in Section 4.4. However, clinical sites may modify the non-mandatory elements as required by local logistics for scheduling procedures and tests.

4.5.1 Completion of Baseline Medications Form

The clinic staff will interview each participant regarding the medications currently taken, which have been brought to the visit, as well as the reasons for usage. This information will be recorded on the Baseline Medications Form. This will help to determine whether a participant is taking a drug for a condition that would preclude trial participation. Refer to Appendix E, Procedures for Interviewing Participants, for detailed instructions.

The classes of exclusionary drugs consist of antianginal agents, oral steroid preparations, anticoagulants, and medications for treatment of asthma, major depression (tricyclics, serotonin re-uptake inhibitors, monamine oxidase inhibitors), mood disorder (Lithium), schizophrenia, or other psychotic disorders (neuoroleptics), as well as insulin treatment for diabetes mellitus. Participants reporting treatment for the following disease conditions would also be excluded: Parkinson's disease or

systemic rheumatic conditions (rheumatoid arthritis, psoriatic arthritis, Reiter's disease, systemic lupus erythematosus, etc.). If a participant is still eligible for the trial after review of his/her current medication usage, then proceed to the next section, blood pressure measurement.

A list of exclusionary prescribed medications by class has been compiled and is presented in Table 4.2. This list contains names of commonly prescribed drugs by category. This list will help to determine whether a screenee's current medication disqualifies him/her from trial participation. However, the list is not exhaustive of all possible exclusionary drugs. Consult your local clinician for classification of questionable medications reported.

Note that beta-blockers and calcium channel-blockers listed in Table 4.2 are not considered exclusionary medications if prescribed for treatment of hypertension. However, they are exclusionary if prescribed for control of angina.

4.5.2 Measurement of Blood Pressure

Resting systolic and diastolic blood pressure measurements will be obtained before the limited physical examination is performed. A standard sphygmomanometer will be used with the appropriate size cuff. After five minutes of rest, three readings of blood pressure, spaced 30 seconds apart, will be taken while the participant is seated quietly. The readings will be recorded on the SV1 Blood Pressure Form. Refer to Appendix F, Measurement of Physical Parameters, for specific instructions for blood pressure measurement.

The three readings taken are made to the nearest **even** digit. Any reading which appears to fall **exactly** between markings on the column should be read to the next marking immediately **above**. After recording all three pairs of measurements, use a hand calculator to determine average systolic and diastolic readings for this visit by adding the three corresponding readings obtained and dividing by three.

currently for 3 mos

The average readings obtained will be used for eligibility determination. **If the average systolic blood pressure is greater than 180 mm Hg or the average diastolic blood pressure is greater than 100 mm Hg, the participant is not eligible for the trial.** Blood pressure levels beyond these values would indicate the need for blood pressure control and stabilization before entry into the trial. If the prospective participant remains eligible, then proceed to the next section, the physical examination.

4.5.3 Physical Examination

A standard limited physical examination (described in Appendix F, Measurement of Physical Parameters) will be performed by an experienced health care professional (nurse practitioner, physician's assistant, or physician). The examiner will review the Demographics and Medical History Form and the Baseline Medications Form before initiating the exam. The findings will be entered on the Physical

Exam Form.

The examiner will pay special attention to identify those prospective participants with an exclusionary active medical condition. Significant clinical findings disqualifying a potential participant would include evidence of coronary heart disease, cerebral vascular disease, peripheral vascular disease, arrhythmias, valvular heart disease, cancer (except non-melanomatous skin cancer), insulin-requiring diabetes mellitus, pulmonary disease, and severe systemic disease. A detailed list of exclusionary medical conditions appears on page 7 of the ACT Protocol. If the prospective participant remains eligible, then proceed to the next section, the seven-day physical activity recall (PAR).

4.5.4 Seven-Day Physical Activity Recall (PAR)

The PAR interview technique is used to estimate an individual's daily energy expenditure in physical activity, a primary endpoint. Energy expenditure is assessed by a structured interview in which the participant is asked to estimate the amount of time spent during the last seven days in five categories of activities. Daily kilocalories/kg can be estimated from the hours recalled at the various levels of intensity. Instructions for interviewer administration of the PAR are contained in Appendix C, Procedures for Seven-Day Physical Activity Recall.

4.5.5 Graded Exercise Test (GXT)

Cardiorespiratory endurance, a primary endpoint, will be assessed by measuring maximal oxygen uptake (VO_2 max in liters/minute) using a graded maximal treadmill exercise protocol. The GXT will be conducted with physician supervision. Results of the GXT will be recorded on the Max Graded Exercise Test Form. Heart rate variability, a secondary endpoint, will be measured in conjunction with the GXT. Findings for heart rate variability will be recorded on the Heart Rate Variability Form. Refer to Appendix B, Procedures for Graded Exercise Test, for detailed instructions.

A participant will be excluded from participating in the trial based on the following findings: 1) a resting ECG suggestive of a history of myocardial infarction, a serious arrhythmia, or underlying coronary heart disease; or 2) physical signs or symptoms of ischemia or underlying coronary heart disease. Refer to Appendix B for a thorough explanation of the exclusion criteria.

4.6 Distribution of Health-Related Quality of Life (HRQL) Questionnaire/Influences on Activity Questionnaire and Diet Questionnaire

If a prospective participant remains eligible throughout SV1, he/she will be given a copy of two self-administered forms, the HRQL Questionnaire/Influences on Activity Questionnaire and the Diet Questionnaire, for completion at home and return at SV2. Detailed instructions for questionnaire self-administration are presented in Appendix D, Procedures for Self-Administered Forms.

4.7 Scheduling SV2

All participants still eligible at the conclusion of SV1 will be scheduled for SV2, to be held within four to 30 days of SV1. Instruct the participant to fast (nothing by mouth, except water) for 12-16 hours prior to blood drawing at SV2. He/she should also be told to abstain from alcohol for 24 hours, from vigorous activity for 12 hours, and from smoking for one hour prior to blood drawing. The participant should also be instructed to wear lightweight, loose-fitting clothing for the submaximal exercise test.

4.8 Instructions for Completion of SV1 Disposition Form

The SV1 Disposition Form must be completed for every participant attending SV1 to document eligibility status. It is recommended that the form be filled out as soon as possible after the screening visit has terminated.

The first part of the form, the upper shaded portion, contains the following standard identifiers: participant ID (the six-digit identification number), Acrostic (the six-character alphabetic code), the date of the visit (month/day/year), and the staff code assigned to the individual completing the form.

The next item, "Has informed consent been obtained for participation in study?" must be answered affirmatively before proceeding to the next section of the form, the "Eligibility Checklist" portion. If informed consent is not obtained, be sure to check "No." In this case, nothing further should be completed on the form since the participant refused any additional data collection activities.

Regarding the "Eligibility Checklist" section, mark "Yes" or "No" to indicate the participant's eligibility status for those procedures/measurements which were completed at this visit. If a participant is ineligible, all the items listed do not have to be answered (since the visit is halted at the first ineligibility encountered). If "No" is checked for medications, physical exam, ECG or graded exercise test, be sure to enter the specific exclusion in the box provided. If more than one exclusion was noted, just enter the first one encountered on the corresponding form. For example, if two medications listed on the Baseline Medications Form disqualify the participant for trial participation, just specify the first one in the box provided on the SV1 Disposition Form.

If the participant is eligible for each item listed in the "Eligibility Checklist" box, then proceed to answer the next item, "Is this person still willing to participate in the trial?" Check the appropriate response. If the response is "Yes," indicating that the participant is still interested in participating in the trial, then proceed to the next item, "In the opinion of the clinic staff, is this participant an appropriate candidate for ACT?" If "No," enter an explanation in the box provided. Otherwise, the participant is still eligible at the completion of SV1, so schedule an appointment for SV2 and enter the date and time of the return visit in the boxes provided at the end of the form.

4.9 Recycling of Temporarily Ineligible Participants at SV1

Prospective participants may be declared temporarily ineligible and then later allowed to reenter the screening process. This would require repeating all data collection procedures, beginning with SV0, to ensure that the participant's study data are current.

Temporary exclusions for which screenees may be recycled include the following: elevated blood pressure (once the blood pressure is under control and the participant has been on a stable dose of antihypertensive agent(s) for three months).

4.10 Data Entry and Forms Handling

After the forms are thoroughly reviewed for completeness and consistency, the data coordinator or data entry operator will enter the data from the data collection forms completed at SV1. **Be sure to enter the SV1 Disposition Form after entering all other SV1 forms.** This will serve as an additional check of the participant's eligibility status before proceeding to SV2. Refer to Chapter 10, Data Management, concerning instructions for data entry operations.

Upon data entry, the screenee's eligibility status may be different from what was determined by the staff member completing the SV1 Disposition Form. If this occurs, the data coordinator will inform the study coordinator so that the screenee can be notified of the change in eligibility status and appropriate action taken to cancel or schedule SV2.

After the data are keyed, the original copy of each two-part form should be removed from the form booklet, stapled together in the upper left hand corner, and mailed to the Coordinating Center on a weekly basis. The second copy will be retained for the participant's local clinic records.

Table 4.1 SV1 Procedures and Corresponding Data Collection Forms

Procedure	Form Name
Provision of locating information	Contact Information Form (for return at SV1)
Ascertainment of current medication usage	Baseline Medications Form
Blood pressure measurement	SV1 Blood Pressure Form
Physical examination	Physical Exam Form
Measurement of daily energy expenditure	Physical Activity Recall
Measurement of maximal oxygen uptake	Max Graded Exercise Test Form
Measurement of heart rate variability	Heart Rate Variability Form
Summary of eligibility status	SV1 Disposition Form
Measurement of health-related quality of life/influences on activity	HRQL Questionnaire/Influences on Activity Questionnaire (for completion at home and return at SV2)
Measurement of dietary intake	Diet Questionnaire (for completion at home and return at SV2)

Table 4.2 Exclusionary Medications by Class

Antianginal Agents

Nitrates
Transdermal
Minitran
Nitro-Dur
Deponit NTG Film
Nitrodisc
Lingual Aerosol
Nitrolingual spray
Ointment
Nitrobid
Nitrol
Nitrong
Capsule
Dilatrate
Isosorbide (Ismo) (Isordil)
Nitro-Bid
Nitrogard
Nitroglycerin
Nitroglyn
Nitrospan
Peritrate
Sorbitrate
Sublingual
(Nitrostat)
Erythrityl Tetranitrate (Cardilate)
Nitrogara
Isosorbide (Isordil)
* Beta-Blockers
Atenolol (Tenormin)
Labetalol (Normodyne)
Metoprolol Tartrate (Lopressor)
Nadolol (Corgard)
Pindolol (Visken)
Propranolol (Inderal)
Timolol (Blocardren)
Betaxolol (Kerlone)
Acebutolol (Sectral)
* Calcium Channel-Blockers
Diltiazem (Cardizem)
Nifedipine (Procardia)
Verapamil (Calan) (Isoptin)
Nicardipene (Cardene)
Isradipine (Dyna Circ)
Nimodipine (Nimotop)

* not ex. if used for hyptnsn.

Table 4.2 Exclusionary Medications by Class (continued)

Steroid Preparations (Oral)
- Aristocort
- Celestone
- Cortone acetate
- Decadron
- Hydrocortone
- Medrol
- Prednisolone
- Prednisone

Anticoagulants
- Coumadin
- Dicumarol
- Heparin
- Parwarfin

Psychotropic Medications

Neuroleptics
- Chlorpromazine (Thorazine)
- Perphenazine (Trilafon)
- Thioridazine (Mellaril)
- Trifluoperazine (Stelazine)
- Haloperidol (Haldol)
- Fluphenazine (Prolixin)
- Thiothixene (Navane)
- Clozapine (Clozaril)

MAO Inhibitors
- Tranylcypromine (Parnate)
- Isocarboxazid (Marplan)
- Phenelzine (Nardil)

Tricyclics
- Amitryptilene (Elavil)
- Imipramine (Tofranil)
- Desipramine
- Nortriptyline

Serotonin Re-uptake Inhibitors
- Fluoxetine (Prozac)
- Doxepin (Sinequan) (Adapin)
- Trazodone (Desyrel)

Anti-manic Agents
- Lithium (Eskalith) (Lithobid)

Hypoglycemic Agents
- Insulin

Table 4.2 Exclusionary Medications by Class (continued)

Asthma Medications

Theophylline (Theo-Dur)
Albuterol (Proventil) (Ventolin)
Isoetharine (Bronkosol)
Metaproterenol (Alupent)
Terbutaline (Brethine)
Ipratropium (Atrovent)
Pirbuterol (Maxair)

Steroid Inhalers
Triamcinolone (Azmacort)
Beclamethasone (Beclovent) (Becanase)
Flunisolide (Aerobid)

4.11 SV1 Disposition Form (following pages)

ACT SV1 Disposition Form

ID ☐☐☐☐☐☐ Acrostic ☐☐☐☐☐☐

Date of Visit ☐☐☐☐☐☐ Mon Day Year

Completed by ☐☐ (staff code)

Has informed consent been obtained for participation in study? ☐ Yes ☐ No

Eligibility Checklist

Please summarize the participant's eligibility status with respect to the items listed below.

Item	Participant Eligible?	
Baseline Medications Form	☐ Yes ☐ No	Specify exclusion(s):
Blood Pressures		
SBP≤180	☐ Yes ☐ No	
DBP≤100	☐ Yes ☐ No	
Physical Exam	☐ Yes ☐ No	Specify exclusion(s):
Graded Exercise Test		
ECG Results	☐ Yes ☐ No	Specify exclusion(s):
Other GXT Results	☐ Yes ☐ No	Specify exclusion(s):

Acrostic ☐☐☐☐☐☐

Is this person still willing to participate in the trial? ☐ Yes ☐ No

In the opinion of the clinic staff, is this participant an appropriate candidate for ACT?

☐ Yes
☐ No — Specify why not:

Was SV2 scheduled for this participant?

☐ Yes
☐ No

Date scheduled ☐☐/☐☐/☐☐☐☐ (Mon / Day / Year)

Time scheduled ☐☐ : ☐☐ ☐ am ☐ pm

CHAPTER 5
SCREENING VISIT 2 (SV2)

5.1 Overview 2

5.2 Eligibility Determination 2

5.3 Mandatory Order for Data Collection Activities 3

5.4 Suggested Order for Data Collection Activities 3
5.4.1 Measurement of Blood Pressure 3
5.4.2 Venipuncture and Blood Processing 3
5.4.3 Anthropometrics 4
5.4.4 Staff Review of Self-Administered Forms 4
5.4.5 Submaximal Exercise Test 4

5.5 Instructions for Completion of SV2 Disposition Form 4

5.6 Scheduling Six-month Follow-up Visit 5

5.7 Recycling of Temporarily Ineligible Participants at SV2 5

5.8 Data Entry and Forms Handling 6

Table 5.1 SV2 Procedures and Corresponding Data Collection Forms 6

5.9 SV2 Disposition Form . . . . .

CHAPTER 5
Screening Visit 2 (SV2)

5.1 Overview

Those prospective participants still eligible for the trial after completing SV1 will return for SV2 within four to 30 days. A four-day interval between SV1 and SV2 is required to allow the participant time to recover from the maximal graded exercise test before performing the submax graded exercise test. It is recommended that no more than 30 days elapse between these two consecutive visits. However, a longer time span will be acceptable as long as the total time between SV0 and SV2 does not exceed 90 days. This should permit some flexibility in scheduling screening visits.

Before a scheduled SV2, clinics should contact the participant by phone or mail to remind him/her of the date and time of the visit. He/she should be instructed to fast (nothing by mouth, except water) for 12-16 hours prior to blood drawing. He/she should also be told to abstain from alcohol for 24 hours, from vigorous activity for 12 hours, and from smoking for one hour prior to blood drawing. The participant should also be instructed to wear lightweight, loose-fitting clothing for completion of the submaximal exercise test.

At this visit, the screenee will return the self-administered forms (HRQL Questionnaire /Influences on Activity Questionnaire and Diet Questionnaire) for staff review during the visit. After blood pressure measurement, the prospective participant will undergo a fasting venipuncture for plasma lipids and lipoproteins, plasma insulin, and plasma fibrinogen. After a light snack, anthropometric measurements and a submaximal exercise test will be performed.

If a participant remains eligible for the trial throughout the visit, he/she will have qualified for entry into the trial.

It is estimated that this clinic visit will take approximately 1.5 hours to complete in full. The procedures and corresponding data collection forms to be completed during SV2 are displayed in Table 5.1.

5.2 Eligibility Determination

As each participant proceeds through SV2, he/she must successfully pass a series of eligibility checks before proceeding to the next procedure. Once a participant is declared ineligible, he/she will be offered an explanation of the exclusion criterion, thanked, and then excused from completing the remaining procedures. As a result, study resources and staff time can be more efficiently directed at screening participants who remain potentially eligible.

The eligibility status of each participant attending SV2 will be summarized on the SV2 Disposition Form. Detailed instructions for completing this form are presented in Section 5.5, and a copy of the form, in Section 5.9.

5.3 Mandatory Order for Data Collection Activities

Each clinical site will exercise local discretion in ordering many of the data collection activities to be completed during SV2, with a few exceptions noted below. For participant safety and in order to achieve reliable, standardized, and high-quality study data, **the following order should be strictly adhered to: 1) obtain blood pressure measurements before performing the venipuncture; and 2) after the venipuncture, provide a snack or light meal and then wait about 20-30 minutes before conducting the submaximal exercise test.**

5.4 Suggested Order for Data Collection Activities

This section describes a suggested sequence for conducting data collection procedures at SV2, incorporating the mandatory elements mentioned above in Section 5.3. However, clinical sites may modify the non-mandatory elements as required by local logistics for scheduling procedures and tests.

5.4.1 Measurement of Blood Pressure

Resting systolic and diastolic blood pressure measurements will be obtained before the fasting blood draw is performed. A standard sphygmomanometer will be used with the appropriate size cuff. After five minutes of rest, three readings of blood pressure, spaced 30 seconds apart, will be taken while the participant is seated quietly. The readings will be recorded on the Clinical Measures Form. Refer to Appendix F, Measurement of Physical Parameters, for specific instructions for blood pressure measurement and requirements for certification.

The three readings taken are made to the nearest **even** digit. Any reading which appears to fall **exactly** between markings on the column should be read to the next marking immediately **above**. After recording all three pairs of measurements, use a hand calculator to determine average systolic and diastolic readings for this visit by adding the three corresponding readings obtained and dividing by three.

The average readings obtained will be used for eligibility determination. **If the average systolic blood pressure is greater than 180 mm Hg or the average diastolic blood pressure is greater than 100 mm Hg, the participant is not eligible for the trial.** Blood pressure levels beyond these values would indicate the need for blood pressure control and stabilization before entry into the trial. If the prospective participant remains eligible, then proceed to the next section, the venipuncture.

5.4.2 Venipuncture and Blood Processing

A fasting blood draw will be performed after blood pressure measurement. Plasma will be analyzed for triglycerides, HDL-cholesterol, LDL-cholesterol (calculated from the Friedewald equation), total cholesterol, insulin, and fibrinogen. Refer to Appendix G, Procedures for Blood Specimens, for instructions for blood drawing, processing, and shipping.

If a participant has forgotten to fast before the visit or if, for some other reason, it was not possible to obtain a blood sample at this time, reschedule the procedure. If repeated attempts to obtain a blood sample are unsuccessful, the participant is still eligible for trial participation.

After the blood drawing and before the submaximal exercise test, a snack or light meal will be provided to the participant.

5.4.3 Anthropometrics

Height will be measured in centimeters using a wall-mounted stadiometer and weight will be measured in kg using a balance beam scale with the participant wearing light indoor clothing and no shoes. One measurement each of height and weight will be taken.

Following the NHANES III protocol, circumferences using a steel tape measurer will be taken in cm at the waist (at the suprailiac crest) and at the hips (at the maximum extension of the buttocks). Measures of skinfold thickness, using Harpendon calipers, will be taken in mm at the chest (for men only), triceps, subscapular, suprailiac, abdominal, and thigh sites. Two readings of circumferences and skinfolds at each site will be made. If the two circumference measurements differ by more than 1.0 cm, then a third measurement must be made. Likewise, if the two skinfold thickness measurements differ by more than 3.0 mm, then a third measurement must be obtained.

All anthropometric measurements obtained will be recorded on the Clinical Measures Form. Consult Appendix F, Measurement of Physical Parameters, for detailed instructions and certification requirements.

5.4.4 Staff Review of Self-Administered Forms

The staff will review the self-administered forms returned at SV2 (HRQL Questionnaire/Influences on Activity Questionnaire and Diet Questionnaire) for completeness and consistency. If any problems are noted, a staff member will question the participant to rectify any omissions or inconsistencies. However, the participant is free to refuse to answer any item he/she so chooses. Refer to Appendix D, Procedures for Self-Administered Forms, for specific guidelines.

5.4.5 Submaximal Graded Exercise Test

Based on the results of the maximal treadmill test performed at SV1, the treadmill workload at 50% and at 75% of VO_2 max will be determined for each participant. A submaximal exercise test will be performed as the participant walks on the treadmill for five minutes at these reduced workloads. The results will be recorded on the Submax Graded Exercise Test Form. Refer to Appendix B, Procedures for Graded Exercise Test, for detailed instructions.

5.5 Instructions for Completion of SV2 Disposition Form

The SV2 Disposition Form must be completed for every participant attending SV2 to document

eligibility status. It is recommended that the form be filled out as soon as possible after the screening visit has terminated.

The first part of the form, the upper shaded portion, contains the following standard identifiers: participant ID (the six-digit identification number), Acrostic (the six-character alphabetic code), the date of the visit (month/day/year), and the staff code assigned to the individual completing the form.

The next item, "Was blood sample obtained successfully?," will be checked "Yes" or "No." This will help to cross-reference laboratory values reported by the central lab in order to track results. Recall that a participant is still eligible for the trial if a blood sample could not be obtained.

Regarding the "Eligibility Checklist" section, mark "Yes" or "No" to indicate the participant's eligibility status with respect to blood pressure, systolic and diastolic. If the participant is blood pressure-eligible, then proceed to answer the next item, "Is this participant's English comprehension and fluency adequate?" In general, an eighth-grade reading level is required for comprehension of data collection forms and intervention materials. Check the appropriate response. If the response is "No," then the participant is not eligible and the form is complete. If the response is "Yes," then proceed to the next item, "In the opinion of the clinic staff, is this participant an approprate candidate for ACT?" If "No," enter an explanation in the box provided (the participant is not eligible and the form is complete). If "Yes," then proceed to the next item, "Is this person still willing to participate in the trial?" Check the appropriate response. If the response is "Yes," then answer the final question, "Is this participant eligible for randomization?" The response to this item should reflect the participant's overall eligibility status after completing all three screening visits (SV0, SV1, and SV2).

5.6 Scheduling Six-Month Follow-up Visit

All participants eligible at the conclusion of SV2 and still willing to participate in the trial will be scheduled for a six-month follow-up visit to occur six months after the upcoming visit to a participating study physician. This upcoming doctor's visit constitutes the beginning of the intervention period for the participant. Instruct the participant to fast (nothing by mouth, except water) for 12-16 hours prior to blood drawing at the six-month follow-up visit. He/she should also be told to abstain from alcohol for 24 hours, from vigorous activity for 12 hours, and from smoking for one hour prior to blood drawing. The participant should also be instructed to wear lightweight, loose-fitting clothing for the graded exercise test (GXT).

5.7 Recycling of Temporarily Ineligible Participants at SV2

Prospective participants may be declared temporarily ineligible and then later allowed to reenter the screening process. This would require repeating all data collection procedures, beginning with SV0, to ensure that the participant's study data are current.

ACT SV2 Disposition Form

ID ☐☐☐☐☐☐ Acrostic ☐☐☐☐☐☐

Date of Visit ☐☐ Mon ☐☐ Day ☐☐ Year

Completed by ☐☐ (staff code)

Was blood sample obtained successfully? ☐ Yes ☐ No

Eligibility Checklist

Please summarize the participant's eligibility status with respect to the items listed below.

Item	Participant Eligible?
Blood Pressures	
SBP≤180	☐ Yes ☐ No
DBP≤100	☐ Yes ☐ No

Is this participant's English comprehension and fluency adequate? ☐ Yes ☐ No

In the opinion of the clinic staff, is this participant an appropriate candidate for ACT?

☐ Yes
☐ No — Specify why not: _____

Is this person still willing to participate in the trial? ☐ Yes ☐ No

Is this participant eligible for randomization? ☐ Yes ☐ No

Temporary exclusions for which screenees may be recycled include the following: elevated blood pressure (once the blood pressure is under control and the participant has been on a stable dose of antihypertensive agent(s) for three months).

5.8 Data Entry and Forms Handling

After the forms are thoroughly reviewed for completeness and consistency, the data coordinator or data entry operator will enter the data from the data collection forms completed at SV2. **Be sure to enter the SV2 Disposition Form after entering all other SV2 forms.** This will serve as an additional check of the participant's eligibility status before the upcoming doctor's visit. Refer to Chapter 10, Data Management, concerning instructions for data entry operations.

Upon data entry, the screenee's eligibility status may be different from what was determined by the staff member completing the SV2 Disposition Form. If this occurs, the data coordinator will inform the study coordinator so that the screenee can be notified of the change in eligibility status.

After the data are keyed, the original copy of each two-part form should be removed from the form booklet, stapled together in the upper left hand corner, and mailed to the Coordinating Center on a weekly basis. The second copy will be retained for the participant's local clinic records.

Table 5.1 SV2 Procedures and Corresponding Data Collection Forms

Procedure	Form Name
Blood pressure measurement	Clinical Measures Form
Fasting blood drawing	(none for central data entry)
Measurement of anthropometrics	Clinical Measures Form
Measurement of health-related quality of life/influences on activity	HRQL Questionnaire/Influences on Activity Questionnaire (for staff review at SV2)
Measurement of dietary intake	Diet Questionnaire (for staff review at SV2)
Submaximal exercise test	Submax Graded Exercise Test Form
Summary of eligibility status	SV2 Disposition Form

5.9 SV2 Disposition Form (following page)

ACT SV2 Disposition Form

ID ☐☐☐☐☐☐ Acrostic ☐☐☐☐☐☐

Date of Visit ☐☐/☐☐/☐☐ (Mon Day Year) Completed by ☐☐ (staff code)

Was blood sample obtained successfully? ☐ Yes ☐ No

Eligibility Checklist

Please summarize the participant's eligibility status with respect to the items listed below.

Item	Participant Eligible?
Blood Pressures	
SBP≤180	☐ Yes ☐ No
DBP≤100	☐ Yes ☐ No

Is this participant's English comprehension and fluency adequate? ☐ Yes ☐ No

In the opinion of the clinic staff, is this participant an appropriate candidate for ACT?

☐ Yes
☐ No — Specify why not: _____

Is this person still willing to participate in the trial? ☐ Yes ☐ No

Is this participant eligible for randomization? ☐ Yes ☐ No

CHAPTER 6
RANDOMIZATION

6.1 Eligibility Check 2

6.2 Touch Tone Randomization 2

Randomization Access Code Report 4

ACT Touchtone Randomization Report 5

ACT Coordinating Center Randomization Report for Clinic 1 - Sample 6

CHAPTER 6
RANDOMIZATION

6.1 Eligibility Check

Upon completion of SV2 and completion of data entry of SV2 forms, the staff will run the eligibility verification program by selecting the eligibility verification option on the main menu of the Data Base Management System (DBMS) (see Section 10.2). If the subject is eligible based on the data in the local PC database, the program will print on the screen and provide a printout of a 10 digit randomization access number. The Randomization Access Code Report is presented in Section 6.2. This form is to be sent (FAX, mailed, hand delivered), to the heath educator. The method of delivery should depend on local sites logistics and capabilities and on urgency depending on time until the patient's scheduled office visit. The subject should then be contacted (by phone or mail?) to confirm they are eligible for the study, confirm when their physician appointment is and that they should expect to be at their physician visit for up to an additional 30-60 minutes beyond the normal time for an office visit. The staff at the measurement site must forward the Randomization Access Code Report to the appropriate health educator at the physician site where the subject will be seen.

If the patient does not meet all eligility criteria, clinic staff should review the criteria listed on the screen and verify their accuracy. Then refer to the appropriate forms to investigate any criterion that was not met. If they are valid, clinic staff should discuss with the appropriate personnel whether to inform the subject that they are not eligible for the study or whether the condition causing the ineligibility can be brought under control and have the subject come back for new SVs for recycling (see Sections 4.9 and 5.7).

6.2 Touch Tone Randomization

The health educator needs to have received the randomization access code from the measurement site prior to the subjects scheduled visit. Upon completion of the subject's office visit, the health educator will need to use a touch tone phone to call the telephone randomization system at (910) 716-0725. The computer will ask the educator to enter their staff code number with password and the subject's access code. The computer will verbally respond with one of the three intervention groups to which the subject has been randomized. Within 48 hours, the Coordinating Center will fax a paper copy of the subject's i.d. and the randomization group to the health educator and others identified by the PI at the clinical site who need this information and do not need to be blinded to randomization arm (see report, ACT Touchtone Randomization Report (in Section 6.2). A separate report generated at the CCC identifying the participants and the date these subjects had been randomized will be sent to the measurement site (who need to remain blinded to intervention group)(see sample report, ACT CCC

Randomization Report for Clinic 1, in 6.2). The staff will enter this into the DBMS to plan and monitor schedule follow-up visits and phone contacts (See Chapter 10 on Data Management).

There is a possibility that contact may not be possible with the ACT telephone randomization system due to: 1) prior notification by the Coordinating Center that the system will be temporarily down, 2) received busy signals after 3 attempts within 3 minutes, 3) unable to receive a ringing signal after 2 tries, or 4) system does not pick up after 5 rings on 2 separate tries. In the event that contact with the ACT telephone randomization is not possible, the health educator should use the back-up randomization procedure involving filling out the backup randomization log printed on the randomization envelope and opening the randomization envelope in the possession of each health educator. Immediately after the session with randomized patient, the health educator should call or leave a message with Susan Anthony (910/716-7067) or EMail Anthony@phs.bgsm.wfu.edu. at the Coordinating Center indicating that a back up randomization procedure has occurred. The randomization envelope that was used and the log sheet should then be mailed to Susan Anthony at the Coordinating Center.

Participant ID Number: 100011	**Acrostic:** DOEJO-

Name: JOHN DOE

Address: ANYSTREET
ANYTOWN XX 99999-1111

Phone Number: 999-999-9999

Date of Birth: 04/21/60

Gender: MALE

Occupation: STATISTICIAN

Appointment Date: 10/05/95

Physician ID: 1 11

Randomization Access Code: XXXXXXXX

ACT TOUCHTONE RANDOMIZATION REPORT

This is to confirm that the following participant was randomized to the intervention arm listed. Please review the following information and report any discrepancies to Susan Anthony at (910) 716-7067.

Date: 10/18/95 Time: 15:38:11

Clinic: Stanford Intervention: Group C / Staff Counseling

Participant Id: 303111 Interventionist Id: 123456

ACT Coordinating Center
Randomization Report for Clinic 1

For the week ending October 6, 1999

PARTICIPANT ID	ACROSTIC	DATE OF RANDOMIZATION
100001	ABCDEF	10/01/99
100002	JKLMNO	10/01/99
100003	GHIJKL	10/02/99
100006	UVWXYZ	10/03/99

CHAPTER 7
SCHEDULED FOLLOW-UP VISITS

SCHEDULE OF ACTIVITIES (Table 1) 2

7.1 Overview 3

7.1.1 Timing of Follow-up Contacts 3
7.1.2 Scheduling of Follow-up Contacts 3
7.1.3 Windows around Follow-up Contacts 3
7.1.4 Preparations for Follow-up Visits 5
7.1.5 Follow-up Visit Conduct and Activities 5
7.1.6 Retention of Participants During Follow-up 6
7.1.7 Obtaining follow-up data by phone for "no show" participants 7
7.1.8 Separation of Participants from ACT Physicians 7
7.1.9 Follow-up Data to Participants or Physicians 8

7.2 Follow-up Forms and Contacts 8

7.2.1 Summary 8
7.2.2 Follow-up Disposition Forms 9
7.2.2.1 Completion of Six Month and 24a/24b Month Disposition Forms 9
7.2.2.2 Completion of Twelve Month Disposition Form 10
7.2.3 Study Termination Form 11
7.2.3.1 Overview 11
7.2.3.2 Completion of Study Termination Form 11
7.2.4 Follow-up Contacts 12
7.2.4.1 Mandatory Order for Data Collection 12
7.2.4.2 6-Month Follow-up Visit Forms 13
7.2.4.3 12-Month Follow-up Phone Contact 16
7.2.4.4 18-Month Mailback Contact 18
7.2.4.5 24 a-Month Follow-up Visit Forms 18
7.2.4.6 24 b-Month Follow-up Visit Forms 19

7.3 Protocol for 6-month follow-up GXT 20
7.3.1 Instructions to participants regarding physical activity the day before GXT testing 20
7.3.2 Maximal Exercise Test 20
6-Month Protocol for GXT Testing 21
7.3.3 Submaximal Exercise Test 23
7.3.4 Additional GXT Information 23
7.3.5 Contraindications to performing follow-up GXT testing 23
Table 4 - Contraindications to Exercise Testing 24

TABLE 1.
SCHEDULE OF ACTIVITIES

	Clinic Chart Review	Phone Prescreen	SV0 Orient. Visit	SV1	SV2	Initial MD Visit	6mo FU Visit	12mo Phone Call	18 Month Ph Mail	24mo(a) FU Visit	24mo(b) FU Visit
Eligibility and Recruitment/Tracking											
Age and other eligibility data	X										
Telephone recruitment		X									
Informed Consent			X	X							
Demographics and Medical Hx and health habits			X								
7-Day Physical Activity Recall			X	X			X	X		X	X
Contact information; distribute at SV0				X							
Medications Inventory				X			X			X	
Physical exam				X							
Randomization						X					
Primary/Secondary Outcomes											
VO2max during GXT				X			X			X	
Submaximal Exercise Test (HR @ 50 & 75% V02max)					X		X				X
Heart Rate Variability				X			X			X	
Total Chol, HDL-C					X		X				X
Triglycerides, LDL-C (calculated)					X						X
Fibrinogen/clotting factors					X		X				X
Fasting insulin					X						X
SBP, DBP, resting HR				X	X		X			X	X
BMI					X		X				X
Anthropometrics (skinfolds, girths)					X						X
Diet Questionniare; distribute at SV1; mail for FU					X		X				X
Follow-up Health Habits							X	X		X	
HRQL/IOA; distribute at SV1; mail for FU					X		X				X
Activities Inventory Form								X			X
Initiate ACT Interventions						X					
Process Evaluation/Measures of Compliance	**collected regularly 0-24 mo.**										
Self report: Physical Activity Logs (IntGrpOnly)											
Documentation of Interventions Delivered (IntGrpOnly)											
Cost analysis data collection											
Safety and Adverse Effects											
Musculoskeletal, cardiovascular							X	X	X		X
Hospitalizations/deaths							X	X	X		X

CHAPTER 7
SCHEDULED FOLLOW-UP VISITS

7.1 OVERVIEW

7.1.1 Timing of Follow-up Contacts

Participant follow-up contacts by ACT measurement staff will take place according to the following post-randomization schedule, with specified data being collected at each contact:

6 month visit

12 month phone contact

18 month mail contact

24a month visit

24b month visit

This chapter does not consider intervention visits by the ACT health educator nor intervention-related data collection. Consult the ACT Intervention Manual of Operations for these specifics.

The three follow-up visits at 6 months, 24a months and 24b months will collect much of the same data that were obtained during the screening process (See **Table 1** in this chapter for a summary of tests to be administered/performed). ACT staff will additionally contact each participant by phone at 12 months post-randomization to administer the 7-day Physical Activity Recall and the Activities Inventory Form, and to collect information on health habits as well as adverse events that may have occurred since the 6 month visit. At 18 months post-randomization, an abbreviated adverse events form will be sent to participants for them to complete and return to the measurement clinic. Follow-up phone calls will be made to those participants who indicated on the form that they had experienced an adverse event within the last 6 months.

7.1.2 Scheduling of Follow-Up Contacts

At the conclusion of an SV2 visit or as soon as randomization has taken place, measurement staff should schedule the 6-month measurement follow-up appointment for that participant. Similarly, after the 6-month visit has been completed, personnel should schedule the date for the 12-month phone call. At the end of the 12-month phone call, clinic staff and participants should establish the dates for both 24-month visits. Clinic staff should also keep track of the target date for mailing the 18-month follow-up materials to participants.

7.1.3 Windows around Follow-up Contacts

The ACT clinics should schedule all follow-up contacts and collect all data within the visit-specified windows noted in **Table 2.** If a 6-month visit is split into 2 consecutive visits, the two visits should be scheduled within 2 weeks of each other. Under some circumstances, a maximum of 1 month may elapse

July 11, 1997 ACT STEERING COMMITTEE CONFERENCE CALL MINUTES

Next Steering Committee meeting: Tuesday, August 26, one day after the August 25th subcommittee meetings in Arlington, VA.

Present: *Tim Morgan, Denise Simons-Morton, John Taylor, Scott Allender, Walt Ettinger, Bill Haskell, Bill Applegate, Steve Blair, Abby King, Susan Margitić*

NHLBI

Budget negotiations with the ACT sites have gone very well. All sites need to submit their revised budgets to the Project Office by the end of July. There is some discrepancy across the sites in terms of funding needed during Phase III of the study, when the measurement closeout visits take place. Denise suggested that part of today's call be devoted to determining what staffing tasks are needed at this point in the study, so that all sites could more consistently detail their budgetary needs.

Other decisions affecting funding need to be discussed as well. These include the number of Steering Committee meetings during the final study phase, the need for additional health educator training sessions beyond the upcoming August, '97 session, and the kinds of debriefing visits between participants and study staff (to present study results and individual participant data).

IMPORTANT ISSUES RELATED TO FUNDING AND STUDY PROCEDURES

Deadline date for closing out all study participants (24a an 24b)

A motion passed (4 in favor, 1 abstention) to *establish March 31, 1999 as the final date to see participants for their 24b-month visits. This is a "hard" date, which means that the Coordinating Center will accept no participant data beyond the 31st.*

To allow more flexibility in scheduling participants for their 24a and 24b visits, it was also agreed to *expand the 22-26 month window on the front end to 21-26 months, in order to bring subjects in for their final measurement visits earlier.*

Policy on providing study results to participants and their ACT physicians

During the upcoming August face-to-face meetings, the Measurement s/c will establish a standardized set of study result/individual participant information that will be made available to the participant and his/her ACT physician after the final results of the study have been determined. Each clinic will decide if they want to conduct group debriefing sessions to present these data (as opposed, for example, to mailing out this information).

between the 6a- and 6b-month visits. The Coordinating Center will collect data on the number of **follow-up visits/calls/mailings** that occur within and outside these windows.

No data should be collected for a participant if the date of the contact falls outside the windows noted in Table 2. The Disposition Form for any follow-up contact must be completed on or before the last day of the window for that contact. If there is certainty that a participant will not be available for a particular follow-up contact, the corresponding Disposition Form can be completed earlier (to be coded as a "missed visit."

21
(see previous page

TABLE 2
WINDOWS AROUND ACT FOLLOW-UP CONTACTS

Follow-up Contact	Window[1]
6 month visit	5 - 10 months [2]
12 month call	11-14 months
18 month mail response	17-20 months
24a and 24b-month visits	22-26 months
Time between 24a and 24b-month visits	7-30 days [3]

[1] Time spans represent the time from the date of randomization;

[2] This window was widened by the Steering Committee on 8/6/96 to reduce the burden of overlapping screening and 6-month follow-up visits.

[3] The 7-day minimum is necessary to avoid overlap of the 2 consecutively administered 7-day PAR questionnaires.

To facilitate timely scheduling of follow-up contacts, ACT staff can use a utilities program on their ACT PC to generate a participant-specific list of target dates for future follow-up contacts. A copy of this list should be given to the participant, and a copy should be retained in the participant's file. **In addition, the Coordinating Center will regularly issue a list to each site that indicates the ID numbers of those participants who are nearing the closing dates for a particular follow-up window. For example, a list would be generated of ID numbers for those participants who are > 8 months post-randomization and for whom no 6-month Disposition Forms have been generated.**

7.1.4 Preparations for Follow-up Visits

Several weeks before each follow-up visit, participants should be reminded of the upcoming visit or phone call by either phone or postcard. This contact can determine if phone number or address changes have occurred, enabling staff to seek out current information.

The 12-month phone call should be preceded by a letter to the participant thanking him/her for his/her one-year participation in ACT and requesting that he/she contact the clinic to arrange a date and time for the phone call interview.

Participants should also be reminded to prepare accordingly for particular procedures scheduled for their next visit. For example, a blood draw at the 24b-month visit calls for having participants fast 12 hours prior to the visit, and refrain from vigorous activity, smoking and alcohol intake a given number of hours before the visit, etc. (consult Appendix G, Procedures for Blood Specimens, for details). In preparation for treadmill testing, participants should be instructed to refrain from any unusually vigorous physical activity the day before the follow-up treadmill test, whereas performance of one's regular exercise program is appropriate. A Medications Inventory form to be completed at the 6 month and 24a month visits necessitates that participants be reminded to bring in all their current medications. *The Health-related Quality of Life/Influences on Activity (HRQL/IOA) and Diet Questionnaires will be sent to the participants 10 days before the 6 month follow-up visit, and can be given to participants at the 24a-month follow-up visit, for completion and return at the 24b month visit.* Participants need to be reminded to complete these forms at home and to bring them in at their next visit for submission and review.

ACT staff should be well-prepared for the follow-up visits. Participant files with sets of forms to be completed during the visit should be ready and accessible. Be sure and have the Contact Information Form that was completed during screening ready for review with the participant in case there are any changes. All supplies and appropriate equipment should be prepared for procedures to be completed. Follow-up visit slots should be adequately spaced so that participants do not have to wait long in the reception area. Clinic operations should be well established to facilitate clinic flow and participant activities during the measurement visits (6, 24 and 24b month visits).

7.1.5 Follow-up Visit Conduct and Activities

Data collection procedures such as taking measurements, administering the ACT forms or reviewing self-administered forms with the participant should be undertaken only by appropriately trained (and for some measures, certified) ACT personnel. Consult appropriate sections of the MOP for specifics regarding protocols for ACT measurements. Consult Appendix E for information about procedures for interviewing participants. Appendix H discusses procedures for forms completion and correction.

Once data on the forms have been obtained from and reviewed with the participant and reviewed once

more by ACT personnel in preparation for data entry, trained staff should enter the data as soon as possible. It is critical that a timely system for data entry be established. *Allowing backlogs of unentered forms to accumulate can seriously impair a clinic's progress to keep up with the study.*

7.1.6 Retention of Participants during Follow-up

Some participants randomized into ACT may not actively participate, i.e., they may not adhere to the ACT intervention and/or attend the clinic measurement visits. This may be due to any of a number of reasons, such as logistical difficulties (e.g., transportation problems), advice from their family, or personal situations (divorce, job loss or retirement). Regardless of the reason, these participants should be followed until the end of the study, and the measurement staff should attempt to make contact at 6, 12, 18 and 24 months. These contacts are intended to remind the participant that they are still a part of ACT and to encourage them to show up for the 6, 24a and 24b office visits, and to respond to the 12-month phone call and 18-month mailback card. *The only reason to abandon any future contact with a participant is if, after a number of attempts to convince them to keep their clinic measurement appointments or respond to inquiries for data, they request that ACT personnel no longer try to contact them.* Should this occur, a Study Termination Form (see Section 7.2.3 and the form near the end of this chapter) should be completed. This form alerts the Coordinating Center that no more data will be collected on this participant.

Before giving up on a participant "refuser" or "dropout," study staff should make every effort to persuade the participant to continue his/her involvement in ACT. Finding out the source of noncompliance can prove helpful. Logistical problems such as lack of transportation to the clinic would be an easy problem to resolve, if the clinic could arrange and pay for taxi or other transportation to the clinic.

Ideally, all pre-determined data should be collected on a participant. If the participant is unwilling to undergo all tests/procedures and to answer all questionnaires, efforts should be made to obtain at least primary outcome data. This strategy may call for negotiating with the participant. For example, ask the individual what he/she would be willing to continue doing versus not doing. Try to convince the participant to at least attend clinic measurement visits for measurement of the primary outcomes, VO_2max and 7-day Physical Activity Recall. If the participant refuses to attend future measurement visits, could the clinic staff periodically call the person to obtain some important information by phone (adverse events and PAR data; see next section)?

Refer to Sections 9.3 (Promoting attendance for scheduled clinic visits), Section 9.4.1 (Missed visits) and Section 9.5 (Promotion and maintenance of adherence) of the MOP for description of strategies to enhance participant retention in ACT.

Adherence to scheduled follow-up visits and corresponding windows will be monitored by the CCC in regular reports.

7.1.7 Obtaining Follow-up Data by Phone for "No-show" Participants

For "no show" participants who fail to attend a particular scheduled visit and for whom concerted efforts have failed to bring them to the clinic, (e.g., multiple re-schedulings, PI calling participant, etc.), *efforts should be made to obtain adverse events information by phone soon after the date of the appointment. Similarly, the 7-day PAR questionnaire and other information should be administered by phone* if the "no show" participant is willing to provide this information. Any data collection by phone should be indicated by immediately placing a colored sticker on the appropriate form that indicates that these were "phone-collected data" (for Adverse Events, PAR and Disposition Forms). This sticker will then inform data entry personnel that when entering these data into the database, they need to indicate (in the database) that this information was obtained by phone (as opposed to a face-to-face visit). (Fields added to the AE, PAR and Disposition Forms database indicate "phone-collected data;" these should be checked appropriately.) Remember that if only partial data are obtained for a particular visit, the appropriate Study Disposition Form (see end of this chapter) should still be completed; this form accommodates incomplete ascertainment of data, missed visits (indicate reason for missed visit), as well as complete data collection.

7.1.8 Separation of Participants from ACT Physicians

During the course of ACT, it is possible that some randomized participants may switch to non-ACT physicians or an ACT physician may leave his/her practice...and the study. The following strategies should be taken:

1. During the first visit to the Health Educator, the randomized participant will be urged to inform ACT personnel if he/she later switches to a non-ACT physician. The participant will be advised to give the name and address of the new physician to ACT personnel so that the new physician can be informed about his/her patient's involvement in ACT and so that pertinent follow-up data can be forwarded to the new physician.
2. ACT data collection should be maximized, with emphasis being placed especially on ascertainment of the 2 primary endpoints: 7-day PAR and $V0_2max$. Some data, such as adverse events and the 7-day PAR, can be collected via phone.
3. Even if an ACT participant switches to a non-ACT physician, continued implementation of the originally assigned intervention by the Health Educator should occur as much as possible.

7.1.9 Follow-up Data to Participants or Physicians

ACT participants asking about their follow-up progress on primary and secondary outcomes such as GXT cardiorespiratory fitness (VO_2max), lipids and blood pressure should be told that the measurement staff do not have access to this information until the end of the study. Staff can make general comments to participants regarding, for example, a GXT follow-up test by indicating that the participant performed well or that the results looked "OK or normal." Participants can be told that once the study is closed, they will receive measurement information on their progress during the course of the study.

(For follow-up GXT reporting, the physician letter should express GXT results only as positive or negative.) (For follow-up reporting of heart rate, blood pressure, ECG, weight and lipid results, the same information can be provided that was given at baseline.) See Section 8.3 for example of physician letter. Abnormal follow-up findings such as abnormal ECG reports can be sent to the physician's attention, if in the best interest of the patient.

7.2 FOLLOW-UP FORMS AND CONTACTS

7.2.1 Summary

The ACT follow-up forms are discussed in this section. A number of these forms are the exact same forms that were used during ACT screening. For these forms, the reader is referred to that section of the MOP containing a copy of the form and corresponding instructions. Other forms contain minor revisions, and the reader is again referred to that section of the MOP containing a copy of the original form and corresponding instructions. Incorporated revisions for this second category of forms will be discussed below. Those forms which are completely new are discussed in more detail below, with copies being included at the end of this chapter. **Table 3** summarizes which forms are exactly the same as the screening forms, which have some revisions, and which are completely new.

TABLE 3
Summary of ACT Follow-up Forms

Forms unchanged from screening	Forms with minor revisions	New forms
7-day PAR	Medications Form	FU Disposition Forms
6 & 24 b mo.BP & Anthro.	24a Blood Pressure Form	(6,12 24a & 24b mo.)
Diet Questionnaire		Study Termination Form
HRQL/IOA		FU Adverse Events
HR Variability		Worksheet & Form
Max Graded Exercise Test		Follow-up Health Habits
Submax Exercise Test		Activities Inventory
		Form

7.2.2 Follow-up Disposition Forms

Similar to the screening Disposition Forms, these newer versions provide a summary status of each participant contact. They serve as summary reports for fully completed contact information, semi-completed contact information and missed contact information. *A disposition form should be completed for every participant at the end of every follow-up visit or phone call.* (There is no Disposition Form for the 18-month mail contact.) The Disposition Forms address adverse events, serve as a checklist for visit/call-specific forms to be completed and ask for information regarding missed visits or partial information.

7.2.2.1 Completion of Six Month and 24a and 24b Month Disposition Forms

Question #1--Adverse experiences (6 mo and 24b months):

Adverse event information is initially obtained from the newly created Follow-up Adverse Events Worksheet [see end of this chapter], which lists the various adverse events in conjunction with "yes" and "no" boxes. A "yes" answer would necessitate completing the actual Adverse Events Questionnaire in its entirety, as well as noting this information on the Study Disposition Form, as described below. Although data from the Adverse Events Worksheet need to be transcribed to other forms for data entry, the data on the AE Worksheet itself are not entered into the database.

Question #1 on the 6- and 24b-month Study Disposition Forms is broken down into the 3 categories of adverse experiences or events (see below). Check the appropriate "yes" box if the participant has reported any of the events listed under each category. Any "yes" response would necessitate completion of the Adverse Events Form (see Sections 8.7, 8.8 and 8.10 of the MOP). The adverse events include:

1) *Cardiovascular* (chest pain, difficulty breathing, fainting, dizziness or loss of consciousness);
2) *Musculoskeletal* (any of the following during or after exercise...leg or arm pain, swollen or sore joints, pulled or strained muscle, or broken/fractured bones);
3) *Hospitalization* for any reason.

For "no show" participants who fail to attend a scheduled follow-up visit, adverse events information should be obtained by phone soon after the visit date using the Adverse Events Worksheet, after which the AE data should be transcribed to the Disposition Form and, if needed, to the expanded Adverse Events Form.

***Question#2--Visit status (6, 24a and 24b months)**: Was visit completed as planned?*

If the visit was completed as planned, meaning that the participant visit was in the established window,

and all visit-specific measurement forms were completed, check "yes." If the "no" box is checked, indicate in the inner box:

Was partial information collected?

Check "yes" if partial information was obtained, and indicate which visit-specific forms/tests were missing or were not performed. If 7-day PAR data were obtained by phone on a participant who fails to attend a scheduled follow-up visit, this would constitute an "incomplete" visit, necessitating leaving the 7-day PAR box unchecked--i.e., data obtained--as opposed to checking all other boxes under this section--i.e., data not obtained. (In this example, data entry personnel should check the pink field at the top of the form, which indicates "phone-collected data.") If only partial information is obtained and there is certainty that the remaining measures for a particular visit will not be performed, complete the Disposition Form accordingly.

If no information was obtained, in terms of forms/test completion, and ACT staff are certain that they cannot obtain any of this information from the participant for a particular follow-up contact, enter "no" and indicate the reason for the missing data:

Why was this visit missed?

Reasons include: participant cannot be located, participant located but refused clinic visit, participant died (complete Study Termination Form) and other. Check the appropriate box, and enter an explanation, if "other" was checked.

If a participant misses a scheduled contact/visit and another contact/visit is to be rescheduled, do not complete the Study Disposition Form until the rescheduled contact/visit has been completed. For *6-month split visits*: 1) date each form according to the actual date of data collection; 2) only fill out one 6-month Disposition Form at the end of the second part of the split visit, when the maximum amount of information/measures has been obtained; and 3) enter the date on the 6-month Disposition Form as the date of the second part of the split visit.

For those participants who complete the 24b-month visit, be sure and fill out the Study Termination Form, which indicates that the participant has completed the requisite 24 months of study follow-up and is now being closed out.

7.2.2.2 Completion of Twelve Month Disposition Form

This represents the data collection form for the 12 month follow-up phone call.

Question #1--Adverse experiences?

Inquire about adverse events and complete question # 1 of this form, as described in the previous section.

Question #2--Phone call status: Was phone call completed as planned?

Check the "yes" box if the call was completed as planned. Otherwise, check the "no" box, indicating *Why was this phone call missed?*

Reasons include: participant cannot be located, participant located but refused telephone interview, participant died (complete Study Termination Form) and other. Check the appropriate box or enter an explanation under "other."

7.2.3. Study Termination Form

7.2.3.1 Overview

This form will be completed any time during the study when:

1. *A participant death has occurred*; or
2. *ACT study personnel have given up all hope of obtaining any further data on a participant and no further efforts to contact the participant will be made.* This could be due to a noncompliant individual who is unwilling to continue in the study, or it could be due to a "lost to follow-up," meaning that all attempts to contact the participant have failed. Before a clinic decision is reached to complete a study termination form on a participant, it is critical that ACT staff and investigators make heroic efforts to contact this individual and to try to convince him/her to provide even minimal follow-up data, in which case the Study Termination Form should <u>not</u> be completed. (The appropriate Disposition Form would reflect that partial data were obtained.) See Section 7.1.6 for further information concerning attempts to prevent participant dropouts; or
3. *Routine participant closeouts occur at 24 months. This will happen for all remaining study participants when the 2-year follow-up period for that participant is over.* Once the 24b Disposition Form is completed (the 24b visit represents the final follow-up visit for study participants), *be sure to complete the Study Termination Form at the conclusion of this visit.* This indicates that the participant is officially "closed out," in terms of study follow-up.

Thus, a Study Termination Form will be completed for every ACT participant at some point during or at the end of the study.

7.2.3.2 Completion of Study Termination Form

Enter the participant ID number and acrostic, date of form completion and staff code in the shaded gray portion at the beginning of the form.

Why is this participant being terminated from study follow-up?

Check **box #1** if study termination is due to regular participant closeout at the end of the 24-month follow-up period.

Check **box #2** if the participant refuses any further contact with study personnel.

Check **box #3** if the participant is lost to follow-up, meaning that all attempts to contact the participant have failed.

Check **box #4** if the participant has died. *If a participant death occurs between scheduled visits, the Disposition and Study Termination Forms for the next scheduled visit/call should be completed immediately.* Any hospitalization information related to the death should be entered into the Adverse Events Form (see Section 8.8). It may be necessary to obtain medical records to discern the cause of death in order to complete this form. Each Clinical Center will be responsible for obtaining a copy of the death certificate for any participants that die during the follow-up period. *A photocopy of the death certificate should be forwarded to the Coordinating Center.* Complete the attached box-in information, which queries about the death. Enter:

- date of death
- cause of death
- state where the death occurred.

Check **box #5** if the participant is being terminated from the study for reasons other than those stated above, then enter the specific reason(s) for participant termination.

7.2.4 Follow-up Contacts

For a particular follow-up contact, a pre-determined number of measures are performed, with data being written onto the ACT data collection forms. Consult **Table 1** for the schedule of activities for each type of contact. If a particular measurement is not obtained, do not complete the corresponding form if that form exclusively addresses the particular measure. As an example, if the GXTsubmax test was performed on a participant, but the GXTmax was not obtained, there is no need to complete any information on the GXTmax Form, not even the shaded area at the top that deals with standard identifiers. On the other hand, some forms, like the GXTmax Form, do address multiple tests, such as the GXTmax and ECG information. For this form, it would be appropriate to provide partial (e.g., ECG) information.

7.2.4.1 Mandatory order for data collection

Each clinical site will exercise local discretion in ordering many of the data collection activities to be completed during the follow-up visits, with a few exceptions. For participant safety and in order to achieve reliable, standardized and high-quality data, the following order should be strictly adhered to: 1) obtain blood pressure measurements before conducting the physical examination; 2) obtain blood pressure measurements before performing the venipuncture; and 3) perform a physical examination and the 7-day PAR before the GXT.

7.2.4.2 Six- month Follow-up Visit Forms

Forms to be completed are listed below.

Contact Form (to be updated)

Information originally obtained on this form during screening should be updated during each follow-up contact, to ensure that the information is current. Also, when communicating with an ACT participant during follow-up, *inquire about any scheduled appointments with the ACT physician.* This information would prove useful to the health educators, who may be unaware of upcoming appointments.

Medications Form

The participant should be reminded ahead of the visit to bring in all his/her medications so that this form can be completed accurately. One additional category has been added to the follow-up version of this form. This relates to use of insulin. New versions of these forms will identify them as follow-up (as opposed to screening) forms. Consult Appendix E for comprehensive instructions on completing this form.

Follow-up Health Habits Form

The original version of the Follow-up Health Habits Form was revised in September, 1996 to include three additional questions related to marital and employment status and quality of life.

Question #1-The following questions are about cigarette smoking:

a. Have you ever smoked cigarettes?

For a "no" response, skip to question #2. If "yes" is checked, move to b:

b. Do you currently smoke cigarettes?

If the "yes" box is checked, ask the participant:

On an average day, how many cigarettes do you smoke?, and enter the number in the corresponding box. If the "no" box is checked, ask:

Did you quit smoking before you began participating in ACT?

If the participant responds "yes", check the corresponding box and skip to Question #2. If the response is "no", check this box and ask the following 2 questions:

When did you quit smoking? Enter the month and year in the corresponding box. *If the participant is unable to remember the month, enter -5s into the "month" spaces on the form.*

Before quitting, on an average day, how many cigarettes did you smoke? Enter the number in the appropriate box.

Question #2-Since your last visit, have you tried to lose weight?

For a "no" response, skip to Question #3. For a "yes" response, ask the participant:

*Did you try to lose this weight by..*check the appropriate box and enter an explanation, if "other" is checked.

Question #3-*What is your current marital status?*

Enter the participant's response by checking the appropriate box.

Question #4-*Euroqol Score*

This is an alternative scale measuring quality of life, that asks the participant to indicate on a 100-point scale how good or bad his/her health is today. *Although the Follow-up Health Habits Form is staff-administered, it is very important that the participant actually read this question him/herself, view the analogue scale and draw the line between the "your own health state below" box and what they perceive to be the scale value that best represents their current state of health.*

Question #5-*What is your current employment status?*

Enter the participant's response by checking the appropriate box.

7-Day Physical Activity Recall

Consult Appendix C for instructions on completion of the 7-day PAR.

Diet Questionnaire

This form should be mailed to the participant (along with the Health-related Quality of Life/Influences on Activity Form) 10 days prior to the 6 month visit, with a cover letter asking the participant to complete the form and bring it with him/her the day of the clinic visit. The participant should be called 1 or 2 days in advance of the scheduled visit to remind him/her of the visit and to remind him/her to bring in the completed form. Clinic staff should review the completed form with the participant, with special attention being given to missing information, inconsistencies, and clarification (foods needing special codes). Consult appendix D for further instructions on completion of the Diet Questionnaire.

Health-related Quality of Life/Influences on Activity

This form should be mailed to the participant 10 days in advance of the scheduled appointment for

completion and return with the participant. Along with the Diet Questionnaire, clinic staff should review this completed form with the participant. Consult appendix D for further information.

Clinical Measures (blood pressure, height and weight)

For the 6-month visit, clinical measures will include blood pressure, height and weight. To relieve the burden of overlap of screening visits with 6-month follow-up visits, *no waist and hip circumference measures will be performed at 6 months, nor will skinfold thickness be obtained.* Although these data are listed as part of the Clinical Measures Form (the same form that was used during screening) *these sections should be left blank for the 6-month visit.* Consult Appendix F for pertinent information on completion of this form

Venipuncture

To reduce the burden of overlapping screening and 6-month follow-up visits, *the 6-month blood test will be done on a non-fasting sample.* Thus, the 6-month assay will measure only total cholesterol, HDL and fibrinogen (but not LDL, triglycerides and insulin, as with SV2 and the 24b-month visit). Consult Appendix G for description of the procedures for collection of blood specimens.

Physical Examination

An abbreviated physical exam should be performed prior to initiating treadmill testing, to rule out any contraindications to treadmill testing. Use the Follow-up Physical Exam Form (see end of chapter) for this purpose. For this visit as well as for the 24-month visit, this information will be kept in the participant's file, but will not be keyed as part of the ACT database.

Heart Rate Variability

See Appendix B of the MOP for instructions on completion.

Submaximal Exercise Test

See Section 7.3 of this chapter.

VO_2max during GXT

Participants should be instructed to refrain from any unusually vigorous physical activity the day before the follow-up treadmill test; however, performance of one's regular exercise program is appropriate.
See Section 7.3 of this chapter for details about the follow-up GXT protocol.

6 Month Disposition Form

See Section 7.2.2.1 above for explanation.

Adverse Events Worksheet and Adverse Events Form, if appropriate

Adverse event information is initially obtained from the newly created Follow-up Adverse Events Worksheet [see end of this chapter], which lists the various adverse events in conjunction with "yes" and "no" boxes. A "yes" answer would necessitate completing the actual Adverse Events Questionnaire in its entirety, as well as noting this information on the Study Disposition Form. Refer to Sections 8.7, 8.8 and 8.10 of the MOP for detailed information on completion of the Adverse Events Form.

7.2.4.3 Twelve-Month Follow-up Phone Call

Two weeks prior to the 12-month phone call, the participant should receive from the ACT clinic a cover letter that reminds the participant of the time, date and purpose of the call. Several days prior to the scheduled call, the participant should be contacted by phone to remind him/her of the upcoming follow-up phone call.

Forms to be completed during the 12 month phone contact include the following:

7-day Physical Activity Recall

12-month Follow-up Activities Inventory Form

The 12-month Follow-up Activities Inventory form is designed to collect information about physical activities in which participants have engaged during the first year of the study. The form is to be administered via telephone immediately following the Physical Activity Recall (PAR). The participant can report on up to five activities, which are to be coded on the form by the interviewer using the "COMPENDIUM OF PHYSICAL ACTIVITIES" that follows. The form is scripted and items appearing on the form in quotation marks should be read verbatim during the interview. Following are item-by-item instructions for completing the form.

- **Identifying Information--Complete identifying information in the first box, including participant ID number and acrostic, date the form was completed and the two-digit code identifying the interviewer.**
- **Item 1--Read quoted text to participant. If the participant responds that he/she has INCREASED his/her activity during the past year, mark the appropriate response on the form and continue to item 2. If the participant responds that his/her physical activity has**

decreased or stayed about the same as it was before enrolling in ACT then mark the appropriate response and stop the questionnaire here.

- **Item 2--Read quoted text to participant. If the participant is unsure or does not think he/she will remember everything, tell him/her that you understand that it is a long period of time, but that their "best guess" or "best recollections" will be fine. Tell the participant that they do not have to be exact, just report the physical activities that they recall doing most often.**
- **Primary Activity--Read quoted text to participant. Record responses in spaces provided. For frequency questions, if participant gives a range of numbers, round up to the next integer. If the participant has trouble recalling how many months he/she did the activity, probe by using the name of the month in which he/she was randomized (e.g., "Think back to last February...did you begin doing the activity then?"). If the participant does not know how many times, on average, he/she did the activity per month, ask how many times the activity was performed in an average week and extrapolate by rounding up to the next integer, then multiply the response by 4 to get the average per month.**
- **Item 3--Read quoted text to participant. If he/she answers "yes," that he/she did other activities, then mark the appropriate response and continue the questionnaire on the next page by completing the Secondary Activity questions in a similar fashion to the Primary Activity part. If the participant responds that he/she did not do other activities, then mark the appropriate response and end the questionnaire here.**
- **Item 4--Read quoted text to participant. If he/she answers "yes," that he/she did other activities, then mark the correct response and continue to the Tertiary Activities portion of the questionnaire. If he/she answers "no," mark the appropriate response and end the questionnaire here.**
- **Tertiary Activities--Read quoted text to participant. Record up to three responses in the three fields provided on the form.**

After completing the phone call, go to the "Compendium of Physical Activities" provided by the Coordinating Center, find the activity category that best matches the participant's responses, and record the four-digit activity code in the appropriate box beside each response.

Follow-up Health Habits Form

The 12-month version of the Follow-up Health Habits Form, unlike the 6-month version of this form, addresses 3 areas: smoking habits, and marital and employment status (but not quality of life and weight loss, like the 6-month version of this form.)

7.2.4.4 Eighteen-Month Follow-up Contact

18-Month Adverse Events Form and Adverse Events (long) Form (if appropriate)

1. Purpose and General Instructions

One week prior to the beginning of the 18-month visit window (which is 17 to 20 months after randomization), an 18-Month Adverse Events Form, cover letter with instructions for completion, and pre-addressed postage-paid envelope should be sent to study participants. This form asks participants to report whether or not they have experienced any of the following three broad classes of adverse events during the previous three months: (1) hospitalizations; (2) chest pain, difficulty breathing, or severe dizziness or loss of consciousness at any time; and (3) leg/arm pain, swollen/sore joints, pulled/strained muscles, tendons or ligaments, or broken bones during or following exercise. Upon return of a completed 18-month A.E. Form, a measurement staff member should promptly telephone participants who respond affirmatively to ***any*** of the inquiries and administer the Adverse Events (long) Form via telephone interview.

2. Administration

Prior to mailing the 18-Month A. E. Form to a participant, the "ID," "Acrostic," and "Date Mailed" fields should be completed. The cover letter should be personalized with the participant's name and address and signed by the study coordinator.

Mechanisms for monitoring the process to ensure a timely return of the form will be left to clinic discretion. It is recommended that participants that have not returned the completed form by their 18 month target date be contacted by card or telephone and reminded to complete the form and return it to the clinic promptly. *Before the end of the 18 month window, participants who still have outstanding 18-Month A. E. forms should be contacted by telephone, and the form completed by telephone interview.*

When completed 18-Month A. E. forms are received, the date the form is received should be written in the "Date Returned" field, and participant responses should be reviewed. Patients who respond affirmatively to any of the questions on the 18-Month Adverse Events form should be contacted promptly by a measurement staff member and have the Adverse Events (long) form completed by telephone interview. See MOP section 8.10 "Completion of Adverse Events Form" for instructions on how that form is to be completed.

Date of Letter

Participant
Address
Here

Dear *Participant Name*:

We at the ACT study appreciate your involvement as a study participant and we hope that things are going well for you. It has been about 18 months since you enrolled in the study. Although you are not scheduled to return to the ACT clinic for another six months, there is some information that we would like to obtain from you now.

At your six-month visit to our clinic, and during the "one year" phone call, we asked you if you had been hospitalized or had other health problems during each of the prior six month periods. Enclosed with this letter is a form that asks you to respond to those same questions with regard to your last six months (the months between *[insert **month, year** of 12-month phone call here]* and *[insert **month, year** of 18-month target here]*). Please complete the questionnaire and return it to us in the enclosed postage-paid envelope. As always, the information you provide for us here, like all of your ACT study data, are confidential.

You are very important to us, and you are making a valuable contribution to the study. If you have any questions about this form or any other aspects of the study, please do not hesitate to call me at *[insert your clinic phone number here]*. Thank you for your time and consideration.

Sincerely yours,

ACT Study Coordinator

ACT 18-Month Adverse Events Form

FOR CLINC USE ONLY

ID ☐☐☐☐☐☐

Acrostic ☐☐☐☐☐☐

Date Mailed ☐☐ Mon ☐☐ Day ☐☐ Year

Date Returned ☐☐ Mon ☐☐ Day ☐☐ Year

Have you been admitted to the hospital during the last 6 months for any reason? 1☐ Yes 2☐ No

Have you experienced any of the following problems at any time during the last 6 months:

Chest pain? . . . . . 1☐ Yes 2☐ No

Difficulty breathing? . . . . . 1☐ Yes 2☐ No

Severe dizziness or loss of consciousness? . . . . . 1☐ Yes 2☐ No

Have you experienced any of the following problems during or following exercise during the last 6 months:

Leg or arm pain? . . . . . 1☐ Yes 2☐ No

Swollen or sore joints? . . . . . 1☐ Yes 2☐ No

Pulled or strained muscles, tendons, or ligaments? . . . . . 1☐ Yes 2☐ No

Broken Bones? . . . . . 1☐ Yes 2☐ No

Please return the completed form to the clinic using the enclosed postage-paid envelope. If you have any questions about this questionnaire or your responses, please call the ACT clinic at (___) ___-____.

Reviewed by ☐☐ (staff code)

12 month Study Disposition Form

See Section 7.2.2.2 above for instructions on completion.

Adverse Events Worksheet and Adverse Events Form, if appropriate

7.2.4.4 Eighteen-Month Follow-up Contact

Adverse Events Worksheet and Adverse Events Form, if appropriate

Two weeks prior to the date of a participant's 18 month contact, an Abbreviated Adverse Events form will be sent to study participants that asks them if within the last 6 months they have experienced any chest pain, difficulty breathing or if they have been hospitalized. This mailing will also include a cover letter (on local ACT site stationary) with instructions to complete and return the form to the measurement clinic in the enclosed addressed and prepaid envelope. Participants indicating that they have experienced any of the 3 categories of adverse events noted above will be called by measurement staff so that the more comprehensive (original) Adverse Events form can be completed in its entirety.

7.2.4.5 Twenty-four "a" Month Follow-up Visit

Forms to be completed at this visit are listed below.

Medications Form

Follow-up Health Habits Form (same 5 questions as for 6-month visit)

7-day Physical Activity Recall

24a Visit Blood Pressure Form

For the 24a visit, blood pressure information only is collected, similar to SV1 (i.e., no anthropometric measures), so the 24a visit utilizes the "24a Visit Blood Pressure Form. Consult Appendix F for information on completion of this form.

Physical Exam

See Section 7.2.4.2, under "Physical Exam."

Heart Rate Variability

$V0_2$max during GXT

24a Disposition Form

See Section 7.2.2.1 for explanation

Adverse Events Worksheet and Adverse Events Form, if appropriate

7.2.4.6 Twenty-four "b" Month Follow-up Visit

Forms to be completed at this visit are listed below.

7-day Physical Activity Recall

24-Month Activities Inventory Form

(To be updated later.)

Diet Questionnaire

The Diet and Health-related Quality of Life/Influences on Activity (HRQL/IOA) Questionnaires can be given to participants at the 24a-month follow-up visit, for completion and return at the 24b month visit.

Health-related Quality of Life/IOA

See above.

Clinical Measures Form (blood pressure and anthropometrics)

The 24b-month Clinical Measures Form is the same as the form used at SV2 (collection of blood pressure and anthropometric data). Consult Appendix F for information on completion of this form.

Venipuncture

The 24b-month blood draw, like that for SV2, will be a fasting sample, which will allow for measurement of total cholesterol, fibrinogen, LDL, HDL, triglycerides and insulin. Participants should be reminded at the 24a-month visit to fast for the upcoming 24b-month visit. Consult Appendix G for description of the procedures for collection of blood specimens.

Physical Exam

Although no more than 30 days should elapse between performance of the GXTmax at the 24a-month visit and the GXTsubmax at the 24b-month visit, it is recommended that at least a brief physical exam be performed to rule out any contraindications to the submaximal test.

Submaximal Exercise Test

24b Disposition Form

See Section 7.2.2.1 for explanation

Adverse Events Worksheet and Adverse Events Form, if appropriate

7.3 Protocol for 6-month follow-up GXT

7.3.1 Instructions to participants regarding physical activity the day before GXT testing

Participants should be instructed to refrain from any unusually vigorous physical activity the day before the follow-up treadmill test; however, performance of one's regular exercise program is appropriate.

7.3.2 Maximal Exercise Test

In addition to the following writeup on the next page, review the section near the end of Appendix B entitled "Modifications of GXT Procedures for 6-month Visit."

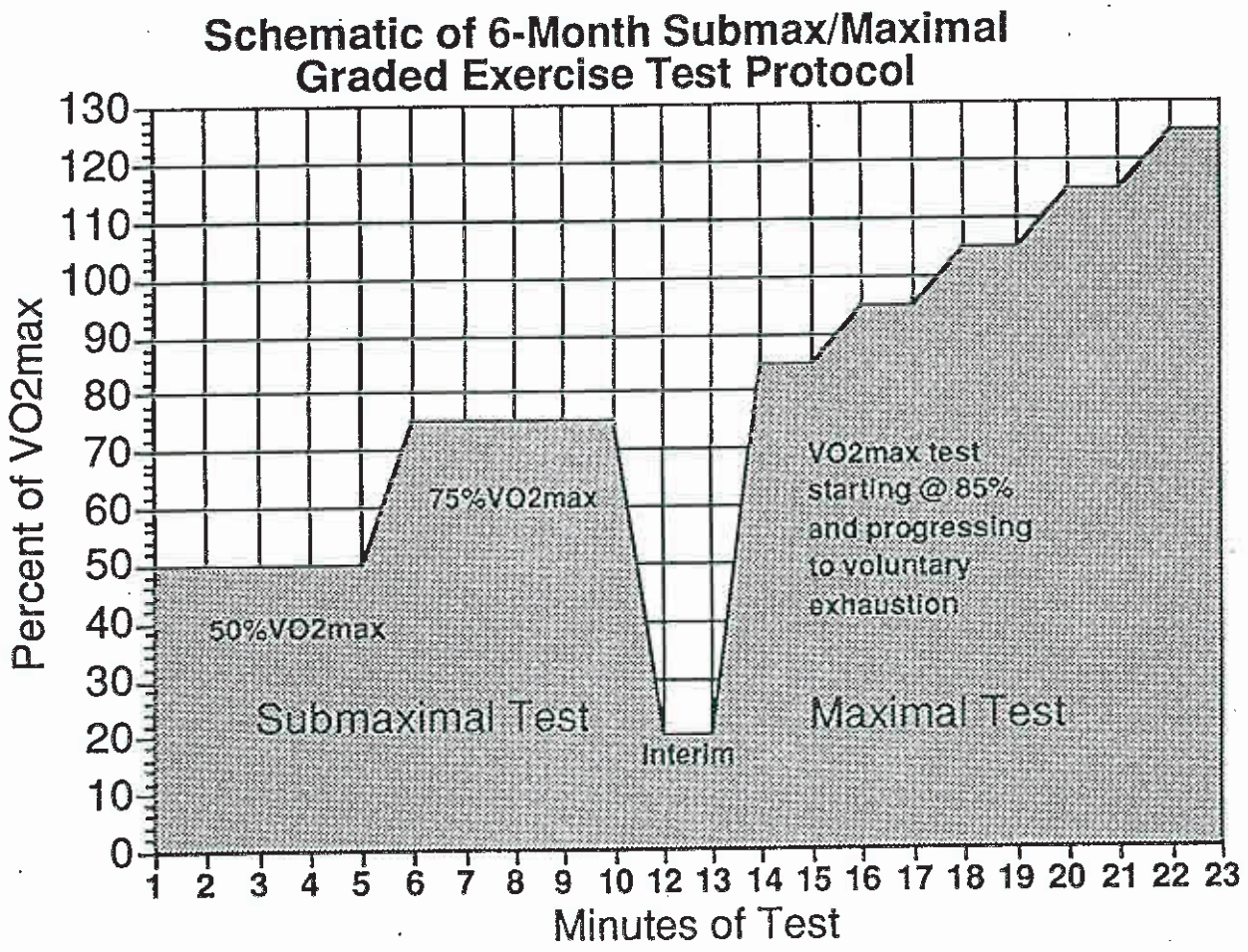
SEE FOLLOWING 2 PAGES FOR 6-MONTH PROTOCOL FOR GXT TESTING

Protocol for Six-Month GXT in ACT

Introduction to Six-Month Visit

At the six-month evaluation, the subject will return to the testing laboratory for only a single visit. Therefore, a combined protocol must be utilized that includes both the standardized submax protocol from SV2 and the V02max protocol from SV1. During the preparation for this test it should be explained to the subject that they will perform a test that utilizes the original submaximal protocol as a warm-up, followed by a brief (2-minute) interim period prior to the VO2max protocol that they performed six months earlier.

A schematic of the protocol for the Six-Month Graded Exercise Test is provided below:



It is important to understand that this protocol should be established prior to the arrival of the subject after a careful study of the submaximal and the maximal graded exercise tests performed at SV1 and SV2. This protocol must be programmed into the software that controls the treadmill prior to the arrival of the subject. The submaximal phase has two 5-minute segments, the interim phase is 2 minutes in duration, and the maximal protocol should be programmed for at least 2 additional stages **above** that obtained during the SV1 GXT to ensure that an increased functional capacity can be accommodated as a consequence of the 6 month training period. The first stage of the VO2max protocol should be set at approximately 85% of the VO2max, i.e., at ~2% grade higher than the grade utilized for the 75% portion of the submaximal test. These calculations can be determined using the Givoni & Goldman VO2 chart for level and grade walking (***JAP*** 30:429, 1971).

Submaximal workloads: Subjects will replicate the identical submaximal protocol that they performed at SV2, which consists of two submaximal workloads of 5 minutes each at a predetermined speed which will elicit ~50% and ~75% V02max to evaluate their physiological response to submaximal work. The subject will be monitored by a 12-lead ECG during the submaximal protocol with SBP/DBP, HR, and RPE obtained at the identical points as obtained at SV2. The subject will **not** be wearing the mouthpiece for expired air collection during this phase of the test.

Interim workload: A 2-minute interim workload will be interspersed between the submaximal and the maximal protocols to allow a brief walking or standing recovery period before the maximal test and also to prepare for the expired air collection required for the maximal protocol. This interim workload should be set at approximately 2 or 3 mph @ 0% grade -- or whatever is comfortable to the subject. If the subject has a very low functional capacity and would be fatigued by a walking recovery prior to starting the maximal test, then it may be better to allow the subject to stand during the interim period. The most important point to remember is that the subject must be able to attach the noseclip and insert the mouthpiece in a comfortable and a safe manner prior to commencing the max test so that the metabolic cart flow rate can be confirmed prior to expired air collection. During this time subjects will be also reminded about the hand signals, the RPE scale, and the need for the subjects to exert themselves to a voluntary maximal effort.

Maximal workload: At the end of the interim workload, the speed and grade will automatically increase to elicit the ~85% load established earlier. With speed held constant throughout the max protocol, the grade is then increased by 2% every 2 minutes until volitional exhaustion to determine V02max. The physiologic data (VO2, HR, BP, and RPE) are recorded as obtained during the VO2max test at SV1. The test is continued to volitional exhaustion followed by a 1-minute walking cool-down and a 6-minute supine recovery.

7.3.3 Submaximal Exercise Test

The only change from the screening version of this form (see Appendix B) relates to the positioning and number of "grade" boxes. The number of "grade" boxes for 50% $V0_2$max and 75% $V0_2$ max have been reduced to 2 (one for each test) and these have been moved from the "Treadmill measurements" table to near the top of the page. See Appendix B for further information, and the end of this chapter for the follow-up GXTmax and GXTsubmax Forms.

7.3.4 Additional GXT information

Primary outcome: The primary outcome VO_2max is recorded on the form using 3 expressions: ml/min, ml/kg/min, and METs.

Ventilatory threshold: The ventilatory threshold is recorded on the form using 3 expressions: L/min, ml/min, and as %VO_2max. The ventilatory threshold is calculated by the software program of the MedGraphics unit. In the event that the data are insufficient to make the calculation, missing data are recorded..

7.3.5 Contraindications to performing follow-up GXT testing

All participants should undergo a physical exam before taking the follow-up treadmill tests. Clinical judgement, in conjunction with nationally recognized guidelines, should be used to determine whether or not the participant should proceed with the GXT (see below, **Table 4**, Contraindications to Exercise Testing - Absolute and Relative). Relative blood pressure contraindications to exercise testing (as reflected by nationally recommended guidelines) are as follows: resting diastolic blood pressure > 115 mm Hg or resting systolic blood pressure >200 mm Hg.

Table 4 -- Contraindications to Exercise Testing - Absolute and Relative [a]

Absolute Contraindications

1. A recent significant change in the resting ECG suggesting infarction or other acute cardiac event
2. Recent complicated myocardial infarction (unless patient is stable and pain-free).
3. Unstable angina
4. Uncontrollable ventricular arrhythmia
5. Uncontrolled atrial arrhythmia that compromises cardiac function
6. Third degree AV heart block without pacemaker
7. Acute congestive heart failure
8. Severe aortic stenosis
9. Suspected or known dissecting aneurysm
10. Active or suspected myocarditis or pericarditis
11. Thrombophlebitis or intracardiac thrombi
12. Recent systemic or pulmonary embolus
13. Acute infections
14. Significant emotional distress (psychosis)

Relative Contraindications

1. Resting diastolic blood pressure > 115 mm Hg or resting systolic > 200 mm Hg
2. Moderate valvular heart disease
3. Known electrolyte abnormalities (hypokalemia, hypomagnesemia)
4. Fixed-rate pacemaker (rarely used)
5. Frequent or complex ventricular ectopia
6. Ventricular aneurysm
7. Uncontrollable metabolic disease (e.g., diabetes, thyrotoxicosis, or myxedema)
8. Chronic infectious disease (e.g., mononucleosis, hepatitis, AIDS)
9. Neuromuscular, musculoskeletal, or rheumatoid disorders that are exacerbated by exercise
10. Advanced or complicated pregnancy

[a]Source: ACSM, ACSM's Guidelines for Exercise Testing & Prescription, 5th Edition, Baltimore: Williams & Wilkins, 1995 (p.42)

ACT 24 Month A Follow-up Disposition Form

ID [| | | | | |] Acrostic [| | | | | |]

Date of Visit [| | | | | |] Mon Day Year

Completed by [| |] (staff code)

Visit Status:

Was visit completed as planned?

1☐ Yes

2☐ No

Was partial information collected?

1☐ Yes

Indicate below the items that are ***missing or were not performed***:

- 1☐ Max Exercise Test
- 1☐ PA 7-day Recall
- 1☐ Blood Pressure
- 1☐ F/U Health Habits
- 1☐ Heart Rate Variability
- 1☐ Medications Usage

2☐ No

Why was this visit missed?

- 1☐ Participant cannot be located.
- 2☐ Participant located but refused clinic visit.
- 3☐ Participant died (***complete Study Termination Form***)
- 4☐ Other_____
  (Specify)

ACT 24 Month B Follow-up Disposition Form

ID [ ][ ][ ][ ][ ][ ] Acrostic [ ][ ][ ][ ][ ][ ]

Date of Visit [ ][ ] Mon [ ][ ] Day [ ][ ] Year Completed by [ ][ ] (staff code)

1. Adverse Experiences:

   Has participant experienced chest pain, shortness of breath, severe dizziness or loss of consciousness during the last 6 months?

   1☐ Yes (***complete Adverse Events Form***)
   2☐ No

   Has participant experienced any of the following during or following exercise during the last 6 months: leg or arm pain; swollen or sore joints; pulled or strained muscle, tendon, or ligaments; or broken bones?

   1☐ Yes (***complete Adverse Events Form***)
   2☐ No

   Has participant been hospitalized during the last 6 months?

   1☐ Yes (***complete Adverse Events Form***)
   2☐ No

2. Visit Status:

   Was visit completed as planned?

1☐ Yes

2☐ No —

Was partial information collected?

1☐ Yes —

Indicate below the items that are ***missing or were not performed***:

1☐ PA 7-day Recall	1☐ Submax Exercise Test
1☐ Anthropometrics	1☐ Blood Collection
1☐ Blood Pressure	1☐ Diet Questionnaire
1☐ Health Related QOL/Influences on Activity	

2☐ No —

Why was this visit missed?

1☐ Participant cannot be located.
2☐ Participant located but refused clinic visit.
3☐ Participant died
4☐ Other_____
(Specify)

Complete Study Termination Form at conclusion of this visit.

ACT Study Termination Form

ID ☐☐☐☐☐☐ Acrostic ☐☐☐☐☐☐

Date of Test ☐☐/☐☐/☐☐ (Mon/Day/Year) Completed by ☐☐ (staff code)

Why is this participant being terminated from study follow-up?

1☐ Participant has completed 24-month follow-up evaluation.

2☐ Participant refuses further contact and has requested to be terminated from the study.

3☐ Participant has been lost to follow-up (all attempts to contact participant have failed).

4☐ Participant has died:

Date of Death ☐☐/☐☐/☐☐ (Mon/Day/Year)

Cause of Death:

_____

_____

State in which participant died:

1☐ Tennessee 2☐ Texas 3☐ California

4☐ Other _____ (Specify)

Obtain copy of death certificate from state in which participant died.

5☐ Participant terminated from study for other reason(s):

Specify reason(s) for termination:

_____

_____

_____

ACT Follow-up Medications Form

Clinic Use Only

ID

Acrostic

Date Completed (Mon / Day / Year)

Visit Code

If participant does not take *any* medications on a regular basis, check here: ☐

	Medication Name	Dose	Times per Day	Anti-Hypertensive	Lipid-Lowering	Hypoglycemic	Insulin	Estrogen
1.								
2.								
3.								
4.								
5.								
6.								
7.								
9.								
10.								
11.								
12.								
13.								
14.								
15.								
16.								
17.								
18.								
19.								
20.								

Completed by ☐☐ (staff code)

ACT Clinical Measures Form

ID ☐☐☐☐☐☐ Acrostic ☐☐☐☐☐☐

Date of Visit ☐☐/☐☐/☐☐ (Mon / Day / Year) Visit Code ☐☐☐

Resting Blood Pressures

Arm Circumference ☐☐.☐ cm

Time of Day ☐☐:☐☐ ☐ AM ☐ PM

Cuff Size

☐ Pediatric (16.0-22.5 cm)	☐ Adult (22.6-30.0 cm)
☐ Large Arm (30.1-37.5 cm)	☐ Thigh (37.6-43.7 cm)

Pulse Disappearance Pressure ☐☐☐ mmHg

\+ 3 0

Maximal Inflation Level ☐☐☐ mmHg

Blood Pressures (mmHg)

	Systolic	Diastolic
First BP	☐☐☐ /	☐☐☐
Second BP	☐☐☐ /	☐☐☐
Third BP	☐☐☐ /	☐☐☐

Average of 3 BPs

SBP ☐☐☐ / DBP ☐☐☐

Comments?

☐ Yes

☐ No

Measured by ☐☐ (staff code)

This page not completed for 6-month measures only.

Acrostic

Anthropometry Measurements

Height ☐☐☐.☐ cm

Weight ☐☐☐.☐ kg

Waist/Hip Circumferences (cm)

	First	Second	Third*
Waist	☐☐☐.☐ cm	☐☐☐.☐ cm	☐☐☐.☐ cm
Hip	☐☐☐.☐ cm	☐☐☐.☐ cm	☐☐☐.☐ cm

*Make third measurement only if first two differ by >1.0 cm.

Skinfold Thicknesses (mm)

	First	Second	Third**
Chest (men only)	☐☐ mm	☐☐ mm	☐☐ mm
Triceps	☐☐ mm	☐☐ mm	☐☐ mm
Subscapular	☐☐ mm	☐☐ mm	☐☐ mm
Abdominal	☐☐ mm	☐☐ mm	☐☐ mm
Suprailiac	☐☐ mm	☐☐ mm	☐☐ mm
Thigh	☐☐ mm	☐☐ mm	☐☐ mm

**Make third measurement only if first two differ by >3.0 mm.

Comments?

☐ Yes
☐ No

☐ Skinfolds greater than 65 mm (specify): _____
☐ Could not be measured (specify): _____
☐ Participant refused (specify): _____
☐ Other (specify): _____

Measured by ☐☐ (staff code)

ACT Max Graded Exercise Test Form

ID [ ] Acrostic [ ]

Date of Test [ ] [ ] [ ] [ ] [ ] [ ] Visit Code [ ] [ ] [ ]
Mon Day Year

Age [ ] Height [ ] cm Weight [ ] kg

Age-predicted Max HR (220-age) [ ] bpm

60% Age-predicted Max HR [ ] bpm

70% Age-predicted Max HR [ ] bpm

Patient on medications?

1 ☐ Yes — Specify Meds:
2 ☐ No

Resting Measurements

ECG Results:

1 ☐ Normal
2 ☐ Abnormal — Specify abnormalities:
3 ☐ Uninterpretable

Any contra-indications to treadmill testing?

1 ☐ Yes — Specify contra-indications:
2 ☐ No

Course of action taken:

1 ☐ GXT performed 2 ☐ Subject excluded (GXT **not** performed) 3 ☐ GXT rescheduled

Supine: SBP [ ] mmHg DBP [ ] mmHg HR [ ] bpm

Standing: SBP [ ] mmHg DBP [ ] mmHg HR [ ] bpm

Treadmill Measurements

Warm-up: HR [ ] bpm %HR_{max} [ ] TM Speed [ ]

Stage	Time	Grade	HR	RER	SBP	DBP	RPE	AP	ST	Arr	Comments
1	0-2										
2	2-4										
3	4-6										
4	6-8										
5	8-10										
6	10-12										
7	12-14										
8	14-16										
9	16-18										

Acrostic

Total Treadmill Time ____ min Reason for stopping: ____

Post-exercise Measurements

Time	HR	SBP	DBP	Signs, Symptoms, ECG Changes
Immediate*				
2 minute				
4 minute				
6 minute				
8 minute				

* If no BP was obtained at peak exercise, obtain one immediately after stopping.

GXT Interpretation:

1 ☐ Negative

2 ☐ Positive

Specify result or problem:

Is this a contra-indication to further treadmill testing? 1 ☐ Yes 2 ☐ No

Will this subject be excluded from participation in ACT? 1 ☐ Yes 2 ☐ No

☐ Uninterpretable

Criteria for VO_2 max

maximal heart rate ____ b/min

maximal RPE ____

maximal RER ____

maximal VE/VO_2 ____

maximal respiratory rate ____

maximal VO_2 ____ ml/min

VO_2 @ (max stage - 1) ____ ml/min

VO_2 @ (max stage - 2) ____ ml/min

Primary Outcome

VO_2 Max Measurements ____ ml/min

____ ml/kg/min

____ METS

Ventilatory Threshold

Ve (BTPS) ____ L/min

VO_2 ____ ml/min

$\%VO_2$ max ____

Test performed by ____ (code)

COMMENTS:

ACT Submax Graded Exercise Test Form

ID [ ][ ][ ][ ][ ][ ] Acrostic [ ][ ][ ][ ][ ][ ]

Date of Test [ ][ ] Mon [ ][ ] Day [ ][ ] Year Visit Code [ ][ ][ ]

BL VO_2 Max [ ] ml/min

50% Max Test
Speed [ ]
Grade [ ]

75% Max Test
Speed [ ]
Grade [ ]

Patient on medications?

1 ☐ Yes — Specify Meds:
2 ☐ No

Resting Measurements

Standing: SBP [ ] mmHg DBP [ ] mmHg HR [ ] bpm

Treadmill Measurements

Stage	Time	HR	SBP	DBP	RPE	Comments, Symptoms, ECG Changes
50% VO_2 Max	1					
	2					
	3					
	4					
	5					
75% VO_2 Max	1					
	2					
	3					
	4					
	5					

Recovery Measurments

Time	Speed	Grade	HR	Comments, Symptoms, ECG Changes
3	2	0%		

Test performed by [ ][ ] (code)

CHAPTER 8

SAFETY MONITORING

8.1	Goals	2
8.2	Measurement information given to participants	2
8.3	Measurement information forwarded to personal physicians	3
8.3a	Measurement information forwarded to non-ACT parties	4
8.4	Blood Pressure	4
8.5	Lipids	4
8.6	Beck Depression Inventory	5
8.7	Musculoskeletal and cardiovascular events	7
8.8	Deaths	8
8.9	Central Monitoring of Trial-Wide Safety	8
8.10	Adverse Events Form	9

CHAPTER 8
SAFETY MONITORING PROCEDURES

8.1 Goals

While we are not engaged in the primary care of ACT participants, it is important for us to be active in monitoring aspects of their health that we measured as part of the study and to ensure that safety-related information is routed back to the participants and their personal physicians. It is also important for us to record adverse events that may be related to participation in ACT so that we can assess both the costs and benefits of following the ACT interventions.

The principal data for monitoring safety during ACT appear in the following table. In this chapter, we will describe the ACT protocol related to each of these measures.

Source of Data	Collection
Blood pressures	Standardized clinic measurements at SV1, SV2, 6 months, and 24 months
Lipids	Samples collected at SV2, 6 months, and 24 months for central laboratory assays
Beck Depression Inventory	Self-administered form collected at SV2, 6 months, and 24 months
Cardiovascular Events and Symptoms	Self report (every 6 months) followed by a more detailed Adverse Events Form
Musculoskeletal Injuries	Self report (every 6 months) followed by a more detailed Adverse Events Form
Hospitalizations	Self report (every 6 months) followed by a more detailed Adverse Events Form
Deaths	Disposition and Study Termination Forms and Adverse Events Form, if appropriate

If, during the interactions with ACT participants, you become concerned about their safety for other reasons, please discuss your concerns with your local ACT physician and use your judgement to take appropriate actions.

8.2 Measurement information given to participants

All sites should informally provide certain measurement results to participants at the time of the baseline tests (except for lipids; participants can be told that their lipid results will be sent to their personal physician in about 3 months, the maximum time it should take to obtain lipid results from the ACT Central Laboratory). Resting blood pressure results will be given to the participants immediately, as will height and weight measures. A brief summary of the baseline GXT will be presented to the participant, in the context of

poor, fair, average or good performance according to the 1995 AHA exercise standards. GXT measurement staff should always emphasize to participants that there is room for improvement, in order to keep them motivated. No written information reflecting these data will be given to the participant, although participants will be told that this information will be sent to their doctors.

ACT participants asking about their follow-up progress on primary and secondary outcomes such as GXT cardiorespiratory fitness (VO_2max), lipids and blood pressure should be told that the measurement staff do not have access to this information until the end of the study. **Staff can make general comments to participants regarding, for example, a GXT follow-up test by indicating that the participant performed well or that the results looked "OK or normal".** Participants can be told that once the study is closed, they will receive measurement information on their progress during the course of the study.

Screening information may be given to ineligible subjects who request this information.

8.3 Measurement information forwarded to personal physicians

Before their patients are randomized, physicians will be sent a letter on ACT letterhead by the measurement clinic informing them that their patients are enrolled in ACT and that patient general information will be forwarded to them at the 6-month and 24-month follow-up visits. Personal physicians will be sent letters indicating their patients' resting blood pressures, lipid values and a brief description of the GXT. The following form letter, to be signed by an ACT physician at the measurement site, has been developed for adaptation at each site:

Dear Dr. _____:

Thank you very much for allowing your patient _____ to participate in the Activity Counseling Trial (ACT). We evaluated _____ on a treadmill exercise test today and he/she demonstrated a (poor, fair, average, good) exercise capacity by American Heart Association Exercise Standards, with a normal heart rate and blood pressure response. **(For follow-up GXT reporting, the physician letter should express GXT results only as positive or negative.)** There were no symptoms or ECG evidence of ischemia. His/her average resting blood pressure readings were ____/____ mmHg, and the height and weight were _____ cm and _____kg, respectively. Blood lipid values will be sent to you once we receive this information. **(For follow-up reporting of heart rate, blood pressure, weight and lipid results, the same information can be provided that was given at baseline.) Abnormal baseline or follow-up findings such as abnormal ECG reports can be sent to the physician's attention, if in the best interest of the patient.**

Sincerely,

_____

ACT Clinic M.D.

8.3a Measurement information forwarded to non-ACT parties.

If an ACT participant requests that some of his/her ACT baseline data be forwarded to a non-ACT party (e.g., GXT results sent to the participant's insurance company), such requests should be considered on a case-by-case basis by the ACT Measurement Subcommittee. If approval is granted, it would be important that a statement requesting forwarding of such information be signed by the participant.

8.4 Blood Pressure

The procedures for measuring blood pressures during ACT are described in Chapter 5 and Appendix F of this Manual of Procedures. These are the average of three separate measurements taken about 30 seconds apart. For entry into ACT, the average resting systolic blood pressures collected at SV1 and SV2 both must be less than 180 mmHg, and the average resting diastolic blood pressures collected at these visits must both be less than 100 mmHg.

The average blood pressure measurements collected at each visit should be routinely provided to the ACT screenees and participants, and to their personal physicians. Clinical sites will want to prepare form letters for notifying the physician. If ACT screenees and participants ask for interpretation of their blood pressure readings, we must be careful not to interfere with the relationship that they have with their clinicians. You may suggest that participants discuss the readings with their physicians in the context of the broader picture of their overall health. Each clinic may wish to keep a supply of literature on blood pressure that can be made available to screenees and participants.

8.5 Lipids

Section 5.4.2 of the ACT Manual of Procedures describes the protocol for the collection and processing of screenees' and participants' blood for measuring concentrations of total cholesterol, high density lipoprotein cholesterol (HDL-C), low density lipoprotein cholesterol (LDL-C), and triglycerides. This blood is to be collected on everyone at the SV2, 6 month, and 24 month visits.

There is likely to be a maximum lag time of 3 months before these measurements will be available to the clinical centers, due to the necessary shipping, assaying, and data transfer. It will be standard protocol for the ACT measurement clinic to forward these data to the participants' physicians. Participants can be told that their lipid results will be sent to their personal physician in about 3 months, the maximum time it should take to obtain lipid results from the ACT Central Laboratory. As lipoprotein assays are completed, the Central Laboratory

will sort and tabulate the data for transmission to the clinical centers in standardized reports. Concentrations of total cholesterol, HDL-C, LDL-C, and triglycerides (all in mg/dl) will be listed also with screening IDs. It will be the responsibility of the clinical center staff to transcribe these data into form letters to the personal physicians. This letter will be printed on ACT letterhead and signed by an ACT measurement clinic physician.

If participants wish to discuss the interpretation of lipid data, you may wish to be prepared with literature to give to them. You may wish to suggest that the participants may want to discuss their data with their physicians in the context of the broader picture of their overall health.

8.6 Beck Depression Inventory

The Beck Depression Inventory for measuring depression is part of the self-administered HRQL questionnaire that screenees and participants fill out at SV2, 6 months and 24 months. This comprises item number 45 ("I do not feel sad") through number 65 ("I have not noticed any recent change in my interest in sex.") on this form. This standardized scale is scored using a computer algorithm built into the data entry screen for these forms. After these data are entered, the computer will compute an overall score. A message will appear on the screen if either

i. the total score is greater than or equal to 18 or

ii. the individual checks any of the following responses (to item 53 on the SV2 form):

I have thoughts of killing myself, but I would not carry them out.

I would like to kill myself.

I would kill myself if I had the chance.

If this message occurs, *the ACT physician should be informed immediately so that she/he can contact the individual's personal physician.* **The enclosed draft letter should be adapted and used to forward this information to the participant's physician.**

Dear Dr. _____:

Your patient, _____ recently attended a screening (or follow-up) visit for the Activity Counseling Trial (ACT). During this visit, we routinely administer a number of health-related quality of life questionnaires including the Beck Depression Inventory (BDI). The BDI is a well-validated and respected tool for assessing depression in both clinical and free-living populations. We are required to notify you of patients who score 18 or more on this questionnaire (indicating moderate to severe depression) and/or who check any positive answer relating to thoughts of suicide.

Your patient:

☐ **Had a BDI score of 18 or greater[1]**

☐ **Checked a positive answer on the thoughts of suicide question**

We have enclosed a copy of this patient's BDI questionnaire for your records. A summary of the BDI scoring criteria appears below for your information. If you require any further information, please call:

Principal Investigator, Activity Counseling Trial (phone: _____)

Sincerely,

Activity Counseling Trial Clinical Staff

[1]NOTE: BDI Scoring criteria

<10 = none to mild depression;

10-18 = mild to moderate;

19-29 = moderate to severe;

30-63 = severe

Enclosure

The ACT physician will need to use her/his clinical judgement in handling each case individually. If, in reviewing the self-report form, you note a pattern of responses that may suggest depression, you may want to have the form entered quickly so that the computer can compute the overall score.

There are no eligibility criteria that are based specifically on the Beck Depression Inventory. If, however, a screenee appears to have significant depression based on responses to this instrument, the ACT clinical staff may wish to use their judgement as to whether the participant would be suitable for randomization into ACT.

The ACT protocol defines a score greater than or equal to 18 on the Beck Depression Inventory or the responses related to suicide listed above as constituting alert conditions. The Coordinating Center, Steering Committee and ACT Data and Safety Monitoring Committees will monitor the occurrences of these alert levels.

8.7 Musculoskeletal and cardiovascular events

All randomized participants will be free of overt cardiovascular disease at baseline. While patients will be excluded from the study for musculoskeletal problems that are sufficient to functionally limit them in walking one-quarter mile or climbing ten steps, minor musculoskeletal problems may be present at baseline (clinical staff may exclude for other reasons at their discretion).

During follow-up, musculoskeletal and cardiovascular events will be queried using standard protocol every six months. At the 6 and 24b month visits, this will be done as part of the visit disposition forms. At 12 months, this will be part of the disposition form for the telephone survey. At 18 months, this information will be collected using a ~~5" x 7"~~ pre-addressed, postage-paid ~~card~~ letter that the participant can complete and return by mail. Either the visit disposition forms or the postage-paid ~~card~~ letter will query (yes/no responses) for 3 adverse event categories during the specified time period:

1) ***Cardiovascular*** (chest pain, difficulty breathing, fainting, dizziness or loss of consciousness);
2) ***Musculoskeletal*** (any of the following during or after exercise...leg or arm pain, swollen or sore joints, pulled or strained muscle, or broken/fractured bones);
3) ***Hospitalization for any reason.***

A positive response to any of these items requires that the more detailed Adverse Events Form be filled out. (See Section 8.10 for more detailed information on completion of this form.)

Adverse events occurring before the 6-month visit will be captured at the 6-month visit, at which time the Disposition and Adverse Events Forms should be completed. If a participant death occurs between visits, the Disposition and Study Termination Forms for the next scheduled visit/call should be completed immediately. Any hospitalization information related to the death should be entered into the Adverse Events Form. See Section 8.8 below for more detailed information.

When any adverse events or symptoms are noted by the above means, the case should be referred to the Clinic Coordinator, who will initiate the process of informing the personal physician. Adverse event (AE) data collected during follow-up will be incorporated into the doctor's letter discussed above. AE information ascertained at the 12-month phone call will be forwarded to the personal physicians as well. When the ACT Interventionist becomes aware of an AE, the personal physician should be informed. Efforts should, however, be made to keep physicians blinded to ACT patient treatment assignments.

The ACT interventionists will also monitor participants for adverse events that may affect how interventions should be tailored to individual participants. *Since clinic staff (i.e., those performing ACT measurements) should be blinded to information collected by the interventionists, interventionists should not inform ACT measurement staff about participant adverse events.*

8.8 Deaths

It may be that no deaths will occur among the ACT participants during the trial. For completeness, however, it will be important to document if any deaths do occur and to determine the cause of death.

ACT personnel should become aware of deaths while investigating missed 6 and 24 month visits or when making the 12-month phone call or when obtaining information from the 18-month mail-back card (query family member if card is not returned). If these occur, a Disposition Form (for the next scheduled visit or call) and the Study Termination Form should be completed, with death being entered as the reason for the missed visit. Any hospitalization information related to the death should be entered into the Adverse Events Form.

If study personnel become aware of a participant death between follow-up visits or the 12-month phone call, the Disposition Form for the next scheduled visit or call and the Study Termination Form should be completed immediately. Any hospitalization information related to the death should be entered into the Adverse Events Form. For example, if a participant death occurs before the 6-month visit, the 6-month Disposition and Study Termination Forms should be completed immediately, followed by the Adverse Events Form, if appropriate. A participant death occurring between the 6 month visit and 12 month follow-up phone call should be documented on the 12-month Disposition Form and the Study Termination Form. Any participant death occurring after the 12 month follow-up visit should be reported on the 24b month Disposition Form and the Study Termination Form.

It may be necessary to obtain medical records to discern the cause of death in order to complete this form. Each Clinical Center will be responsible for obtaining a copy of the death certificate for any participants that die during the follow-up period. A photocopy of the death certificate should be forwarded to the Coordinating Center.

8.9 Central Monitoring of Trial-Wide Safety

The National Heart, Lung, and Blood Institute (NHLBI) has appointed the ACT Data and Safety Monitoring Board, whose charge includes reviewing the overall safety of ACT participants and the ACT interventions. This committee will meet approximately every 6 months, and more frequently if needed, to discuss detailed reports prepared by the Coordinating Center and to make recommendations to the NHLBI and ACT investigators on safety. Committee members will be completely unblinded to safety and intervention data.

Participant safety will be routinely reviewed by the ACT Steering Committee, based on reports prepared by the Coordinating Center. The Coordinating Center, Steering Committee and ACT Data and Safety Monitoring Committees will monitor the occurrences of blood pressure alert levels, defined as greater than 140 mmHg and diastolic blood pressures greater than 90 mmHg, in accordance with consensus national guidelines (e.g. National High Blood Pressure Education Program. The Fifth Report of the Joint National Committee on Detection, Evaluation, and Treatment of High Blood Pressure. Arch Intern Med. 1993;153:154-183.).

The Coordinating Center, Steering Committee and ACT Data and Safety Monitoring Committee will also monitor the occurrences of lipid alert levels, defined as HDL-C levels less than 35 mg/dl and LDL-C levels greater than 140 mg/dl, in accordance with consensus national guidelines (National Cholesterol Education Program).

Also included in Coordinating Center safety reports will be the timeliness and completeness of adverse events.

8.10 Completion Adverse Events Forms

1. Purpose

As noted in Section 8.7, if information collected on either the disposition forms (6- or 24b-month visits; 12-month phone survey) or the mail-back card (sent at 18 months follow-up) indicate that the participant had experienced cardiovascular or musculoskeletal adverse events or had been hospitalized, the more detailed Adverse Events form must be completed. Adverse events noted by means of the mailed self-report card at 18 months should trigger an immediate phone call to complete the Adverse Events form. If ACT measurement personnel become aware of an AE before the next scheduled follow-up visit/call/mail contact, the AE information should be documented for later completion of the Adverse Events Form at the next scheduled contact (death would be the only exception that would trigger immediate completion of the appropriate Disposition and Study Termination Forms). However, if appropriate, personal physicians could be notified of these AEs, which occurred between regularly scheduled participant contacts.

The Follow-up Adverse Events Worksheet facilitates the initial querying about adverse events. Any "yes" response would necessitate completing the more detailed Adverse Events Questionnaire in its entirety. Information on this worksheet will not be data entered. Rather this information needs to be transcribed to the appropriate Disposition Form, from which the data will be entered. Data collected on the actual AE Questionnaire will also be entered. Because the worksheet is not part of the ACT database, this document will not be printed. This should be reproduced locally.

The interviewer-administered Adverse Events form, which appears at the end of this chapter, is designed to capture greater detail concerning the three primary categories of adverse events: 1) cardiovascular, 2) musculoskeletal and 3) hospitalizations. It should be completed during the same session (clinic visit or phone call), whenever possible. Adverse Events form data should be entered into the ACT computer expeditiously so that the Coordinating Center can keep an up-to-date accounting of participant safety.

2. Administration

Even if only one section of the Adverse Events form needs to be completed, (i.e., with appropriate "yes" responses), the form should be completed in its entirety.

Top portion of form -- Enter participant ID, acrostic, date of completion and appropriate visit and staff codes at the beginning of the form. See Section H.3 of the MOP for detailed instructions on completion of this portion of the form.

Hospitalizations (Question 1) -- If the participant was hospitalized during the last 6 months, enter the total number of admissions and the total number of nights stayed for all admissions. Write in the reason(s) for the hospitalization.

Cardiovascular adverse events (Questions 2-5) -- These address chest pain, difficulty breathing, and fainting/dizziness/loss of consciousness. Any "yes" response should lead to completion of the appropriate inner box(es).

Musculoskeletal adverse events (Questions 6-9) -- These address specific musculoskeletal problems encountered during or following exercise. Categories include leg or arm pain; swollen or sore joints; pulled or strained muscle, tendon or ligament; and any broken or fractured bones. Any "yes" response should lead to completion of the appropriate inner box(es).

ACT Follow-up Adverse Events Questionnaire

ID ☐☐☐☐☐☐ Acrostic ☐☐☐☐☐☐

Date Completed ☐☐/☐☐/☐☐ (Mon / Day / Year) Visit Code ☐☐☐

Form completed by: ☐☐ (staff code)

1. ***Were you hospitalized during the last 6 months?***

1☐ Yes —

Number of admissions ☐☐ Total number of nights stayed ☐☐☐

Reason(s) for hospitalization :

_____

_____

2☐ No

The following questions are about adverse experiences.

2. Have you experienced ***chest pain*** during the past 6 months?

1☐ Yes —

a) Did the chest pain affect your physical activity routine?

1☐ Yes —

i) Did you stop your routine?

1☐ Yes —

For more than 1 week?

1☐ Yes→ How many weeks? ☐☐.☐

2☐ No

2☐ No

ii) Did you shorten your routine? 1☐ Yes 2☐ No

iii) Did you decrease the intensity of your routine? 1☐ Yes 2☐ No

1☐ Yes —

b) Did you see a physician for your chest pain?

1☐ Yes→ How many times? ☐☐

2☐ No

2☐ No

c) Were you hospitalized for your chest pain?

1☐ Yes→ How many nights did you stay? ☐☐

2☐ No

d) Did you have surgery because of your chest pain? 1☐ Yes 2☐ No

e) Did you miss any work because of your chest pain?

1☐ Yes→ How many days? ☐☐.☐

2☐ No

Acrostic ☐☐☐☐☐☐

3. Have you experienced ***difficulty breathing*** during the last 6 months?

1☐ Yes
2☐ No

a) Did this breathing problem affect your physical activity routine?

1☐ Yes
2☐ No

i) Did you stop your routine?

1☐ Yes
2☐ No

For more than 1 week?
1☐ Yes→ How many weeks? ☐☐.☐
2☐ No

ii) Did you shorten your routine? 1☐ Yes 2☐ No

iii) Did you decrease the intensity of your routine? 1☐ Yes 2☐ No

1☐ Yes
2☐ No

b) Did you see a physician for your breathing problem?
1☐ Yes→ How many times? ☐☐
2☐ No

c) Were you hospitalized for your breathing problem?
1☐ Yes→ How many nights did you stay? ☐☐
2☐ No

d) Did you have surgery because of your breathing problem?
1☐ Yes 2☐ No

e) Did you miss any work because of your breathing problem?
1☐ Yes→ How many days? ☐☐.☐
2☐ No

Acrostic [ ][ ][ ][ ][ ][ ]

4. Have you experienced ***severe dizziness or loss of consciousness*** during the last 6 months?

1☐ Yes
2☐ No

a) Did the fainting or dizziness affect your physical activity routine?

1☐ Yes
2☐ No

i) Did you stop your routine?

1☐ Yes
2☐ No

For more than 1 week?
1☐ Yes→ How many weeks? [ ][ ].[ ]
2☐ No

ii) Did you shorten your routine? 1☐ Yes 2☐ No

iii) Did you decrease the intensity of your routine? 1☐ Yes 2☐ No

b) Did you see a physician for your fainting or dizziness?
1☐ Yes→ How many times? [ ][ ]
2☐ No

c) Were you hospitalized for your fainting or dizziness?
1☐ Yes→ How many nights did you stay? [ ][ ]
2☐ No

d) Did you have surgery because of your fainting or dizziness?
1☐ Yes 2☐ No

e) Did you miss any work because of your fainting or dizziness?
1☐ Yes→ How many days? [ ][ ].[ ]
2☐ No

Acrostic ☐☐☐☐☐☐

Please tell us whether or not you have experienced any of the following conditions in the past 6 months ***during or following exercise***.

5. Have you experienced ***leg or arm pain***?

1☐ Yes
2☐ No

a) Did the leg or arm pain affect your physical activity routine?

1☐ Yes
2☐ No

i) Did you stop your routine?

1☐ Yes
2☐ No

For more than 1 week?
1☐ Yes→ How many weeks? ☐☐.☐
2☐ No

ii) Did you shorten your routine? 1☐ Yes 2☐ No

iii) Did you decrease the intensity of your routine? 1☐ Yes 2☐ No

b) Did you see a physician for your pain?
1☐ Yes→ How many times? ☐☐
2☐ No

c) Were you hospitalized for your pain?
1☐ Yes→ How many nights did you stay? ☐☐
2☐ No

d) Did you have surgery because of your pain?
1☐ Yes 2☐ No

e) Did you miss any work because of your pain?
1☐ Yes→ How many days? ☐☐.☐
2☐ No

f) In which limbs did you have this pain (mark all that apply):
1☐ Right arm 1☐ Left arm
1☐ Right leg 1☐ Left leg

Acrostic ☐☐☐☐☐☐

6. Have you experienced ***swollen or sore joints***?

1☐ Yes
2☐ No

a) Did the swollen or sore joints affect your physical activity routine?

1☐ Yes
2☐ No

i) Did you stop your routine?

1☐ Yes
2☐ No

For more than 1 week?

1☐ Yes→ How many weeks? ☐☐.☐
2☐ No

ii) Did you shorten your routine? 1☐ Yes 2☐ No

iii) Did you decrease the intensity of your routine? 1☐ Yes 2☐ No

b) Did you see a physician for your joint problem?

1☐ Yes→ How many times? ☐☐
2☐ No

c) Were you hospitalized for your joint problem?

1☐ Yes→ How many nights did you stay? ☐☐
2☐ No

d) Did you have surgery because of your joint problem?

1☐ Yes 2☐ No

e) Did you miss any work because of your joint problem?

1☐ Yes→ How many days? ☐☐.☐
2☐ No

f) In which part(s) of your body did you have this joint problem (mark all that apply):

1☐ Right wrist	1☐ Left wrist
1☐ Right elbow	1☐ Left elbow
1☐ Right shoulder	1☐ Left shoulder
1☐ Right ankle	1☐ Left ankle
1☐ Right knee	1☐ Left knee
1☐ Right Hip	1☐ Left hip

1☐ Other _____
(Specify)

Acrostic ☐☐☐☐☐☐

7. Have you experienced ***a pulled or strained muscle, tendon, or ligament***?

1☐ Yes
2☐ No

a) Did the muscle/ligament strain affect your physical activity routine?

1☐ Yes
2☐ No

i) Did you stop your routine?

1☐ Yes
2☐ No

For more than 1 week?
1☐ Yes→ How many weeks? ☐☐.☐
2☐ No

ii) Did you shorten your routine? 1☐ Yes 2☐ No

iii) Did you decrease the intensity of your routine? 1☐ Yes 2☐ No

b) Did you see a physician for your muscle/ligament strain?
1☐ Yes→ How many times? ☐☐
2☐ No

c) Were you hospitalized for your muscle/ligament strain?
1☐ Yes→ How many nights did you stay? ☐☐
2☐ No

1☐ Yes
2☐ No

d) Did you have surgery because of your muscle/ligament strain?
1☐ Yes 2☐ No

e) Did you miss any work because of your muscle/ligament strain?
1☐ Yes→ How many days? ☐☐.☐
2☐ No

f) In which part(s) of your body did you have this muscle/ligament strain (mark all that apply):

1☐ Right hand	1☐ Left hand
1☐ Right arm	1☐ Left arm
1☐ Right foot	1☐ Left foot
1☐ Right leg	1☐ Left leg
1☐ Abdomen	1☐ Neck
1☐ Trunk or ribs	1☐ Chest
1☐ Lower back	1☐ Upper back

1☐ Other_____
(Specify)

Acrostic ☐☐☐☐☐☐

8. Have you experienced ***any broken or fractured bones***?

1☐ Yes
2☐ No

a) Did the fracture affect your physical activity routine?

1☐ Yes
2☐ No

i) Did you stop your routine?

1☐ Yes
2☐ No

For more than 1 week?
1☐ Yes→ How many weeks? ☐☐.☐
2☐ No

ii) Did you shorten your routine? 1☐ Yes 2☐ No

iii) Did you decrease the intensity of your routine? 1☐ Yes 2☐ No

b) Did you see a physician for your fracture?
1☐ Yes→ How many times? ☐☐
2☐ No

c) Were you hospitalized for your fracture?
1☐ Yes→ How many nights did you stay? ☐☐
2☐ No

1☐ Yes
2☐ No

d) Did you have surgery because of your fracture?
1☐ Yes 2☐ No

e) Did you miss any work because of your fracture?
1☐ Yes→ How many days? ☐☐.☐
2☐ No

f) In which part(s) of your body did you have this fracture (mark all that apply):

1☐ Right hand	1☐ Left hand
1☐ Right arm	1☐ Left arm
1☐ Right foot	1☐ Left foot
1☐ Right leg	1☐ Left leg
1☐ Trunk or ribs	1☐ Back
1☐ Head	1☐ Neck

1☐ Other_____
(Specify)

ACT Study Termination Form

ID ☐☐☐☐☐☐ Acrostic ☐☐☐☐☐☐

Date of Test ☐☐ ☐☐ ☐☐ (Mon Day Year) Completed by ☐☐ (staff code)

Why is this participant being terminated from study follow-up?

1☐ Participant has completed 24-month follow-up evaluation.

2☐ Participant refuses further contact and has requested to be terminated from the study.

3☐ Participant has been lost to follow-up (all attempts to contact participant have failed).

4☐ Participant has died:

Date of Death ☐☐ ☐☐ ☐☐ (Mon Day Year)

Cause of Death:

_____

_____

State in which participant died:

1☐ Tennessee 2☐ Texas 3☐ California

4☐ Other _____ (Specify)

Obtain copy of death certificate from state in which participant died.

5☐ Participant terminated from study for other reason(s):

Specify reason(s) for termination:

_____

_____

_____

ACT 6 Month Follow-up Visit Disposition Form

ID ☐☐☐☐☐☐ Acrostic ☐☐☐☐☐☐

Date of Visit ☐☐ Mon ☐☐ Day ☐☐ Year

Completed by ☐☐ (staff code)

1. Adverse Experiences:

   Has participant experienced chest pain, difficulty breathing, severe dizziness or loss of consciousness since randomization?

   1☐ Yes (***complete Adverse Events Form***)
   2☐ No

   Has participant experienced any of the following during or following exercise since randomization: leg or arm pain; swollen or sore joints; pulled or strained muscle, tendon, or ligaments; or broken bones?

   1☐ Yes (***complete Adverse Events Form***)
   2☐ No

   Has participant been hospitalized during the last 6 months?

   1☐ Yes (***complete Adverse Events Form***)
   2☐ No

2. Visit Status:
   Was visit completed as planned?

   1☐ Yes
   2☐ No

   Was partial information collected?

   1☐ Yes

   Indicate below the items that are ***missing or were not performed***:

1☐ Max Exercise Test	1☐ Submax Exercise Test
1☐ PA 7-day Recall	1☐ Heart Rate Variability
1☐ Anthropometrics	1☐ Blood Collection
1☐ Blood Pressure	1☐ Medications Usage
1☐ Diet Questionnaire	1☐ F/U Health Habits
1☐ Health Related QOL/Influences on Activity	

   2☐ No

   Why was this visit missed?
   1☐ Participant cannot be located.
   2☐ Participant located but refused clinic visit.
   3☐ Participant died (***complete Study Termination Form***)
   4☐ Other_____
   (Specify)

ACT 12 Month Telephone Follow-up Disposition Form

ID ☐☐☐☐☐☐ Acrostic ☐☐☐☐☐☐

Date of Call ☐☐ Mon ☐☐ Day ☐☐ Year

Completed by ☐☐ (staff code)

1. Adverse Experiences:

   "Have you experienced chest pain, difficulty breathing, severe dizziness or loss of consciousness during the last 6 months?"

   1☐ Yes (***complete Adverse Events Form***)
   2☐ No

   "Have you experienced any of the following problems during or following exercise in the last 6 months: leg or arm pain; swollen or sore joints; pulled or strained muscle, tendon, or ligaments; or broken bones?"

   1☐ Yes (***complete Adverse Events Form***)
   2☐ No

   "Have you been hospitalized during the last 6 months?"

   1☐ Yes (***complete Adverse Events Form***)
   2☐ No

2. Phone Call Status:

   Was phone call completed as planned?

   1☐ Yes

   2☐ No

   Why was this phone call missed?
   1☐ Participant cannot be located.
   2☐ Participant located but refused interview.
   3☐ Participant died (***complete Study Termination Form***)
   4☐ Other_____
   (Specify)

ACT 24 Month B Follow-up Disposition Form

ID ☐☐☐☐☐☐ Acrostic ☐☐☐☐☐☐

Date of Visit ☐☐ Mon ☐☐ Day ☐☐ Year

Completed by ☐☐ (staff code)

1. Adverse Experiences:

   Has participant experienced chest pain, difficulty breathing, severe dizziness or loss of consciousness during the last 6 months?

   1☐ Yes (***complete Adverse Events Form***)
   2☐ No

   Has participant experienced any of the following during or following exercise during the last 6 months: leg or arm pain; swollen or sore joints; pulled or strained muscle, tendon, or ligaments; or broken bones?

   1☐ Yes (***complete Adverse Events Form***)
   2☐ No

   Has participant been hospitalized during the last 6 months?

   1☐ Yes (***complete Adverse Events Form***)
   2☐ No

2. Visit Status:

   Was visit completed as planned?

   1☐ Yes

   2☐ No

   Was partial information collected?

   1☐ Yes

   Indicate below the items that are ***missing or were not performed***:

   1☐ PA 7-day Recall
   1☐ Anthropometrics
   1☐ Blood Pressure
   1☐ Submax Exercise Test
   1☐ Blood Collection
   1☐ Diet Questionnaire
   1☐ Health Related QOL/Influences on Activity

   2☐ No

   Why was this visit missed?

   1☐ Participant cannot be located.
   2☐ Participant located but refused clinic visit.
   3☐ Participant died
   4☐ Other_____
   (Specify)

Complete Study Termination Form at conclusion of this visit.

CHAPTER 9
PROMOTION OF COMPLIANCE WITH DATA COLLECTION

9.1 Introduction 2

9.2 General Discussion 2

9.3 Promoting Attendance for Scheduled Clinic Visits 4

9.4 Management of Non-Adherence 4
9.4.1 Missed Visits 4
9.4.2 Refusals 5

9.5 Promotion and Maintenance of Adherence 5
9.5.1 Participant-Staff Relationship 5
9.5.2 Continuity of Care 5
9.5.3 Clinic Environment 5
9.5.4 Participant-Staff Communications 6
9.5.5 Convenience and Accessibility 6
9.5.6 Time in Clinic 6
9.5.7 Appointment Reminders 6
9.5.8 Interim Contact Between Scheduled Follow-up Visits 7
9.5.9 Participant Identity with ACT 7
9.5.10 Involvement of Family Members 7
9.5.11 Staff Meetings 8
9.5.12 Participant ID Cards 8
9.5.13 ACT Relationship with Private Source of Care 8
9.5.14 Re-Education 8

9.6 Monitoring Clinic Retention 9

CHAPTER 9
PROMOTION OF COMPLIANCE WITH DATA COLLECTION

9.1 Introduction

In order for ACT to succeed, it will be important for us to describe as fully as we can the experience of the ACT cohort. This means that it will be very important for us to adhere to the planned data collection schedule for every randomized participant, regardless of which intervention arm that they have been assigned to, how regularly they receive intervention contacts, and whether they adhere to the interventions or other aspects of the ACT protocol.

In this chapter, we focus on ways to promote adherence to data collection visits. Some general guidelines and suggestions that should be considered to help promote and improve clinic attendance are presented. It is very important that attendance to clinic visits be emphasized uniformly to all participants, and to be presented in a way that does not interfere with or confound the aims of the ACT interventions. It will be important for clinic staff to review with the ACT intervention staff their plans to promote clinic attendance to ensure that these plans are appropriate.

As with other chapters of this Manual, the target audience is members of the ACT clinic staff and ACT investigators. (A separate discussion of adherence and retention issues for ACT interventionists appears in the Intervention Manual.) The suggestions that are provided are based on experience from other National Institutes of Health trials such as the Systolic Hypertension in the Elderly Program (SHEP), the Postmenopausal Estrogen/Progestin Interventions (PEPI) trial, the Asymptomatic Carotid Artery Progression Study (ACAPS), and the Trial of Nonpharmacologic Interventions in the Elderly (TONE) study. Not every clinic will be able to use every technique, but this discussion should be useful to clinics for planning their strategies to enhance the completeness of data collection in ACT.

Although the experience of other trials is useful, actual experience with ACT participants will be invaluable in deciding what works and what does not. During the trial, clinics with good attendance records will be asked to share whatever compliance techniques they have found to be fruitful.

9.2 General Discussion

Efforts to promote adherence to scheduled data collection should begin during the Pre-Screening interview (SV0), which may be the first time a potential participant will discuss the study with ACT staff. At this time, potential participants will be educated about some of the public

health concerns related to physical activity. An informed person is more likely to comprehend the goal of ACT: to help clinical practices make decisions about the best ways to promote physical activity among their patients.

Although convincing evidence is lacking, it seems reasonable that a truly informed subject is more likely to adhere to the study protocol. Therefore, for scientific, as well as ethical concerns, each person considered for ACT should clearly understand the study and adequate time should be spent so that they understand what is expected of them. This should include a discussion of the main features of the study, the possible intervention regimens to be followed over the duration of the study, laboratory tests and procedures required, and the timetable for clinic and intervention visits. A potential participant should be encouraged to consult with their family or private physician prior to signing consent forms in order to minimize the chance that they may change their mind later and drop out.

From the beginning, the clinical center staff should make it clear to the prospective participant what test results they will receive and when these tests will be performed during the course of the study. In general, screening test results will be available immediately; however, follow-up test results (exercise test measures, blood pressures, and laboratory results), unless they indicate a possible abnormal finding, will not be made available until the end of the study.

Before enrollment, several steps will be taken to minimize compliance problems related to data collection. Because ACT requires a dedicated commitment to an examination schedule, we must select appropriate subjects and assess their potential for following the protocol before randomizing them. Only those persons who are likely to follow the study protocol should be enrolled.

It is usually advisable to exclude certain types of people from participation in a trial. ACT exclusion criteria include indications that persons are addicted to drugs or alcohol, live too far away, are likely to move before the scheduled termination of the trial, or are involved in other clinical research that may interfere with ACT. The judgement of clinical center staff is essential in determining overall eligibility with respect to adherence.

It is especially critical in studies of long duration to maintain good attendance after randomization. Providing clear, easy-to-follow, written instructions for returning for follow-up visits is important. Reviewing these instructions with the participant periodically during follow-up should be a priority, especially if demonstrated compliance problems exist. Involving the subject's spouse or other family members in these reviews can be useful.

Attempts should be made to maintain continuity of follow-up care. Whenever possible, the same ACT staff should see the subject throughout the study.

Every attempt should be made to make each clinic visit pleasant. Minimizing waiting time and providing such things as parking facilities, free transportation, and comfortable waiting room facilities will make the visit more pleasant and make the participant more likely to keep their subsequent appointments.

9.3 Promoting Attendance for Scheduled Clinic Visits

During the follow-up phase, participants are required to attend the clinic 6 and 24 months after randomization. Attendance at scheduled clinic visits is documented by the completion of the appropriate Follow-Up Visit and Missed Visit forms.

Clinics are advised to keep detailed records of rescheduled and broken appointments for each individual participant. It is important to monitor each participant and identify persons who need support. Records of participants consenting to only a portion of the follow-up procedures, i.e. partial compliance, should also be maintained. Local summary reports of such difficulties are important to identify problems. Critical review of such problems may suggest solutions.

9.4 Management of Non-Adherence

Plans should be made to handle non-attendance at the clinic. The procedures discussed below may be used for handling and documenting these cases.

9.4.1 Missed Visits

Participants not attending the clinic during the required time frame are considered to have missed a visit. Careful documentation and monitoring of missed visits is important in the specific, as well as the overall, management of these cases. The following procedures should be implemented as appropriate in each clinical center:

1) Preparing for the next visit at the end of each current visit by making the appointment and giving instructions for the next visit.
2) Sending out pre-visit reminders.
3) Establishing a mechanism by which clinic attendance for each participant can be charted and monitored locally so that the clinic can be immediately alerted to a missed visit.
4) Immediately contacting (usually by telephone) the participant when they miss a visit.
5) Planning clinic action to rectify the problem within the scope of clinic services.
6) Rescheduling the visit, if at all possible, within the same window.

Examinations that fall outside of the target window remain important and will be used

in ACT analyses. These examinations will be assigned to whichever target time they are closest to: a visit not occurring until 8 months will be recorded using Follow-up Visit 6 forms, while a visit occurring after 9 months will be recorded using 12 month forms. If it becomes apparent that a visit corresponding to a particular set of forms, e.g. a 6 month visit, will not be completed, an ACT Missed Visit form should be filled out.

9.4.2 Refusals

Some participants randomized into the study may not be actively participating, i.e., not adhering to the ACT intervention and/or not attending the ACT clinic. This may be due to any of a number of reasons, such as transportation problems, the advice from their family, or the participant's decision. Regardless of the reason, these participants should be followed until the end of the study, and the clinic staff must attempt to make contact at 6, 12, and 24 months. These contacts are intended to remind the participant that they are still eligible to participate in the study. Considerable effort should be expended to collect physical activity recalls and VO_2max measurements at appropriate times.

9.5 Promotion and Maintenance of Adherence

The following guidelines may help to attain better adherence to the ACT protocol, both in the area of intervention adherence and in clinic attendance. Resources available to a clinic will determine which techniques are most appropriate for that clinic.

9.5.1 Participant-Staff Relationship

The key element in successfully maintaining a participant in a clinical trial is the development of a personal relationship between the individual participant and individual members of the staff. Impersonal form letters or phone calls from someone not known to the participant are far less likely than personal contact to succeed in keeping a participant interested in the trial. This personal element in participant contacts cannot be overemphasized.

9.5.2 Continuity of Care

In general, participants' appointments should be scheduled so that they can be seen by the same clinic staff members on each visit.

9.5.3 Clinic Environment

The clinic environment should be warm and pleasant, and oriented to the comfort of the participant. Personal notes can be made of events in the life of the participant--these can be commented on at the next visit (for example, the birth of a grandchild). If possible and if resources are available, lunch might be provided.

9.5.4 Participant-Staff Communications

Good and consistent communication is essential. Instructions should be clear and interactions should be friendly and individualized. The participant should be helped to understand the beneficial nature of their participation in this program. The written reminders of data collection appointments, which the ACT protocol calls for participants to receive two weeks prior to scheduled visits, offer a good opportunity for communication.

It may be useful for un-masked clinic staff to regularly meet with intervention staff to discuss the consistency of communications from these two groups.

9.5.5 Convenience and Accessibility

An easily accessible clinic location, the availability of transportation, and convenient clinic hours are important factors for maintaining adherence. Each clinical center is responsible for making visits easy for the participants, a factor critical to the ultimate success of the study. Depending on local circumstances, different approaches may be used, but no participant should be unable to attend the clinic because of transportation, hours of clinic operation, or any similar circumstance. If necessary (and if funds are available), participants should be reimbursed for transportation. Pre-arranged parking should be available if at all possible. The ACT protocol calls for the clinical centers to provide free transportation to clinical center visits, if necessary.

Appointments should be scheduled at times and on days that do not interfere with a participant's working schedule. All clinical centers should have at least some clinic sessions on evenings or weekends, outside of usual working hours, if necessary.

9.5.6 Time in Clinic

One element that may be of vital importance in keeping participants returning for interviews over a prolonged period is the time that it takes to be seen at each clinic. Total clinic visit time for a participant at any single visit should be kept to a minimum consistent with maintaining quality. If waiting is necessary, explain the situation and, if possible, offer the option of seeing another staff member or rescheduling. On the other hand, participants ought not to feel rushed or be made to feel unwelcome. ACT participants should feel that in any department they are as important as any other patients. Taking time to visit with the participants and having coffee and the daily newspaper available will help to establish this feeling.

9.5.7 Appointment Reminders

Like the rest of us, participants can forget appointments. Therefore, appointment reminders should be used to prompt participants to come for clinic visits. These written reminders

should be mailed to ACT participants so that they receive them one to two weeks before their scheduled visit date.

9.5.8 Interim Contact Between Scheduled Follow-Up Visits

During the screening and randomization phases, when the study process is still relatively new, ACT staff should contact participants by telephone to remind them of clinic appointments and check to see if they have questions or concerns.

During the period between the follow-up visits, a participant may have second thoughts or develop apathy toward the study. These visits demand that the participant interrupt their normal routine and make a trip to the clinic. Participants with otherwise good intentions may find this an unwelcome task. It is especially important, then, that clinic staff maintain contact with participants between visits.

The first follow-up visit at six months often presents special problems simply in its newness to the participant. Once the route to the clinic site and the personnel and procedures within have become familiar, subsequent visits should not evoke any such anxiety. Clinic staff may aid the participant in overcoming any reluctance to attend the first follow-up visit by any means locally feasible. Maps may be distributed to the participant, showing the location of the ACT clinic.

The participant should not feel, however, that they are being "checked on." Early in the screening process, clinic staff might ask the participant if they would object to a telephone call before the next visit and ask what time of the day and which day of the week that they prefer to be called. Clinic staff should determine what is the best time for calling the participant and schedule the calls accordingly, rather than leaving a message simply asking a participant to call back. However, the participant should be encouraged to call if they have any questions or problems.

9.5.9 Participant Identity with ACT

The clinics should focus on promoting participant identity with ACT. Regular communication will encourage such identity. This could include holiday cards or notices of special events.

9.5.10 Involvement of Family Members

Family members' involvement should be encouraged. A pamphlet describing the trial for the family members may foster successful involvement. The spouse should be informed about the study's purpose, its general design and the study interventions. The importance and need for full cooperation from each study participant should be stressed. The spouse or other household member could, for example, be invited to attend the clinic visits, especially the initial visits, or any

group meetings that are held during the course of the study. Compliance with the study protocol is more likely to be good if the family members get involved in the process. They can also notify the clinic if something happens to the participant.

9.5.11 Staff Meetings

Regular staff meetings should be held to keep the ACT clinic staff informed regarding individual and overall adherence problems and to plan strategies for improvement. An adherence chart should be developed and reviewed for each participant and kept with the participant's record. Notes or clinic visit summaries can be used to indicate adherence problems. The ACT Principal Investigator should be readily available and willing to take personal action or give assistance when adherence problems make their involvement advisable.

9.5.12 Participant ID Cards

If resources are available, every randomized participant in ACT could be given an identification card bearing the following information:

1. the name of the study, and
2. a telephone number for medical advice 24 hours a day, with the instruction that the number be called in case of any medical emergency.

   Participants should carry this identification at all times and present it for all clinic visits and whenever care is sought at a hospital, an emergency room, or a doctor's office for a major medical problem.

9.5.13 ACT Relationship with Private Source of Care

Good communications and maintenance of a positive relationship with the participant's private physician or other outside source of care are important. The physician should be kept advised of the participant's clinical course by reports of abnormal laboratory findings, physical examination findings, and other pertinent information, including any clinical problems encountered. A good rapport with the private physician and his or her support and cooperation with the ACT protocol is essential to a high degree of compliance.

9.5.14 Re-Education

A review at each scheduled clinic visit or phone call of the ACT program with the participant, especially those who have missed visits, for the purpose of promoting clinic attendance can be a strong motivation. At this review, clinic staff should discuss with the participant the purpose of the study, general features of the study, and what the length of the planned follow-up is (this is easily forgotten). In addition they should review the written instructions given to the

participant at the beginning of the study. It may be useful to provide participants with calendars that lay out the expected times for scheduled data collection visits.

9.6 Monitoring Clinic Retention

Adherence to scheduled clinic visits and windows will be systematically monitored by the coordinating center in regular reports. These reports will be reviewed by the Steering Committee, the Data and Safety Monitoring Board, the Project Office, and the Study Coordinator Subcommittee. A feature of each clinic site visit will be a review of the site's recent participant attendance and completeness of data collection.

CHAPTER 10
DATA MANAGEMENT

10.1 Description of System . . . . . .

10.2 Data Entry and Transmission . . . . . .

10.3 Data Monitoring . . . . . .

10.4 Communications . . . . . .

To be added later

CHAPTER 11
QUALITY CONTROL

11.1 Training and Certification 1

11.2 Reporting 2
11.2.1 Clinical Centers 2
11.2.2 Clinical Coordinating Center 5
11.3 Site Visits 6

CHAPTER 11
QUALITY CONTROL

11.1 TRAINING AND CERTIFICATION

Study wide quality control is the ultimate responsibility of the ACT Clinical Centers and the Coordinating Center with guidance from the measurement and Quality Control Subcommittee under the auspices of the Steering Committee. The Clinic Coordinator from each Clinical Center will also serve as the Training and Quality Control Liaison. This person will be responsible for the maintenance of measurement and training standards at the Clinical Center including training of new personnel, in the event of staff turnover, and recertification for existing staff. The ACT Training and Quality Control Liaison must become familiar with ACT requirements and provide input into the scheduling of clinic activities so that there is adequate time for clinic staff to carry out their responsibilities while meeting quality standards.

Key clinic staff from each Clinical Site will be trained at the initial ACT Training Session in Winston-Salem. These key staff will be responsible for training and re-training other staff members. Certification and recertification of training are required for GXT measurements, PAR measurements, blood pressure measurements, and anthropometric measures. Training, but not certification, will be required for laboratory collection and data entry personnel at each Clinical Center. Specific procedures for training clinic staff to obtain each of these measures are provided in the appendices of the ACT Manual of Procedures: GXT in Appendix B, PAR in Appendix C and Anthropometric/Blood Pressure in Appendix F. Forms for certification are also contained in these appendices. More general details regarding frequency of re-certification and for maintaining documentation of certification and recertification are outlined below.

The key staff personnel responsible for training and retraining other personnel hired at the Clinical Sites will be required to be recertified centrally at an annual training session. Other

personnel hired at the Clinical Sites will be required to be recertified every six months for all measurements. Documentation of certification for all staff members will be maintained in a central location at each Clinical Site. Updated lists of personnel certified to perform each type of measurement will be sent to the Coordinating Center when personnel are certified either newly or recertified.

11.2 REPORTING

An extensive system of reporting will be used in ACT to ensure both eligibility of participants enrolled and high quality data during both screening and follow-up. In addition to study wide reports generated by the Coordinating Center, the database application will permit the Clinical Centers to generate some reports specific to the participants within their clinics. Other continuous quality control efforts, that do not necessarily involve the generation of paper or computerized reports, must be undertaken by the Clinical Centers throughout the duration of the study. Below, the quality control responsibilities of both the Clinical Centers and the Coordinating Center are detailed.

11.2.1 Clinical Centers

Specific continuous quality control efforts to be carried out by the Clinical Centers include:

1. Training/retraining and/or certification/recertification of clinic staff by the centrally-trained key staff.
2. Scheduling and monitoring of regular equipment maintenance and reporting of equipment failures to the Coordinating Center when such failures may impact on the quality of data.
3. Regular observation and monitoring of clinical procedures.
4. Monitoring and editing of study data through the distributed data processing system.
5. Compilation, review, and reporting to the Coordinating Center regarding lost laboratory samples, packaging problems, errors in packing, shipping and labeling of specimens.

6. Reporting of quality control concerns or problems to the Coordinating Center.

The Clinic Coordinator and/or Quality Control Liaison should regularly monitor Clinical Center procedures to be certain that they are being carried out properly and with consideration for the ACT participant. Corrective action should be taken immediately if problems are observed.

Because of the relatively short time windows between SV0, SV1, SV2 and Randomization, the Clinical Centers will need to pay particular attention to the amount of time remaining for participants to be eligible for the next visit. To aid in this monitoring, the data entry application will provide the Clinical Centers the ability to print reports detailing for each visit (SV0, SV1, SV2 and Randomization) those patients that are due for the visit, and the number of days since the previous visit. This report also will identify those participants approaching the time limit of the recommended window. Additionally, the data entry application will provide the Clinical Centers the ability to print an up-to-date summary of recruitment activity, including the number of patients successfully completing Telephone Screening, SV0, SV1, SV2, and Randomization. To take full advantage of the capabilities provided by the data entry application, it will be necessary for the Clinical Centers to keep up-to-date on the entry of the SV0, SV1, SV2 and Randomization Disposition forms. Staying up-to-date on data entry (even for ineligible participants) will help the Steering Committee to monitor the overall recruitment process and assist in refining eligibility criteria, if necessary, in order to meet studywide recruitment goals.

As an additional aid in the recruitment process, the data entry system will contain a utility enabling the Clinical Center to access an eligibility checklist report for any patient. Thus, when data entry is up-to-date, this checklist will identify whether individual patients have specific eligibility criterion missing or pending.

Quality control of study data should be carried out locally using the ACT data entry system. Invalid or incomplete forms may be corrected prior to transmitting data to the Coordinating Center.

Monitoring and/or error reports will be distributed to the Clinical Centers by the Coordinating Center to aid in the correction of data entry errors.

The Clinical Center staff are encouraged to communicate with the Coordinating Center about quality control or other concerns or problems.

11.2.2 Coordinating Center

Monitoring of the ACT study data will take place at the Coordinating Center. These activities include validation, selective data re-entry, and report generation. Some of the monitoring and quality control reports will be transmitted to the Clinical Centers for immediate action and attention; other reports monitoring trial performances will be generated for Project Offices/Steering Committee and Data and Safety and Monitoring Committee. During the recruitment period of the trial, bi-weekly reports on recruitment activities by each Clinical Center will be provided to the Chairperson of the Steering Committee, Eligibility and Recruitment Committee, the Principal Investigators, and NHLBI Project Officers. Reports, generated by each Clinical Center and for the overall study, will include summaries of:

1) Recruitment yields,

2) Reasons for ineligibility,

3) Missed screening visits, and participant refusals,

4) Average time between participant visits and data entry,

5) Deviations from protocol,

6) Problems observed or reported at site visits, and

7) Missing forms and/or individual data items.

Items to be reported on during follow-up will include many of the above items in addition to summaries of:

1) Adverse events,

2) Missed follow-up visits, and

3) Participant loss to follow-up.

Annual reports will include a summary of quality control data by Clinical Center. These quality control reports will address issues such as drift in measurements, digit preferences, and intra- and inter-observer agreement. Should the reports indicate that specific problems exist, it is the responsibility of the Coordinating Center to report these findings to the Measurement and Quality Control Subcommittee and/or Steering Committee.

The Coordinating Center will routinely re-key selected items on a subset of data forms to assess data entry accuracy. Reports of errors will be distributed to the Clinical Centers and reports of overall error rates will be provided to the Steering Committee.

The Coordinating Center will regularly perform edit checks of ACT data, such as examining the logical consistency of data across forms collected on each participant. When inconsistencies are detected, the Clinical Center will be notified through edit reports, and will be asked to verify, if possible, some entries. Prompt action with these verification requests is essential for an efficient quality control system.

11.3 SITE VISITS

During recruitment and follow-up, the Coordinating Center, with other study personnel, will site visit each Clinical Center to promote communication, answer questions, and ensure that study procedures are understood and carried out correctly. The site visit program will provide a mechanism to encourage the effective and standardized delivery of recruitment efforts, intervention programs, and the collection of appropriate and valid data within each of the ACT clinic sites. Site visits may also be performed if consistent departures from the Protocol and Manual of Operating Procedures are detected. Retraining and/or recertification may be done as needed during these visits, depending on the availability of staff.

One of our most valuable resources is the ACT Measurement and Intervention Staff who are collecting the data and providing for the delivery of the intervention. It is these individuals that have the day to day experience, and first hand knowledge as well as a practical perspective to identify and help correct problems and/or variations in procedures that clinic centers may experience. Before the visit, the clinical centers will be sent a proposed agenda and a schedule will be worked out in advance. The principal investigator, as well as other staff members, will be involved. The first round of site visits should occur after experience has been gained with the first wave of participants. This will enable us to look at recruitment efforts, the multiple aspects of the intervention, as well as any staffing problems clinics may be encountering.

The site visit will be an ideal time for suggesting solutions for any problems which are identified. It should be noted that outside visitors may not have better answers, however, they may have different answers that may prove useful. Of equal importance will be the lessons that site visitors gain while watching other centers in action. The observational experience can enhance and increase the visitor's own skills at developing problem solving strategies and solutions that may be applicable to other Clinical Centers. Consequently, the site and peer-review visits will be a time when the Coordinating Center staff, peers and clinic site staff review progress and problems, share what has/has not worked, and consider new strategies and solutions.

The Site Visit Team will include representatives from the Coordinating Center and colleagues from the other clinic sites.

A key to a successful site visit is adequate preparation by the Clinical Center, the Coordinating Center, and the Site Visit Team members. Site visits should serve to enhance communication throughout the study, and to personalize interchange among study staff and investigators.

To make the site visit process as efficient as possible, prior to the site visit, the Site Visit Team will provide the Clinical Center with a set of general questions such as those listed below.

1. Do clinics have an adequate number of staff members to provide for effective recruitment, data collection, data entry and intervention delivery? Do staffing patterns match those originally proposed?
2. Are staff roles clearly defined and is there communication and interaction between the various working groups?
3. How is information, such as changes in the MOP or protocol, shared among personnel?
4. What is the overall view of clinic flow?
5. The clinic tracking system will be discussed and the following questions may be asked.
   a) What is the procedure followed when a participant does not show up for his/her appointment?
   b) How does the clinic handle rescheduling for a situation where the participant only partially completes a visit as a result of illness, etc.?
   c) How does the clinic keep track of where an individual is in the study flow so that the participant is scheduled within the appropriate window?

The Clinical Center will be asked to respond in writing to these questions at least 1 week prior to the site visit. The Site Visit Team will review the responses and provide feedback to the Clinical Center during the site visit. Other activities that will take place during the site visit may include discussions of data reports provided by the Coordinating Center and exploration of any concerns or questions that arise. During the site visit, the Site Visit Team may ask to follow a participant through a visit and observe randomly selected procedures.

Chart reviews will also be a major component of the site visit. Questions will be asked about where records are kept and how participant confidentiality is assured. A site visitor will do at least five randomly selected chart reviews to look at items such as: informed consent, appropriate signatures, and complete data forms.

Site visitors also will ask questions concerning study documentation. Some typical questions will include:

1. Where is the MOP located in the clinic and do clinic staff have easy access to it?
2. Do the protocol and MOP have all the updates included?
3. What procedures are used to ensure that changes to the protocol are implemented in every day clinic operations?
4. Where is staffing documentation, including certification, kept?
5. What is the procedure for maintenance on machines? Where are the quality control logs documenting that machines are checked regularly?
6. Where are IRB documents kept and what is the procedure for informing the IRB of protocol changes?

After each site visit, two types of site visit reports will be carried out. The first will be a frank discussion at the end of the visit between the Site Visit Team, the principal investigator and key staff at the clinic site. The Site Visit Team will prepare written reports on the activities of the site visit. A detailed report of the team's observations and recommendations subsequently will be sent to the Principal Investigator of the site being reviewed and the chairs of the Steering Committee and the Quality Control Committee.

CHAPTER 12
APPENDICES

A. Guidelines for Obtaining Informed Consent A-1

B. Protocol for Graded Exercise Training Protocol for Testing and Certification of Graded Exercise Testing Personnel B-1

C. Procedures for 7-Day Recall C-1

D. Procedures for Self-Administered Questionnaires D-1

E. Procedures for Interviewing Participants E-1

F. Measurement of Physical Parameters F-1

G. Procedures for Blood Specimens G-1

H. ACT Forms and Instructions H-1

I. Cost Analysis Data Collection Procedures I-1

J. Pulse Wave Velocity Protocol J-1

K. List of Act Personnel K-1

L. References L-1

APPENDIX A
GUIDELINES FOR OBTAINING INFORMED CONSENT

A.1 Introduction A-2

A.2 Basic Elements of Informed Consent A-2

A.3 The Process of Obtaining Consent A-5

A.4 Informed Consent Forms . . . . .

APPENDIX A
GUIDELINES FOR OBTAINING INFORMED CONSENT

A.1 Introduction

The success of every clinical trial depends on the cooperation of its participants. For ACT to succeed, the participants must be able and willing, before randomization, to increase their levels of physical activity, monitor their physical activity on written "logs," return for follow-up visits as indicated, and report any untoward side effects that may develop. To aid in meeting these objectives, participants must be truly informed and aware of what study participation would entail. If the consent process is simply a mechanical ritual, the trial could be jeopardized by a large number of early drop outs, poor adherence, and confusion about study protocol.

There are two consent forms to be completed in ACT. The "Preliminary Screening Consent," discussed and signed at the beginning of SV0, describes all SV0 procedures. If the screenee remains eligible by the end of this visit, and is willing to continue the screening process, he/she is then given the "Screening and Randomization/Participation Consent" to take home and review. This second consent form addresses all procedures, risks, and benefits, etc. associated with SV1, SV2, and trial participation, should the individual be eligible and willing to be randomized. This form is then reviewed and signed at the beginning of SV1.

The two ACT consent forms need to be approved by local Institutional Review Boards (IRBs) prior to initiating recruitment. Any subsequent changes in either form must be brought to the attention of the IRB immediately.

A.2 Basic Elements of Informed Consent

Department of Health and Human Services (DHHS) guidelines set forth eight essential elements of informed consent:

(1) Participants must be advised that the study involves research. An explanation must be given regarding the purposes of the research, the expected duration of the participant's involvement in the study, and a description of the procedures to be followed, including identification of any experimental procedures.

It is essential that the participant understand that he/she will be randomly assigned to one of three primary-care-based programs to increase physical activity. In other words, each participant has a 1 in 3 chance of being in any one program.

It is important to emphasize that this is primarily a study, rather than a therapeutic program that has been specifically designed for an individual patient. It should also be conveyed to the participant that the standard care control group is of equal importance to the two intervention arms. Thus, a

participant assigned to Group A is making just as valuable a contribution to the trial as someone assigned to Groups B or C.

With respect to routine procedures, participants should be told that they will need to return to the ACT clinic six months and 24 months after beginning the trial for "measurement" visits. Those assigned to either intervention group (B or C) are expected 1) to have periodic visits and phone calls to reinforce their physical activity program and 2) to keep track of their physical activity on written "logs" over the course of the study. To avoid misunderstanding, it should be made clear that the study is expected to last two years for each participant.

(2) Anticipated benefits of the trial must be explained.

Many participants appreciate the opportunity to be involved in relevant research and to contribute to medical knowledge. In the ACT trial, the knowledge gained will be specifically applicable to participants in the study as well as to sedentary adults in general, and this is an added benefit of participation.

Preliminary research indicates that any increase in physical activity in non-active people will benefit their health and cardiovascular status. The potential benefit of reducing heart disease is great among this high-risk group.

The physical examination, laboratory tests, and treadmill tests provided may lead to the early diagnosis of disease, if present. The physical examination and the laboratory studies are provided free of charge.

(3) Attendant discomforts and risks "reasonably to be expected" must be described.

Screenees should be told about the risks of venipuncture, as written in the second consent form (possible temporary pain and later bruising).

In ACT, there is very little likelihood that the participants will be seriously harmed by participating in the trial. To reduce the risks, participants, for whom a graded exercise test is contraindicated, have been purposefully excluded.

In spite of these precautions, however, there exists the rare possibility of certain changes occurring during the treadmill test, including abnormal blood pressure, fainting, dizziness, irregular heart beat, and, in extremely rare instances, heart attack, stroke and death. Emergency equipment and trained personnel are available to deal with unusual situations that may arise.

Other possible risks associated with increasing physical activity include injuries to the muscles, ligaments, tendons, and joints.

(4) Appropriate alternative procedures that might be advantageous for the subject must be disclosed.

The participant should be told what options exist if he/she elects not to participate in the trial.

He/she may choose to increase his/her physical activity level without enrolling in this trial. Private and community resources are readily available for this purpose. Blood tests for cholesterol, insulin, and fibrinogen may be provided by a primary care physician.

(5) The extent to which confidentiality of records identifying the participant will be maintained must be described.

Confidentiality of all participant information is assured in all participating centers. No unauthorized personnel should have access to participant records or results of interviews or tests. Additionally, all record storage rooms should be appropriately secured, and should contain secured files or other storage equipment.

It may be useful to explain that in studies of this nature, numerical and alphabetic codes are assigned by which central study files may be linked to individual participants. Participants are not identified by name in any reports or publications.

(6) Prospective participants must be advised of the availability or non-availability of medical treatment or compensation for physical injuries incurred as a result of participation in the study, and, if available, what they consist of, or where further information may be obtained.

It may be useful to distinguish between providing follow-up tests and procedures free of charge, and financial compensation for injuries incurred. The Federal Government is prohibited by law from committing funds that have not yet been appropriated by Congress, and funds have not been allocated for compensating injured subjects in trials such as ACT. The only recourse for such participants is to seek compensation through the courts or through negotiation with the Clinical Center involved.

(7) Persons responsible for the study must offer an explanation of whom to contact for answers to pertinent questions about the research and the participant's rights, and whom to contact in the event of a research related injury to the participant.

One or more people associated with the trial should be available to answer relevant questions while participants are contemplating participation. Prospective participants should be given the names of these people in writing. If no names are provided, they may ask questions of persons not knowledgeable about the study and be given unclear answers or misinformation.

Once they are enrolled in the study, participants should receive written information regarding whom to contact at any time about possible untoward side effects during the intervention or rights as a volunteer in the study.

(8) Participants must be told that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which he/she is otherwise entitled.

Participants must know that they have the right to withdraw at any time. This option should be conveyed to participants without luring them into the trial on a probationary "look and see" basis. Hesitant participants should be evaluated very carefully to screen out those who are likely to withdraw early.

The right to withdraw from a trial is meaningless if such behavior invokes penalties. This is the reason for the phrase, "without penalty or loss of benefits," and the idea should be explained to participants. If they drop out of the trial, the act of dropping out will not jeopardize their regular care, and they will be welcomed back into the study at any time they wish to return.

A.3 The Process of Obtaining Consent

The eight requirements of informed consent in the DHHS guidelines above refer primarily to categories of information that enable participants to make rational decisions regarding participation in clinical trials. Except for the stipulation that participant inquiries should be answered, these basic elements do not refer to the process of obtaining informed consent.

Various studies indicate that the circumstances under which consent is obtained in clinical trials can have a profound influence on the participant's interpretation of information communicated during the consent discussion and on the freedom of participants to make their own decisions. Following are guidelines to ensure that the consent obtained will be as informed and voluntary as possible:

(1) Participants should be fully informed about the study and have adequate time to evaluate the pros and cons of participation.

The second, more complicated consent form is to be sent home with the participant after Screening Visit 0, so that the screenee may more carefully review it. It should be returned to Screening Visit 1 unsigned. Time should be set aside at Screening Visit 1 for a one-on-one question-and-answer session with an ACT Clinical Center staff member, at which time the pros and cons of participation will be discussed and a signature obtained.

(2) Participants should be encouraged to discuss the study with anyone they wish, particularly family and friends who might be affected (for example, persons who might be needed to provide transportation).

Close associates of the participant may raise questions and considerations that the participant has overlooked, and questions that concern the family are better answered sooner rather than later. Furthermore, there is evidence to suggest that family support for studies of this kind increases the probability of participant cooperation and adherence during the course of the trial. The participant should also be encouraged to discuss study involvement with his/her personal physician.

(3) To be eligible for participation in ACT, participants must have the capacity to give their own informed consent.

If a participant is incapable of understanding what is expected of him/her, it is not permissible to obtain informed consent from a guardian. The study requires performance of daily responsibilities that cannot be easily assumed by substitute persons.

(4) The setting in which consent is obtained should be as private as possible so participants can freely ask questions without embarrassment.

If extraneous parties can hear the conversation, participants may be reluctant to ask appropriate questions.

(5) To avoid pressuring the participant, only one person associated with the study should be present when the participant reviews the consent forms.

If a second witness is required, he or she should be as unobtrusive and non-committal as the situation permits.

(6) The participant should be given a copy of the informed consent forms after they are signed and witnessed.

Even though participants are free to withdraw from the study at anytime, the consent form spells out the trial's obligations to the participant and the participant's obligations to the study while he/she is a subject.

(7) Participants should be encouraged to review the consent forms periodically.

The consent forms contain useful information about the study which participants may want to review from time to time. Blank copies could be kept in the clinic waiting room when participants come for their visits.

A.4 Informed Consent Forms

ACTIVITY COUNSELING TRIAL (ACT)

Preliminary Screening Visit Consent

Your doctor has agreed that you can be asked to participate in the research study called "The Activity Counseling Trial" (ACT), a study of physical activity counseling in persons who are involved in limited physical activity.

Purpose of the study

This study will test the effectiveness of physical activity counseling in the physician office setting on the health status of persons who are sedentary (involved in limited physical activity). Approximately 810 men and women 35-75 years of age will be enrolled at three centers, located in California, Texas and Tennessee. Everyone will be encouraged to remain in the study for 2 years. Legal authority to conduct this research is provided by Section 419 [285b-1] of the Public Health Service Act.

Screening procedures

If you agree to participate in ACT, you will be asked to attend a total of three screening visits (counting today's visit) to determine your continued eligibility. The entire screening process could take up to about 2 months to complete, and the three screening visits will last approximately 4-5 hours in all.

At today's initial screening visit we will give you more detailed information about ACT. You will also be asked to provide some general personal information (so that we can keep in touch with you) and more detailed information about your medical history and level of physical activity. If you remain eligible after today's visit, we will give you one form (contact questionnaire) to take home, fill out and bring back for your next screening visit. If you are not eligible, the reason(s) will be explained to you.

Risks/Discomforts

There are no physical risks or discomforts associated with this visit.

Benefits

Continued eligibility may enable you to participate in ACT. Participation could benefit your general health and cardiovascular status.

Alternatives to participation

You may choose to discontinue this preliminary screening process.

Voluntary participation

Participation in the ACT screening process is voluntary. Refusal to participate will involve no loss of benefits to which you are entitled. Further, you may withdraw from any of the screening visits at any time without penalty.

Significant findings

You will be told of any significant findings that may occur during the course of this study that could relate to your willingness to continue to participate. The investigator and the sponsor reserve the right to terminate the study and discontinue your participation at any time for any reason, in order to ensure your safety.

Confidentiality

Personal medical data will be kept confidential as required by the Privacy Act, 5 U.S.C. 552a. Details from your medical records will be stored on a private computer system, but your name will not be used

in any computer files. Information stored on the computer may be seen by ACT clinic study staff or government staff at the National Heart, Lung and Blood Institute, which funds the study.

Questions

If you have any questions at any time during your screening for ACT or if you believe you have sustained an injury related to the screening process, you can contact either Dr. _____ at _____ or the Health Educator at _____. If you have any questions about your rights as a research subject, contact Dr. _____, the Institutional Review Board Chairman, at _____.

Consent summary

I understand that I am not waiving any legal rights or releasing the local institution sponsoring this study or its agents from liability for negligence. I understand that in the event of physical injury during the ACT screening process, the local institution sponsoring this study does not have funds budgeted for compensation either for lost wages or for medical treatment. Therefore, the local institution does not provide for treatment or reimbursements for such injuries.

I have read the description of the first ACT screening visit and I freely volunteer to participate in it. I have had known possible side effects and adverse reactions (none for this visit) explained as well as having had alternative procedures explained. I have had an opportunity to ask questions to the ACT clinical staff and I have received acceptable answers. I understand that I may withdraw from the ACT screening program at any time and I will still receive standard treatment for my condition.

_____	_____
Signature of participant	Date
_____	_____
Signature of witness	Date
_____	_____
Signature of Principal Investigator	Date

ACTIVITY COUNSELING TRIAL (ACT)

Screening and Randomization/Participation Consent

Purpose of the study

The objective of this study is to test the effectiveness of physical activity counseling in the physician office setting on the health status of persons who are sedentary (involved in limited physical activity). Approximately 810 men and women 35-75 years of age will be enrolled at three centers, located in California, Texas and Tennessee. Everyone will be encouraged to remain in the study for 2 years. Legal authority to conduct this research is provided by Section 419 [285b-1] of the Public Health Service Act.

Remaining screening procedures

During the remaining two screening visits to determine your eligibility for ACT, you will have a physical examination and will have your blood pressure measured. Blood will be drawn from a vein in your arm (less than 2 tablespoons) to check your levels of cholesterol, insulin, and specific blood clotting factors. Some of this blood will be frozen for later analysis and studies. In preparation for these blood tests, you will be asked to fast (to stop eating and drinking anything except water) for 12 hours before you come in for your third screening visit. At the next two visits, you will walk on an exercise treadmill, which is like walking on a conveyor belt. The treadmill will start going uphill very slowly. You will continue to walk on the treadmill as the uphill increases in steepness. For the first visit this will continue until you cannot proceed further. At the next visit you will walk on the treadmill but it will not be as hard. During this test, you will have your heart rate monitored and you will breath into a breathing tube. Your reactions to the exercise tests will be monitored to assure your safety. We will also ask you to complete some questionnaires that ask about your level of physical activity, what medications you are taking, the types of foods you eat, your smoking history and your quality of life. You will also have height and weight measurements taken.

Study procedures

If you are not eligible to participate in this study, the reason(s) will be explained to you. If you remain eligible for ACT after these next two screening visits, and you agree to participate in the study, you will be assigned by chance to one of the following programs, which involve:

A. Advice from your doctor concerning increasing your level of physical activity and provision of written materials on how to increase your level of physical activity.

B. Advice from your doctor concerning increasing your level of physical activity, provision of written materials on how to increase your level of physical activity, in-person counseling, viewing a video promoting increased physical activity, mailings, occasional phone calls, and referral to community resources. You will be asked to keep track of your physical activity on written "logs" over the two-year course of the study.

C. Advice from your doctor concerning increasing your level of physical activity, provision of written materials on how to increase your level of physical activity, in-person counseling, viewing a video promoting physical activity, phone calls, mailings, written and visual materials, group classes and referral to community resources. You will be asked to keep track of your physical activity on written "logs" over the two-year course of the study.

For all three programs, if you ever have questions about your physical activity program, you can call your Health Educator, who will give you his/her phone number at the time of your first health educator visit.

For all three programs, you will need to return to have several special "measurement" visits. You will also be contacted by study staff by phone at 12 months to provide some information. During the one

6 and two 24 months visits, you will have the same types of tests and procedures that you will have during the next 2 screening visits. The 6- and 24-month "measurement" visits will last approximately 3 to 4 hours. These visits will include the following:

- completion of various questionnaires asking you about your current level of physical activity, your diet, smoking history and quality of life;
- blood pressure measurement;
- height and weight measurements taken;
- a blood test, where blood will be drawn from a vein in your group (less than 2 tablespoons) to check your levels of cholesterol, insulin, and specific blood clotting factors. In preparation for these blood tests, you will be asked to fast (to stop eating and drinking anything except water) for 12 hours before coming in for this visit; and
- exercise treadmill tests, which involve walking on a conveyor belt that starts going uphill very slowly. During these tests, you will have your heart rate monitored and you will breath into a breathing tube. These tests will be the same as at the beginning of the study.

  In addition, a test to determine the degree of stiffness of the main arteries will be done. This test involves placing a pencil-like instrument over the blood vessels of the chest, groin, and/or neck. Recordings will be made on a computer while a partial electrocardiogram is being done. The measurements use high frequency sound waves that are harmless. The procedure will take about 10 minutes while you are lying down in a resting position. You can decline this optional test by crossing out this paragraph.

Risks/Discomforts

The risks of participating in ACT are small. You may experience temporary pain during the blood drawing, with later bruising at the puncture site. Only specially trained staff will be responsible for collection of blood samples. There exists the possibility of certain changes occurring during the treadmill test. These include abnormal blood pressure, fainting, disorder of heart beat and, in rare instances, heart attack, stroke and death. Every effort will be made to minimize these risks by reviewing information about your health and fitness before the test and by closely observing you during the treadmill procedure. Emergency equipment and trained personnel are available to deal with unusual situations that may arise.

Possible risks associated with increasing physical activity include but are not limited to, injuries to the muscles, ligaments, tendons and joints of the body. Other risks associated with exercise include, but are not limited to, abnormal blood pressure, fainting, dizziness, disorders of heart rhythm, and very rare instances of heart attack, stroke, or even death.

Benefits

The physical examination, laboratory tests and treadmill tests may lead to the early diagnosis of disease, if present. The physical examination and the laboratory studies are all free of charge. It is expected that any increase in physical activity in people who are non-active will benefit their general health and cardiovascular status.

Alternatives to participation

To determine your blood levels of cholesterol, insulin and some clotting factors, you could visit your personal health care provider. You may choose to increase your activity level on your own without enrolling in this study. You may choose to have your own health trainer.

Voluntary participation
Participation in the ACT study is voluntary. Refusal to participate will involve no loss of benefits to which you are entitled. Further, you may withdraw from the study at any time without penalty.

Significant findings
You will be told of any significant findings that may occur during the course of this study that could relate to your willingness to continue to participate. Your blood pressure and blood cholesterol results will be sent to your physician. The investigator and the sponsor reserve the right to terminate the study and discontinue your participation at any time for any reason, in order to ensure your safety.

Confidentiality
Personal medical data will be kept confidential as required by the Privacy Act, 5 U.S.C. 552a. Details from your medical records will be stored on a private computer system, but your name will not be used in any computer files. Information stored on the computer may be seen by ACT clinic study staff or government staff at the National Heart, Lung and Blood Institute, which funds the study.

Questions
If you have any questions at any time during the study or if you believe you have sustained an injury related to the study, you can contact either Dr. _____ at _____ or the Health Educator at _____. If you have any questions about your rights as a research subject, contact Dr. _____, the Institutional Review Board Chairman, at _____.

Consent summary
I understand that I am not waiving any legal rights or releasing the local institution sponsoring this study or its agents from liability for negligence. I understand that in the event of physical injury resulting from the research procedures, the local institution sponsoring this study does not have funds budgeted for compensation either for lost wages or for medical treatment. Therefore, aside from the emergency care previously described, the local institution does not provide for treatment or reimbursements for such injuries.

I have read the description of this study and I freely volunteer to participate in it. I have had known possible side effects and adverse reactions explained as well as having had treatment alternatives explained. I have had an opportunity to ask questions to the ACT clinical staff and I have received acceptable answers. I understand that I may withdraw from this study at any time and I will still receive standard treatment for my condition.

_____ _____
Signature of participant Date

_____ _____
Signature of witness Date

_____ _____
Signature of Principal Investigator Date

APPENDIX B
PROTOCOL FOR GRADED EXERCISE TESTING
PROTOCOL FOR TESTING AND CERTIFICATION OF GRADED EXERCISE TESTING PERSONNEL

Procedures for Graded Exercise Testing (SV1) 2

Figure 1 Electrocardiographic Leads Used in Exercise Training 3

Heart Rate Variability 4

Contraindications to Exercise Testing - Absolute and Relative - Table 1 6

Rating of Perceived Exertion Scale - Table 2 7

Absolute and Relative Indications for Termination of an Exercise Test - Table 3 9

Figure 2 Protocol for Maximal GXT (SV1) 12

Procedure for Submaximal Exercise Test (SV2) 14

Figure 3 Protocol for Submaximal GXT (SV2) 16

Protocol for Testing and Certification of GXT Personnel Form 18

GXT (MAX) Form 20

GXT (SUBMAX) Form 22

Heart Rate Variability Form 23

APPENDIX B
PROTOCOL FOR GRADED EXERCISE TESTING
PROTOCOL FOR TESTING AND CERTIFICATION OF GRADED EXERCISE TESTING PERSONNEL

Procedures for Graded Exercise Testing (SV1)

Overview of the determination of VO_2 max

Maximal oxygen uptake (VO_2 max, $L \cdot min^{-1}$) is a primary outcome in ACT and will be assessed using a multi-stage, graded maximal treadmill exercise (GXT) protocol. Oxygen uptake (VO_2) will be measured breath-by-breath throughout the GXT. The test continues until the participant requests to stop because of fatigue or until any one of the criteria listed under ACSM "Indications for Stopping an Exercise Test" (ACSM 1995) is met. The maximal GXT will be supervised by a physician. All staff administering the test will be centrally trained and certified and follow a standardized protocol. The maximal exercise test will be performed at baseline (SV1) and at 6 and 24 months.

Pre-GXT Procedures

1. Thirty minutes before the arrival of the first participant of the day the exercise test technologist will replace the drying tube and turn the main power switch of the CPX/D system on.

2. When system warm-up is complete, a manual calibration will be performed to insure that the instrument is functioning properly.

3. Formula System will be turned on.

4. Following the completion of the Seven-Day Physical Activity Recall at SV1, the participant will be escorted to the treadmill testing area.

5. The exercise test technologist will be responsible for seeing that the top portion of the GXT Data Form (down to "Resting Measurements") has been properly filled out.

6. The exercise test technologist will confirm that an Informed Consent has been completed (see Appendix A) and that the participant knows and understands the purposes and risks associated with the graded exercise test. The test technologist will also confirm that the patient has abstained from caffeine and alcohol for 12h, smoking for 6h, food for 2h and strenuous physical activity for 12h prior to the GXT.

7. The exercise test technologist will weigh the participant according to the protocol detailed in the Anthropometrics Chapter (Appendix F) and record this weight and a self-reported height to be later entered into the MedGraphics CPX/D system and Formula System.

8. The exercise technologist will enter patient information into the CPX/D System while the ECG technician applies ECG electrodes.

Application of ECG Electrodes

1. In the ECG prep area, the participant will remove clothing from the waist up. A hospital gown will be provided to women participants.

2. The skin will be prepped in the areas of electrode application by the removal of excess hair with a razor. The skin will be cleaned with rubbing alcohol and rubbed vigorously with an abrasive pad prior to the application of the electrodes to insure good adherence to the skin.

3. The electrodes will be applied in a configuration like the Mason-Likar placement which permits standard 12-lead electrocardiogram tracings to be obtained during exercise (Figure 1). The ECG tracing will be tested for interference on all leads by observation of the monitor, tapping each electrode to check for artifact. Select "OBSERVE", "EXIT".

Figure 1 - - Electrocardiographic Leads Used in Exercise Training

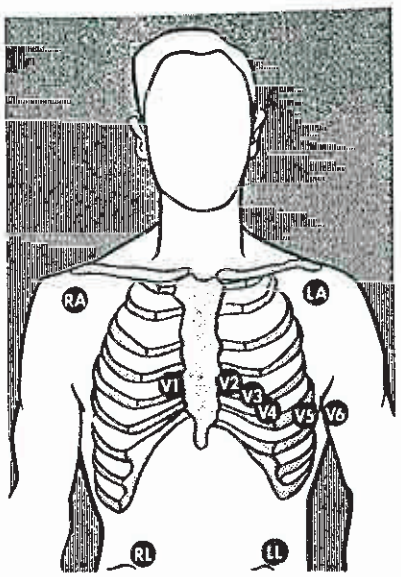


FIG 1
The Mason-Likar simulated standard 12-lead ECG electrode placement for exercise testing.

Electrode Placements:

Leads, I, II, III, AVL, AVR, & AVF:

R. Leg: 1 electrode placed approximately in line with the Anterior Superior Iliac Crest at the level of the umbilicus on the right side

L. Leg: 1 electrode placed approximately in line with the Anterior Superior Iliac Crest at the level of the umbilicus on the left side

R. Arm: 1 electrode placed in the infraclavicular fossa(deltopectoral) triangle on the right side

Leads V1, V2, V3, V4, V5, & V6:

V1: 1 electrode placed in the fourth intercostal space just to the right of the sternum

V2: 1 electrode placed in the fourth intercostal space just to the sternum

V3: 1 electrode placed on a line midway between leads V2 and V4

L. Arm: 1 electrode placed in the infraclavicular fossa(deltopectoral triangle) on the left side

V4: 1 electrode in the midclavicular line in the fifth interspace

V5: 1 electrode in the anterior axillary line at the same level as lead V4

V6: 1 electrode in the midaxillary line at the same level as lead V4

Heart Rate Variability

This will involve 13 minutes of controlled frequency breathing with heart rate variability (RRV) acquired over the last 10 minutes. The subject is seated comfortably in a chair and instructed on breathing in time with a breathing tape to achieve a rate of 12 cycles per minute (0.2 Hertz). At this rate, subjects should adjust their tidal volume so that their breathing feels normal. The subject's heart rate (HR) is monitored during the first 3 minutes. If it appears that the subject is hyperventilating, i.e., HR increases, ask the subject to reduce their tidal volume. The room should be quiet with the lights dimmed so that the subject can relax. There should be no talking and the subject should not be allowed to fall asleep. After 3 minutes , acquire RRV. Note: The treadmill should be turned off throughout the HRV measurement in order to ensure the collection data. Turn treadmill off prior to entering patient information.

The specific sequence of keystrokes to acquire heart rate variability data is as follows:

* select "PATIENT" to enter patient information; patient last name should have ".RRV" as a suffix
* select "OK"
* select "AMAMN"
  * input "ACT PROTOCOL" under indications
  * select "OK"
  * select "EXIT"
  * select "PROTOCOL", "LOAD", "HRV", "EXIT"
  * The subject then begins breathing in time with the tape. Heart rate and breathing pattern are monitored by technician and any adjustments made during this time. At the end of 3 minutes of controlled breathing,
  * select "ACQECG", "PRE-EX", and "EXERCISE",
  * This causes data acquisition to begin; data is then collected for the next 10 minutes.
  * When data collection is complete (at least 256 heart beats must be included),
  * select in rapid succession "ENDSTAGE", "RECOVERY", "POSTRECOVERY", "END", "SAVE", "END"
  * When patient data window appears, select "SAVE"

Pre-Maximal GXT Measurements

1. When heart rate variability measurements have been completed, the participant will move from a sitting position to a supine position on the examining table. While the participant is resting, the Formula System patient information will be updated by changing the patient name suffix to ".MAX". Select "OK", "EXIT'. The maximal GXT protocol will be loaded by selecting "PROTOCOL", "LOAD", "MAX", "EXIT". After 5 minutes, a supine, resting blood pressure measurement will be obtained according to ACT protocol (MOP, Appendix F), entered into the Formula system and recorded on the GXT Data Collection Form. A supine, resting standard 12-lead ECG tracing will be printed and heart rate recorded on the GXT Data Collection Form. The specific sequence of keystrokes to run the ECG is as follows:
    * select "ACQECG"
    * select "PRE-EX"
    * select "BP" and enter blood pressures
    * select "EVENT"
    * select "SUPINE" and tracing will print out

2. Recent medical history, including medications, and resting ECG will be reviewed by the exercise test technologist. The exercise test technologist will verify that the participant is adhering to all prescribed medication regimens. Abnormalities in the ECG, problematic medications and symptoms such as chest pain, palpitations, etc. will be called to the attention of the supervising physician. It is imperative that any contraindications to exercise testing (Table 1) are noted and taken into consideration prior to the administration of the GXT. The supervising physician will make the final decision on whether or not to test the participant with a maximal GXT.

Table 1 -- Contraindications to Exercise Testing - Absolute and Relative [a]

Absolute Contraindications

1. A recent significant change in the resting ECG suggesting infarction or other acute cardiac event
2. Recent complicated myocardial infarction (unless patient is stable and pain-free).
3. Unstable angina
4. Uncontrollable ventricular arrhythmia
5. Uncontrolled atrial arrhythmia that compromises cardiac function
6. Third degree AV heart block without pacemaker
7. Acute congestive heart failure
8. Severe aortic stenosis
9. Suspected or known dissecting aneurysm
10. Active or suspected myocarditis or pericarditis
11. Thrombophlebitis or intracardiac thrombi
12. Recent systemic or pulmonary embolus
13. Acute infections
14. Significant emotional distress (psychosis)

Relative Contraindications

1. Resting diastolic blood pressure > 115 mm Hg or resting systolic > 200 mm Hg
2. Moderate valvular heart disease
3. Known electrolyte abnormalities (hypokalemia, hypomagnesemia)
4. Fixed-rate pacemaker (rarely used)
5. Frequent or complex ventricular ectopia
6. Ventricular aneurysm
7. Uncontrollable metabolic disease (e.g., diabetes, thyrotoxicosis, or myxedema)
8. Chronic infectious disease (e.g., mononucleosis, hepatitis, AIDS)
9. Neuromuscular, musculoskeletal, or rheumatoid disorders that are exacerbated by exercise
10. Advanced or complicated pregnancy

[a]Source: ACSM, ACSM's Guidelines for Exercise Testing & Prescription, 5th Edition, Baltimore: Williams & Wilkins, 1995 (p.42)

3. The participant will be move to the treadmill and stand quietly on the treadmill belt . A blood pressure cuff will be attached securely to the participant's arm with tape and a blood pressure obtained with the participant practicing the technique to be used during the GXT., i.e., participant puts hand on shoulder of exercise test technologist. Standing BP will be entered into the Formula system by selecting "BP" and entering measurements. Blood pressures will also be recorded on the GXT Data Collection Form. A standing resting 12-lead ECG tracing will be obtained by selecting "EVENT", "STANDING" , "EXIT". The standing, resting HR will be recorded on the GXT Data Collection Form.

4. Prior to the test, the participant will be instructed on the use of the Rating of Perceived Exertion (RPE) scale (Table 2). The following script may be used as a model for these instructions:

"Throughout the exercise we are going to ask you to rate your level of exertion, or how hard you perceive yourself to be working. As you look at this scale, you will notice that numbers range from 6 (NO EXERTION AT ALL) to 20 (MAXIMAL EXERTION). A numerical value of 9 is a very light exercise whereas the number 13 is somewhat hard; however, you should have no problem continuing to exercise at this level. On the other hand, a value of 19 represents extremely hard exercise, as strenuous as you have ever experienced. It is important to remember that we are interested in your overall feelings of exertion. Remember, we are interested in the physical demand or exertion required by different levels of work."

Table 2 -- Rating of Perceived Exertion Scale

RPE SCALE	
6	NO EXERTION AT ALL
7	EXTREMELY LIGHT
8	
9	VERY LIGHT
10	
11	LIGHT
12	
13	SOMEWHAT HARD
14	
15	HARD (HEAVY)
16	
17	VERY HARD
18	
19	EXTREMELY HARD
20	MAXIMAL EXERTION

Establish 60-70% predicted HR max

The participant will then be instructed about how to walk on the treadmill. The purpose of this preliminary walk (to attain 60-70% pred. HR max) will be explained. The participant will straddle the treadmill belt, holding onto the handrail with both hands. The Formula System operator will select "DEMO" to start the treadmill belt. Belt speed will be 1.5 mph/0% grade. The participant will step on to the treadmill and begin walking. The speed of the treadmill will gradually be increased so that the participant can walk with a comfortable stride. Treadmill speed will be increased by selecting "SPEED +" and using the "enter" key (each enter = 0.1 mph increase). When a comfortable stride has been achieved, the participant will be taught to release the handrail and walk with a normal arm swing. The treadmill speed will then be further adjusted until the heart rate response is approximately 60-70 % of age-predicted maximum (220-age), or RPE is 11-13 (fairly light to somewhat hard). For participants on beta blockers, the speed will be adjusted according to RPE and not heart rate. This speed will be maintained for 4 minutes. The treadmill will be stopped by selecting "STOP" from the ergometer window. The heart rate at this speed will be recorded as Warm-up HR on the GXT form. The participant will then be given a brief seated rest.

Maximal GXT

1. During the rest period, a thorough explanation of the maximal GXT will be given to the participant. The explanation should include an overview of the protocol, the time of each stage, the measurements to be made at each stage, and the means of participant/technologist communication when the mouthpiece is in place. It is important that all participants be made aware that they should continue to exercise until they feel they can proceed no further. However, it is also important that they understand that the test will be discontinued at any time that the participant wishes to stop due to fatigue, shortness of breath, pain, etc. or when the exercise test technologist or supervising physician decides to stop the test in accordance with established test termination criteria (Table 3).

Table 3 - Absolute and Relative Indications for Termination of an Exercise Test[b]

Absolute Indications	
1.	Acute myocardial infarction or suspicion of a myocardial infarction
2.	Onset of moderate-to-severe angina
3.	Drop in SBP with increasing workload accompanied by signs or symptoms or drop below standing resting pressure
4.	Serious arrhythmias (e.g., second-or-third-degree atrioventricular block, sustained ventricular tachycardia or increasing premature ventricular contractions, atrial fibrillation with fast ventricular response)
5.	Signs of poor perfusion, including pallor, cyanosis, or cold and clammy skin
6.	Unusual or severe shortness of breath
7.	Central nervous system symptoms, including ataxia, vertigo, visual or gait problems, or confusion
8.	Technical inability to monitor the ECG
9.	Patient's request
Relative Indications	
1.	Pronounced ECG changes from baseline [>2mm of horizontal or downsloping ST-segment depression, or >2mm of ST-segment elevation (except in a VR)]
2.	Any chest pain that is increasing
3.	Physical or verbal manisfestations of severe fatigue or shortness of breath
4.	Wheezing
5.	Leg cramps or intermittent claudication (grade 3 on 4-point scale)
6.	Hypertensive response (SBP>260 mm Hg; DBP >115 mm Hg)
7.	Less serious arrhythmias such as supraventricular tachycardia
8.	Exercise-induced bundle branch block that cannot be distinguished from ventricular tachycardia

2. The individualized ACT protocol will be entered in the Formula System. Specific key strokes are as follows:
   * select "EXIT", "PROTOCOL", "EDIT", "PAGE 1"
   * enter the speed just determined in the first 10 stages in the mph column
   * enter the initial grade (usually 0%) in stage 1 and increments of 2% in the subsequent 9 stages
   * select "OK" to save protocol changes on Formula System
   * select "WORK"

[b] Source: ACSM, ACSM's Guidelines for Exercise Testing & Prescription, 5th Edition, Baltimore: Williams & Wilkins, 1995 (p.97)

3. The necessary participant information will be entered in the CPX/D system and an Auto Cal performed to minimize errors resulting from calibration drift. Select F10 (QUIT) and return to Main Menu. Select "Cardiopulmonary Exercise Testing".

4. The participant will stand on the treadmill and be fitted with the mouthpiece and noseclips. The sample line will be connected to the mouthpiece. Select "F1 (BEGIN)" on CPX/D and wait for data to appear on the screen. Select "P WAVE" to confirm that analyzers and pneumotach are operating correctly. Select F10 to quit "P WAVE" off, select "F2 (STOP)", select "F3 (RESTART)", select "YES". The participant will then be instructed to straddle the treadmill belt.

5. On the Formula System, select "ACQECG", select "PRE-EX".

6. Select "EXERCISE" on the Formula. When treadmill starts, participant will step onto the slowly moving treadmill belt, begin walking and release his/her grip on the handrail. The window on Formula will read "Ergometer starting, please wait". When window disappears, the timer on the Formula System will begin. The CPX/D tech should be cued to select "F1" (BEGIN) on the CPX/D as quickly as possible. "F1" should be pressed twice so that data being collected is designated as exercise data. This procedure will cause the ECG and gas exchange data to be temporally aligned.

7. The treadmill will be automatically elevated by 2% in 2-minute stages (Figure 2). Blood pressure, heart rate, and RPE are measured starting at the beginning of the second minute of each stage. Select "BP" to enter blood pressure into the Formula System.

8. The test continues until the participant requests to stop or until any one of the criteria listed under ACSM "Absolute and Relative Indications for Termination of an Exercise Test" (ACSM 1995, Table 3) is met. At maximal effort, select "RECOVERY" on the Formula and simultaneously select "F2 (STOP) on the CPX/D. This will automatically reduce the treadmill speed/grade to 2.0 miles per hour, 0% grade as quickly as possible to allow the participant a one-minute active cool-down before stopping the treadmill belt. If a blood pressure has not been taken at peak exercise, it should be taken as soon as possible during this active recovery. The mouthpiece and noseclip can be removed at this time, the sample line returned to CPX/D system and the vacuum pump turned off. Select "F10 (QUIT) to save data on CPX/D.

9. When the participant has had a one minute active recovery, select "POSTRECOVERY" on the Formula System to stop the treadmill and allow participant to lie supine on the examining table to complete recovery. During recovery, a 12-lead ECG will be obtained at the end of minutes 2,4,6,8 of recovery. Blood pressures will be taken and recorded before each recovery ECG tracing. Signs and symptoms will be recorded when appropriate at these time intervals.

Recovery heart rates and blood pressures should be stable, but not necessarily at pre-exercise levels, before the discontinuation of monitoring. The decision to discontinue monitoring and allow the participant to leave should be that of the supervising physician; usually 8 minutes is sufficient. On the Formula System, select "END", "SAVE", "END", "NEW".

10. A Graded Exercise Test Data Form will be used to record participant responses and signs and symptoms before, during and after the graded exercise test. Pre-exercise information should be recorded on the form before the participant starts to exercise. During exercise, blood pressures will be obtained at approximately the beginning of the second minute of exercise at each stage. Ratings of perceived exertion will be obtained after completion of the blood pressure measurement. Twelve-lead electrocardiograms will be obtained at the end of each stage of exercise. For each exercise stage, treadmill grade, HR (from ECG)*, SBP, DBP and RPE will be recorded on the GXT Data Form. ECG changes as well as other signs and symptoms will be recorded under the appropriate heading on the GXT Data Form. Note that the suggested time intervals at which measurements are made might need to be modified, according to the judgement of the exercise test technologist, as the participant approaches maximal exercise. For example, a blood pressure measure may need to be taken after only 30 seconds of exercise in a specific stage if the participant is approaching a maximal level of exertion. All modifications should be recorded on the GXT Data Form. The two highest 30 second time period VO_2 measurements will be averaged to identify VO_2 max. VO_2 max (L/min) will be recorded on the data form.

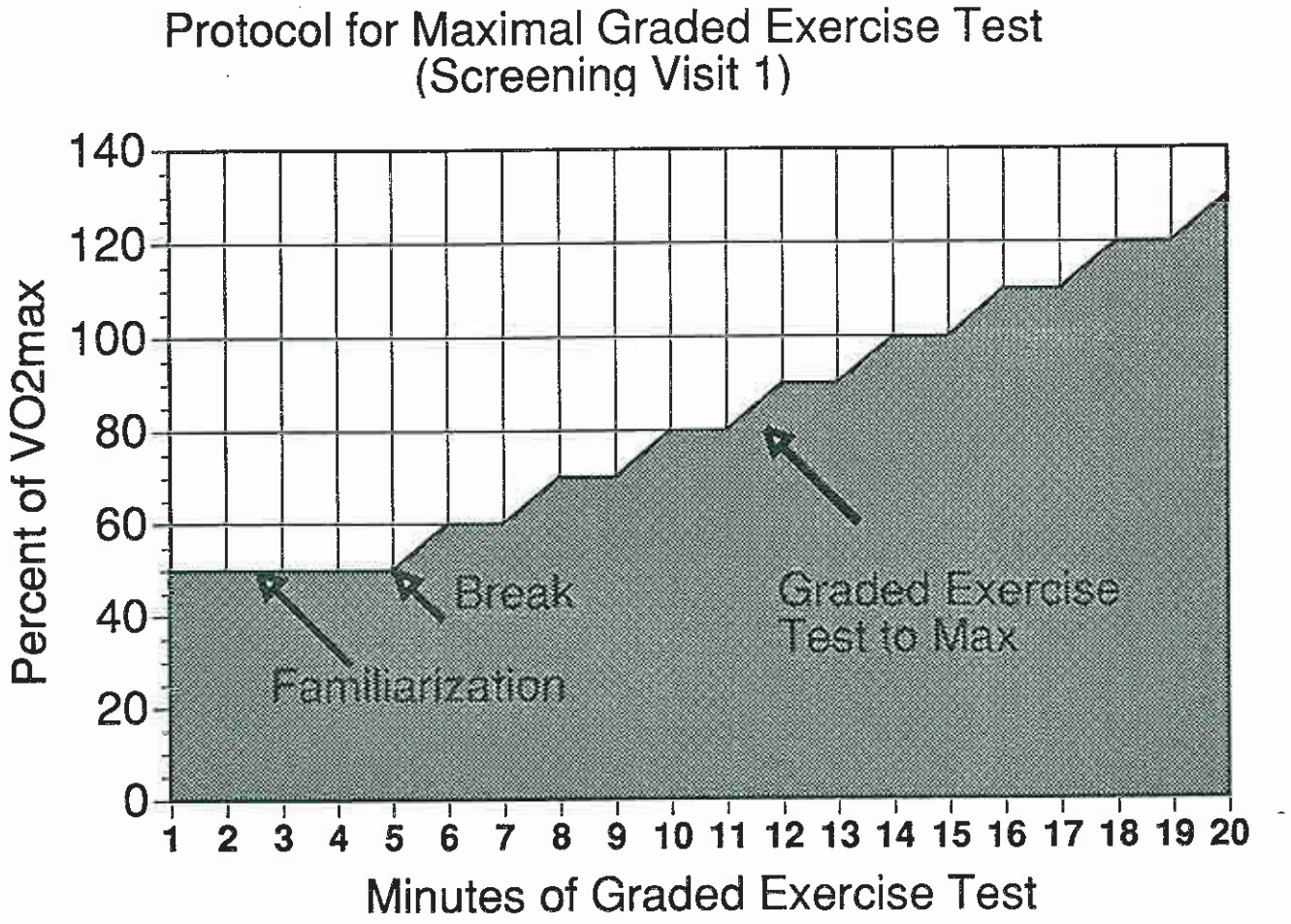
11. The time of onset of significant electrocardiographic changes, chest discomfort, dyspnea, joint pain, and/or other signs and symptoms will be recorded on the data form in the space provided. The supervising physician will also record any pertinent remarks and conclusions on the data collection form and record his interpretation of the results of the graded exercise test.

12. After the participant has adequately recovered and is free of symptoms, he/she will be escorted to the waiting room until the supervising physician has made an initial review of the GXT results.

13. American College of Sports Medicine Guidelines for Exercise Test Administration will be adhered to during all exercise testing.

* Note: Even though the ECG monitoring unit may calculate the heart rate and automatically print it on all ECG tracings, all heart rates should be verified by using an ECG ruler or calipers. If the ECG heart rate is not within ± 4 beats·min^{-1} of that obtained with an ECG ruler or calipers, then the heart rate obtained with the ruler or calipers should be recorded on the tracing.

FIGURE 2


Protocol for Maximal Graded Exercise Test
(Screening Visit 1)
Percent of VO2max
140
120
100
80
60
40
20
0
Break
Familiarization
Graded Exercise
Test to Max
1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20
Minutes of Graded Exercise Test

Post-Maximal GXT Procedures

Following the completion of the maximal GXT, the exercise test technologist will

1. On the CPX/D, select "Cardiopulmonary Exercise Report", select "Print Final Report",

2. Record VE (STPD), VO_2 ml/min, and $\%VO_2$ max at the ventilatory threshold according to the software included in the CPX/D system,

3. Calculate speed/grade for submaximal exercise stages of 50% and 75% VO2 max using ACSM equations.

4. Prepare equipment for the next test, including sterilizing mouthpieces, etc.

5. CPX/D data files should be transferred onto diskette monthly.

The ECG technician will

1. At the end of each test, print summary reports and place them with all ECG tracings in the participant folder.

2. At the end of each testing day, follow procedures for Formula System file conversion and RRV analysis.

3. At the end of each testing day, archive ECG results on floppy disks and clear hard drive.

Initial Review of Results

1. If the GXT interpretation is "Negative", the participant is dismissed with instructions for returning for SV2.

2. If the GXT interpretation is "Positive", the physician meets briefly with the participant to discuss results and follow-up procedures. The physician may also exclude the participant from the study based on exercise test results. Exercise test results and recommended follow-up are communicated to the participant's personal physician at the earliest opportunity.

* Insert Jim's section here Jim Paul

Procedure for Submaximal Exercise Test (SV2)

Cardiovascular response to submaximal exercise is a secondary outcome in ACT. Heart rate, blood pressures and ST segment changes will be measured at 50% and 75% of baseline VO_2 max (as seen in Figure 3). The submaximal exercise test will be performed at baseline (SV2) and at 6 and 24 months.

Submaximal Exercise Test Procedures

1. After completion of all other measurements during SV2, the participant will be escorted to the treadmill testing area.

2. The Formula System will be turned on. Select "PATIENT" to enter patient information; patient name should have ".SUB" as a suffix. Select "EXIT".

3. The submaximal exercise stages will be programmed into the Formula System by selecting "PROTOCOL", "LOAD", "SUBMAX". Observe "submax" at top of screen. Select "EXIT", "PROTOCOL", "EDIT", "PAGE 1". Enter speed and grade calculated to represent 50% VO_2 max for the first 5 minute stage; enter speed and grade calculated to represent 75% VO_2 max for the second 5 minute stage. Select "OK" to save protocol on Formula System.

4. The participant will have electrodes applied as previously described to permit a 12-lead ECG tracing to be obtained. A blood pressure cuff will be attached as previously described.

5. The participant will stand quietly on the treadmill belt while standing resting HR and blood pressure are taken and recorded. The specific sequence of keystrokes to run the ECG is as follows:
   * select "ACQECG"
   * select "PRE-EX"
   * select "BP" and enter blood pressures
   * select "EVENT"
   * select "STANDING" and tracing will print out

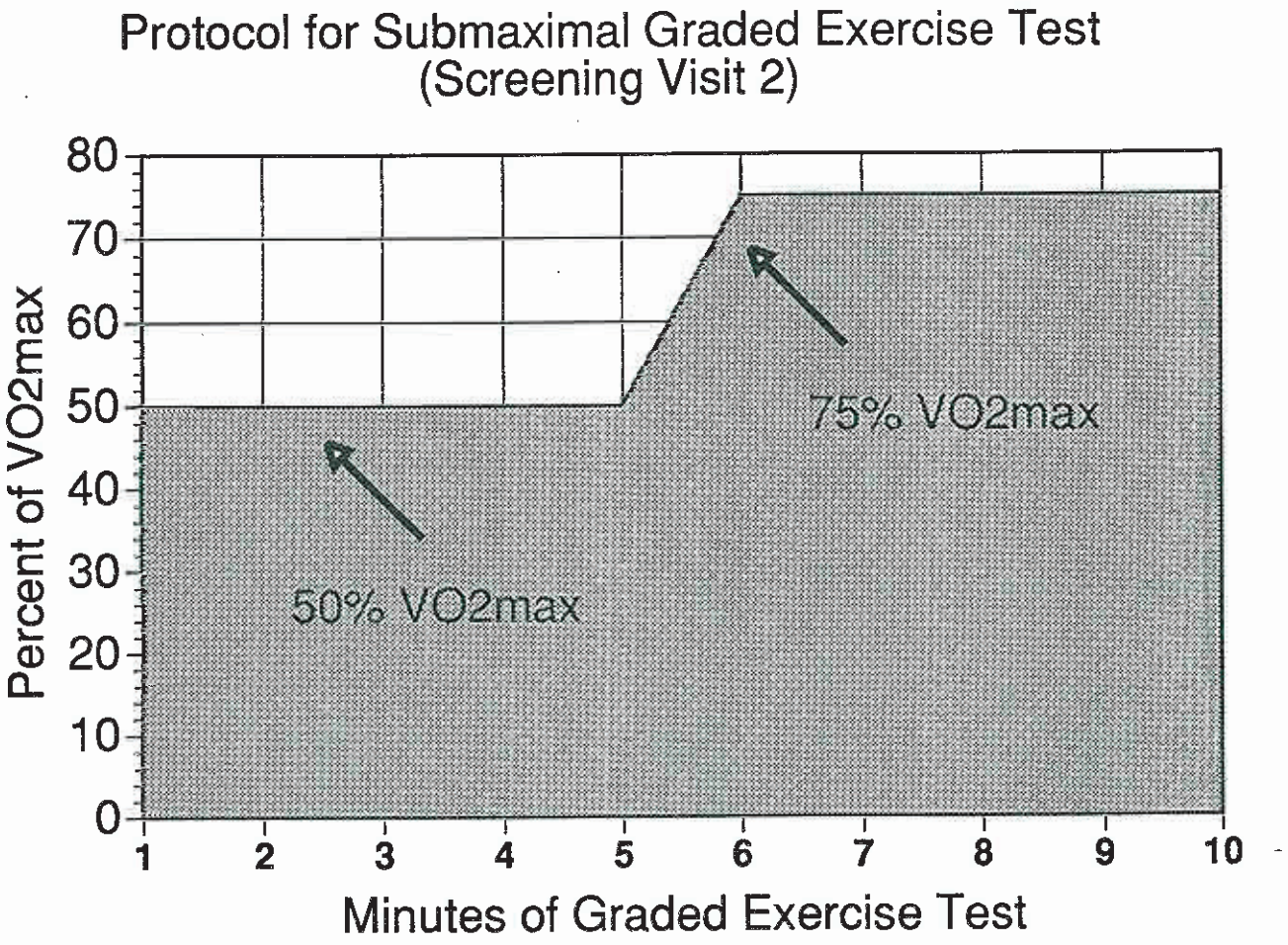
6. The participant will straddle the treadmill in preparation for the treadmill being started. Select "EXERCISE" to start the treadmill. The participant will step on to the treadmill and begin walking on the treadmill as previously described. The treadmill speed and grade will be that previously calculated to represent 50% of VO_2 max for that individual. The participant will release the handrail and continue to walk.

7. The participant will walk at 50% VO_2 max for 5 minutes. During the 3rd minute, blood pressure will be measured and entered in the Formula System. At 4 min 20 sec, select "PRT RT" to print out ECG. At 4 min 45 sec, ECG prints automatically. These two values should be averaged for the 4th minute value to represent HR submax and entered on the form. RPE will be determined and recorded at this time. Any ST segment changes will also be noted and recorded.

8. The treadmill speed/grade will be increased to that previously calculated to represent 75% of VO_2 max for that individual. During the 3rd minute of this stage, blood pressure will be measured and entered in the Formula System. At 4 min 20 sec, select "PRT RT" to print out ECG. At 4 min 45 sec, ECG prints automatically. These two values should be averaged for the 4th minute value to represent HR submax and entered on the form. RPE will be determined and recorded at this time. Any ST segment changes will also be noted and recorded.

9. At the end of 10 minutes, the treadmill will automatically go into recovery (2 mph/0% grade). The participant will walk at this pace for 3 minutes of active recovery. At 2 min 45 sec of recovery, ECG prints automatically. At 3 minutes, select "POST REC" to stop the treadmill. If the participant has tolerated the submaximal exercise with no adverse effects, he/she can be discharged from the treadmill testing area when ECG leads and blood pressure cuff have been removed.

FIGURE 3


Protocol for Submaximal Graded Exercise Test
(Screening Visit 2)
Percent of VO2max
80
70
60
50
40
30
20
10
0
1
2
3
4
5
6
7
8
9
10
Minutes of Graded Exercise Test
75% VO2max
50% VO2max

Procedures for Follow-up Submaximal and Maximal Exercise Tests

At the 6 and 24 month visits, the submaximal and maximal exercise tests will be repeated. At the 6 month visit, submaximal and maximal measurements will be combined into one exercise testing session. The submaximal measurements will be made first, followed by the maximal measurements. At the 24 month visit, procedures for the 24 mo (a) visit will be the same as those on SV1; for 24 mo (b), the same as SV2. For both the 6 and 24 month visits, treadmill speed/grade at 50% and 75% VO_2 max will be the same as they were during SV2.

Modifications of GXT Procedures for 6 month Visit

1. Heart rate variability will be done following the same procedures as at SV1.

2. Calibration of the CPX/D system will be done following SV1 procedure.

3. Supine and standing rest ECGs and blood pressure measurements as well as review of medical history will be as at SV1.

4. The submaximal exercise test will proceed exactly as done at SV2.

5. After completion of the submaximal measurements, the participant will be given a short rest while the exercise test technologist run an Auto Cal on the CPX/D system to confirm calibration. At this time, the exercise test technologist will review the protocol for the GXT, the RPE scale, the means of participant/technologist communication and the importance of exerting a maximal effort with the participant.

6. The participant will be fitted with the mouthpiece apparatus connected to the CPX/D and the system checked to confirm that analyzers and pneumotach are operating correctly.

7. The maximal GXT will commence at the warm-up treadmill speed/grade used in SV1. After 2 minutes (Stage 1), the treadmill speed/grade will be increased to that representing 75% VO_2 max during the submaximal test. The maximal GXT will proceed as in SV1 with all of the same procedures being followed during and after the test. Responsibilities of the exercise test technologist and the physician remain as in SV1.

ACT Activity Counseling Trial
Manual of Procedures

Protocol for Testing and Certification of GXT Personnel

Trainee:_____ **Site:**_____
Examiner:_____ **Date:**_____

By the end of the training session, the trainee should be competent in each of the individuals skills listed below. The trainee will be considered to be certified to perform ACT exercise testing when the form has been signed and each of the following items have been checked, verifying that he/she has properly conducted a maximal GXT and a submaximal exercise test according the ACT protocol in the MOP.

Introduction

____ 1. Introduces self to participant and places participant at ease.
____ 2. Explains purpose/procedures of GXT, verifies understanding of informed consent.
____ 3. Explains protocol for response to medical emergency and presents written code procedure.

Preliminary Measures

____ 1. Obtains height, weight, age, and cardiac medications.

Resting ECG, Heart Rate Variability, and Blood Pressure

____ 1. Locate/explain sites for limb and chest leads for standard 12 lead ECG.
____ 2. Prepares skin and applies electrodes.
____ 3. Prepares instrumentation/environment for HRV and explains protocol.
____ 4. Administers breathing protocol and monitors participant.
____ 5. Collects data for 10 min and acquires data for analysis and storage.
____ 6. Locates brachial artery, measures/chooses cuff size, attaches cuff and places stethoscope in position.
____ 7. Identifies SBP/DBP according to MOP BP protocol.

CPX/D System

____ 1. Prepares CPX/D system for measurement (drying tube, sample line, calibration gas, etc.)
____ 2. Manually calibrates pneumotach, analyzers, runs Auto Cal.
____ 3. Prepares mouthpiece, connects pneumotach, sampling line to CPX/D, conducts p-wave observation.
____ 4. Explains sterilization procedure for mouthpieces/valves.
____ 5. Conducts transfer of participant files from hard drive to diskette. .
____ 6. Prints final report, transfers information onto data sheet, and shuts system down.

12/95

ACSM Guidelines

____ 1. Understands absolute/relative contraindications to GXT.
____ 2. Explains general indications for stopping a GXT.
____ 3. Identifies ECG abnormalities/Sx requiring MD attention prior to GXT. .
____ 4. Contraindications and guidelines for stopping should be posted in lab.

Maximal GXT

____ 1. Explains maximal GXT protocol to participant.
____ 2. Explains use of RPE scale to participant.
____ 3. Explains participant/technologist communication during GXT.
____ 4. Explains test endpoints, including participant request to stop and signs/symptoms of exertional intolerance.
____ 5. Teaches participant how to step on treadmill, release the handrail and walk on treadmill.
____ 6. Demonstrates technique for obtaining SBP & 4th/5th phase DBP.
____ 7. Demonstrates technique for obtaining exercise RPE.
____ 8. Teaches participant to regrasp handrail at termination of GXT.
____ 9. Explains procedure for determining treadmill speed.
____ 9. Demonstrates cool-down procedures and recovery procedures.
____10. Demonstrates ability to run Formula and CPX/D systems, including programming protocol, entering BP, etc.

Submaximal GXT

____ 1. Explains submaximal GXT protocol and use of RPE scale to participant.
____ 2. Establishes correct 50 & 75% VO_2max workloads from max GXT data.
____ 3. Executes a submaximal GXT with all physiologic data acquisition.
____ 4. Demonstrates complete data management after submaximal GXT.
____ 5. Explains incorporation of max and submaximal GXTs into 6 mo. test.

_____ _____
Trainee (Signature) Date

_____ _____
Examiner (Signature) Date

12/95

ACT Max Graded Exercise Test Form

ID ☐☐☐☐☐☐ Acrostic ☐☐☐☐☐☐

Date of Test ☐☐/☐☐/☐☐ (Mon / Day / Year) Visit Code ☐☐☐

Age ☐☐ Height ☐☐☐ cm Weight ☐☐☐ kg

Age-predicted Max HR (220-age) ☐☐☐ bpm 60% Age-predicted Max HR ☐☐☐ bpm 70% Age-predicted Max HR ☐☐☐ bpm

Patient on medications?

1 ☐ Yes — Specify Meds:
2 ☐ No

Resting Measurements

ECG Results:

1 ☐ Normal
2 ☐ Abnormal — Specify abnormalities:
3 ☐ Uninterpretable

Any contra-indications to treadmill testing?

1 ☐ Yes — Specify contra-indications:
2 ☐ No

Course of action taken:

1 ☐ GXT performed 2 ☐ Subject excluded (GXT **not** performed) 3 ☐ GXT rescheduled

Supine: SBP ☐☐☐ mmHg DBP ☐☐☐ mmHg HR ☐☐☐ bpm

Standing: SBP ☐☐☐ mmHg DBP ☐☐☐ mmHg HR ☐☐☐ bpm

Treadmill Measurements

Warm-up: HR ☐☐☐ bpm %HR_{max} ☐☐☐ TM Speed ☐☐☐

Stage	Time	Grade	HR	RER	SBP	DBP	RPE	AP	ST	Arr	Comments
1	0-2										
2	2-4										
3	4-6										
4	6-8										
5	8-10										
6	10-12										
7	12-14										
8	14-16										
9	16-18										

Acrostic [ ][ ][ ][ ][ ][ ]

Total Treadmill Time [ ] min Reason for stopping: [ ]

Post-exercise Measurements

Time	HR	SBP	DBP	Signs, Symptoms, ECG Changes
Immediate*				
2 minute				
4 minute				
6 minute				
8 minute				

* If no BP was obtained at peak exercise, obtain one immediately after stopping.

GXT Interpretation:

1 ☐ Negative

2 ☐ Positive

Specify result or problem:

Is this a contra-indication to further treadmill testing? 1 ☐ Yes 2 ☐ No

Will this subject be excluded from participation in ACT? 1 ☐ Yes 2 ☐ No

3 ☐ Uninterpretable

Criteria for VO_2 max

maximal heart rate [ ] b/min

maximal RPE [ ]

maximal RER [ ]

maximal VE/VO_2 [ ]

maximal respiratory rate [ ]

maximal VO_2 [ ] ml/min

VO_2 @ (max stage - 1) [ ] ml/min

VO_2 @ (max stage - 2) [ ] ml/min

Primary Outcome

VO_2 Max Measurements [ ] ml/min

[ ] ml/kg/min

[ ] METS

Ventilatory Threshold

Ve (BTPS) [ ] L/min

VO_2 [ ] ml/min

$\%VO_2$ max [ ]

Test performed by [ ][ ] (code)

COMMENTS:

ACT Heart Rate Variability Form

ID ☐☐☐☐☐☐ Acrostic ☐☐☐☐☐☐

Date of Visit ☐☐/☐☐/☐☐ Visit Code ☐☐☐

Mon Day Year

Time ☐☐:☐☐ ☐ AM ☐ PM

TIME DOMAIN

VARIABLE	EPOCH1	EPOCH2	MEAN
Interpolated Beats			
R-R Max			
R-R Min			
R-R Mean			
SD			
Variance			
CO Variation (SD Mean)			

FREQUENCY DOMAIN

VARIABLE	EPOCH1		EPOCH2		MEAN	
LF/HF RATIO						
	PSD	NORM	PSD	NORM	PSD	NORM
VLF POWER (0.01 -0.04)						
LF POWER (0.04-0.15)						
HF POWER (0.150-0.50)						
TOTAL POWER ABOVE VLF (0.01-0.50)						
TOTAL POWER (0.00-0.50)						

APPENDIX C

Physical Activity Assessment Procedures

Manual of Operations

Pre-screening procedures

7-day Physical Activity Recall procedures

Table of Contents - Appendix C

TABLE OF CONTENTS 2

ACKNOWLEDGMENTS 3

PHYSICAL ACTIVITY PRE-SCREENING ITEMS 4

I. INTRODUCTION 4
II. TELEPHONE INTERVIEW 4
III. PRE-SCREENING VISIT 4

7-DAY PHYSICAL ACTIVITY RECALL INTERVIEW 6

I. INTRODUCTION 6
II. INTERVIEWER PREPARATION GUIDELINES 7
III. INTERVIEW PROTOCOL AND GUIDELINES 8
A. Page 1 - Work Schedule and Physical Activity Accumulation Questions 8
B. Establishing the Days of the Week for the 7-day Recall and Use of Worksheet 9
C. Sleep 11
D. Overview Of The Interview 12
E. Activity 14
F. Strength and Flexibility Exercises 16
G. Review 17
H. Other Physical Activity Questions. 17
I. Summarizing The Worksheet 18
J. Manual Calculation of the 7 Day Recall Form 19
K. Evaluation Of The Interview By The Interviewer 22
L. Important Procedures The Interviewer Often Overlooks 22
M. Certification and Quality Control Monitoring 24

7-DAY PHYSICAL ACTIVITY ASSESSMENT APPENDIX 26

Acknowledgments

This manual has been produced for use in the Activity Counseling Trial (ACT). It has been adapted from work done at San Diego State University (Project Grad, James Sallis, Ph.D Principal Investigator) and the Cooper Institute for Aerobics Research (Project Active, Steven N. Blair, P.E.D., Principal Investigator). Revisions for the current version of the manual have been led by Laura E. Becker and Harold W. Kohl, Ph.D. (Cooper Institute).

Physical Activity Pre-screening Items

I. INTRODUCTION

An initial eligibility criterion for inclusion in the Activity Counseling Trial (ACT) is a weekly energy expenditure of not more than 35 kcal • kg^{-1} • $week^{-1}$. These values will ultimately be determined by responses evaluated using an interview-administered 7-day Physical Activity Recall (PAR) questionnaire. In order to pre-screen individuals who may exceed these energy expenditure levels, questionnaires will be administered to potential study participants at the initial telephone interview and the prescreening orientation visit (SV0).

II. TELEPHONE INTERVIEW

As part of the initial telephone interview for recruitment eligibility, the following question will be asked of all potential study participants.

1. "Do you currently and regularly participate in any physical activity such as walking, running, aerobic dance, swimming, or playing sports at least three times per week for 30 minutes or longer each time?"
2. "If you have a job, does your job require you to do heavy manual labor for most of your shift?"

If the answer to either question is affirmative, potential participants should be ruled ineligible.

III. PRE-SCREENING VISIT

At the time of the initial pre-screening visit (SV0) all potential participants who satisfied the criteria for the telephone interview will be asked to answer a series of simple questions on physical activity. The purpose of these questions is to further restrict potential study participants to only those who are sedentary. The responses to these questions comprising the 7 day physical activity recall and

the resulting energy expenditure calculation will be used to identify participants who may be ineligible due to excessive energy expenditure.

7-Day Physical Activity Recall Interview

I. INTRODUCTION

The 7-Day Physical Activity Recall (PAR) interview technique is used to estimate an individual's average daily energy expenditure for the previous week. Based upon participant recalls, hours spent in ***moderate, hard***, and ***very hard*** intensity activities are determined and total kilocalories can be estimated from the number of hours engaged at the various levels of intensity. The purpose, therefore, is not to single out specific physical activities but to identify participation in activities at various levels of intensity. With this interview technique, we will be looking at work-related activities, leisure-time activities, sitting patterns, and sleep patterns. By mathematical difference, these data will then be used to estimate activities classified as ***light*** intensity. The purpose of this manual is to standardize the interview process and to increase agreement among interviewers.

Your interview technique should limit bias (it should be objective), and you should try to keep the interview from becoming tedious. To achieve these goals, an interviewer script has been created and is included in the Appendix of this manual. Although the interviewer does not have to memorize this script it should be followed very closely to reduce variability between and within interviewers. A major effort should be made by the person conducting the interview not to be judgmental of participant responses. There are no right or wrong answers to the interview. It is important to set a positive, non-threatening tone and to put the participant at ease at the beginning of the interview. It is also important to remember not to let the study participant sidetrack you. It may be difficult for participants to remember their past week's activity. Some may not try very hard, and others get bogged down in details. You should strive to achieve a happy medium. You should control the pace of the interview; extraneous talk should be avoided. If participants are going into excessive detail, you should remind them that they need not account for every minute but that an average or estimate is expected. For example, you might ask, "How much time in general?" or "about how long?".

It is important to remember that most of the participants you see will spend a vast majority of their waking hours doing ***light*** activity. Many tiring and unpleasant household or occupational tasks do not have a very high energy cost. Clerks in a store, for example, may be on their feet all

day and may feel fatigued, but the energy cost is in the ***light*** category. An exception to this example would be time spent in stocking shelves, which probably would be classified as ***moderate*** activity. Also, for most occupational tasks that require at least moderate energy expenditure, it is important to accurately determine the actual time spent doing the activity. In the stocking clerk example, even though a person might do that activity for an entire shift, it probably would not equal eight hours. You should try to subtract time spent on lunch, breaks, and the like.

II. INTERVIEWER PREPARATION GUIDELINES

A. THE FOLLOWING POINTS SHOULD BE EXPLAINED TO EACH PARTICIPANT BEFORE ACTUALLY BEGINNING THE PHYSICAL ACTIVITY INTERVIEW. REVIEWING THE INTERVIEWER SCRIPT PROVIDED IN THE APPENDIX WILL ASSIST IN COMMUNICATING THIS INFORMATION:

1. They are to think of their physical activities during the past seven days. It is important to stress that this is a recall of actual activities for the past week, not a history of what they usually do.
2. ***Light*** activities, such as desk work, standing, light housework, softball, archery, bowling, and the like (where there is little movement of large muscles) will be considered in a separate part of the physical activity interview. For the 7-day recall, we are interested in occupational, household, and sports activities that make you feel relative to how you feel when you are walking or make you feel like you are working as hard as when you are walking briskly (15-20 minutes per mile).
3. Explain to the participant that he or she will be asked to categorize the intensity of the activity into one of three groups, ***moderate, hard*** or ***very hard***. Explain that the ***moderate*** category is similar to how one might feel while walking at a 15-20 minute per mile pace and that the ***very hard*** category is similar to how one might feel when running. The ***hard*** category falls in between. In other words, if the activity in question seems harder

than walking but not as strenuous as running, place it in the ***hard*** category. Here (prior to the interview) it is a good idea to give examples and interact with the participant enough to allow feedback for a complete understanding of the types and intensities of activities that would fall into these categories. Laminated cards highlighting examples of each of the intensity categories are provided to each interviewer. Prior to conducting the interview, the interviewer should be familiar with the energy cost of many common activities (see Certification and Quality Control section later in this chapter). Study personnel are urged to consult the reprint of Ainsworth et al. (Compendium of Physical Activities, found in Appendix) for a listing of these energy costs.

4. Should any questions arise regarding administration of the PAR during the course of ACT, study personnel are requested to contact the Dallas Center (Laura Becker, 214-701-8001) for clarification and direction. All issues raised during the study will be recorded in a logging book for future reference.

III. INTERVIEW PROTOCOL AND GUIDELINES

Physical activity recall data for ACT will be collected on pre-printed forms and transferred to computerized form. Detailed information on participant interviewing can be found in the interviewer script (Appendix). Detailed information on completion of the pre-printed forms is found below.

A. Page 1 - Work Schedule and Physical Activity Accumulation Questions

1. Start the interview by asking the participant the employment question(s) on the 7-day PAR Questionnaire.
   a. "Were you employed in the last seven days (including paid work and volunteering)?"
      1. Yes
      2. No (Skip immediately to Question 6, page 1)

1. Number of days

c. "How many total hours did you work in the last seven days?"

1. Hours last week

d. "What days of the week do you consider to be your weekend or non-work days?"

e. If the participant reports fewer than 7 days (reported weekdays + weekend days), "Why did you work fewer days this past week than usual?" If the participant's work days and weekend days total more than 7, note the reason for the increased work time.

f. "For the past seven days, and thinking only about activities that are at least of moderate intensity (show laminated cards), how many days did you do activity or exercise that added up to at least 30 minutes each day?"

g. Go to PAR Worksheet

B. Establishing the Days of the Week for the 7-day Recall and Use of Worksheet

1. **To aid the participant in recall you will ask about each day in turn starting with yesterday and working backwards.** "Okay, today is Tuesday, yesterday was Monday." Also make sure to **label the worksheet (see below) with the appropriate days of the week.** Do this by placing yesterday's day of the week in the blank below the column labeled "Yesterday." Then, working backwards with respect to day of the week, write each of the past 6 days of the week in the appropriate space above the columns, ending with the last day of the recall week below the column labeled "One Week Ago." This makes logging the participant's activities much easier. Also, connecting activities to specific days of the week helps the participant to remember more.

2. The PAR worksheet (a Xerox copy of page 2 of the PAR form) is used to help the interviewer summarize the physical activity recall reported by the study participant. Minutes that the participant reports having spent in

study participant. Minutes that the participant reports having spent in moderate, hard, and very hard activities (as well as sleep time) are recorded on the Worksheet. These data will then be transferred to the PAR form and used to calculate an estimate of energy expenditure to determine study eligibility (see Recruitment and Eligibility chapter of MOP) and as a primary outcome variable. Several key points about use of the Worksheet are listed below.

a. Make sure to **label the worksheet with the appropriate days of the week.** This makes logging the participant's activities much easier.
b. **Record time of sleep** in spaces provided on worksheet. Time segments should be recorded in 15 minute (:15), 30 minute (:30), 45 minute (:45), or hour (:00) time blocks. *Rounding to the nearest 15 minutes applies to sleep times only.*
c. **Record activity and time of activity** in spaces provided on worksheet for morning, afternoon, and evening at the various levels of intensity. For activity that is continuously performed, it must have been performed at least 10 minutes to be recorded. Round times spent in activities to the nearest minute. For example, jogging three miles in 27 minutes and 52 seconds would be recorded as follows:

Very Hard	3 mi. jog
	:28

Likewise, walking five miles in 1 hour, 15 minutes and 20 seconds would be recorded as follows:

Moderate	5 mi. walk
	1:15

d. Draw a light, wavy line down the column of the individual's weekend day(s). Remember they may not necessarily be Saturday and Sunday.

C. Sleep

1. The first item on the PAR Worksheet is an assessment of the participant's **sleep** times for the week. The goal in estimating the sleep pattern in the PAR is to get an estimate of an individual's hours spent in bed per night. Even if they claim not to have slept, if they were in a prone position, they used approximately the same number of kilocalories as sleep. The number would be rounded to the nearest 1/4 hour. For example, if the individual reported 20 minutes, round down to 15 minutes (:15). If they report 25 or 35 minutes this would be rounded to 30 minutes (:30), if they have 40 or 50 minutes, round to 45 minutes (:45), and if they report between 55 and 05, round to the nearest hour (:00). Many people will get in bed and get out of bed at consistent hours on the weekdays. This should be determined as an initial step by asking the following:

   a. For the past 5 weeknights, did you usually get in bed and get out of bed at the same time, or did it vary each night?

      1. If the times vary most nights, go day by day beginning with getting in bed last night and getting out of bed this morning (the day of the interview). Work your way back through the week asking for the specific times they got in bed and got out of bed each night and day. Going backwards helps people remember by starting with the most recent time frame.

      2. If the times of getting in bed and getting out of bed are fairly constant during the weekdays, ask what time they got in bed and what time they got out of bed and record these numbers on the worksheet. Ask the participant if there were any unusual weekdays when they might have gotten in bed or out of bed earlier or later.

Record any of these changes on the appropriate day. Next, ask the participant about the past Saturday night getting up on Sunday and the last Friday night (or equivalent weekend days) getting up on Saturday. Record these numbers on the worksheet.

For example, if the interview takes place on a Tuesday, the first night of recorded sleep (working backwards from Tuesday) would be going to sleep Monday night and getting up on Tuesday morning the day of the interview). The total number of hours slept in this time frame would be recorded for Monday night (labeled "yesterday" on the Worksheet). The next night of sleep assessed would be Sunday night, getting up on Monday. This number would be entered into the Sunday column. Therefore, keep in mind that although the labeled column refers to that *day's* activities, it also refers to that *night's* sleep times.

b. Keep in mind that some people may nap during the day or fall asleep while reclined in a chair. This time should be added to the pertinent night's sleep time. To capture this information the participant should be asked if they took any naps or laid down for any period during the last seven days. Interviewers should be particularly alert to this if there was a night of limited or no sleep time.

D. Overview Of The Interview

1. Starting with yesterday and working backward, ask about activities during each day.
2. Ask only about activities that are ***moderate***, (at least the intensity of brisk walking), ***hard*** (intensity between walking and running), and ***very hard*** (intensity of running).

3. Ask about activity during each segment of each day as a separate question. For example, "On Wednesday morning, from the time you got out of the bed until the time you had lunch, did you do anything you would consider moderate, hard, or very hard?" Morning is generally considered from the time they wake up in the morning to the time they have lunch, afternoon is from lunch to dinner and evening is from dinner until the time one goes to bed. The previous question would then be repeated for the remaining segments of the day.
4. It will help recall significantly to have the participant remember what he or she did during the day in question. If the participant is having trouble remembering their activities during each segment of the day, as the general question, "Do you remember what you did on (Tuesday)?" Once the participant starts remembering, switch back to the segments of the day as outlined above (i.e., morning, afternoon, evening).
5. The interview needs to be sensitive to walking. However, people walk many times during the day, and we will not count all of them. For example, we do not want them to add up each time they walk to the refrigerator. **The general rule is that they should do 10 minutes in a given intensity category in a given segment of the day (e.g., morning, afternoon, evening)**. The specific rule for walking is that you only count walking that is continuous for at least 10 minutes or intermittent walking performed during a limited period of time (such as 1-2 hours) which would total 10 minutes or more. An example of intermittent walking that would qualify would be briskly walking through a shopping mall for 60 minutes with the walking time interspersed with stopping to window shop. If the total accumulation of walking was 45 minutes (of the 60) and 15 minutes was spent window shopping, the time to be recorded would be 45 minutes. This would be classified as ***moderate*** unless the participant walked very fast or race-walked.

6. Make sure to emphasize the intensity guidelines. For example, the participant should be asked, "When you are doing the activity, is it similar to how you feel when you are walking at a 15-20 minute per mile pace, or is it similar to how you feel when you are running, or is it somewhere in between?" If the activity is of an intensity less than a brisk walk, it is considered a ***light*** activity and is not included in the worksheet.

E. Activity

1. Frequency:
   a. Probe to determine if the amount of the activity the participant reports is per weekend, per week, or per day, etc. Someone may say, for example, "I did one hour of digging this past weekend " when what they meant is, "I did one hour of digging each of the two days this past weekend."
   b. Some people have trouble recalling or pinpointing the ***moderate*** to ***very hard*** activities they have engaged in over the past seven days. In such cases, **try to cue them** by asking them general questions. For example, "How about any housework that made you feel similar to brisk walking?", "Did you take any walks?", How do you get to and from work?", "Did you participate in any sports?", "Any vigorous family activities?", "Did you do any vigorous home repair or gardening?".
   c. Take a retrospective look back at each day by asking the respondent whether there is any activity they may have forgotten to mention.
2. Intensity:
   a. If you are unsure of the strenuousness of an activity that they may have participated in, **ask them to describe the physical effort involved.** For example, what does the activity entail? We have found that walking and running provide good frames of reference for classifying activities. Everyone should be familiar with the relative intensity of ***brisk*** walking, which is about the midpoint of the moderate activity

category. Therefore, if some other activity that the participant reports seems to be about as strenuous to the individual as **walking briskly,** then the activity should be coded as ***moderate.*** Most running or jogging at any speed falls into the ***very hard*** category. If some activity seems about as strenuous to the individual as running, classify the activity as ***very hard.*** If the activity in question seems harder than walking but not as strenuous as running, place it in the ***hard*** category.

b. For most activities, the rate at which they are performed can make a huge difference in the energy cost. It is possible to play single tennis, for example, so as not to move around much and not expend much energy. **Try to get some indication of how hard they are working at a particular task.** Again, use comparisons to walking and running so they can rate how hard they did the activity.

3. Time:

a. Some people have trouble quantifying the amount of time they spent doing ***moderate***, ***hard***, or ***very hard*** activities. In such cases, **break down all of their activities into specific events and ask them how long they did each activity.** Then sum up the amount of time relevant to each category. If the individual is having difficulty quantifying the amount of time engaged in a particular activity, suggest to the individual possible time frames such as 15 minutes, 30 minutes, 45 minutes, or an hour. However, it is not necessary to round participant answers to anything but the nearest minute.

b. **The activity in question should be performed for a total of 10 minutes, intermittently or continuously, during one segment of the day; morning, afternoon, or evening.** For example, if their activities add up to at least 10 minutes in one intensity category (e.g., ***hard***) for one segment of the day (e.g., Wednesday afternoon), the total time of those activities should be counted. If 10 minutes of activity is spread out over two or more segments of the day, it is not counted. The

purpose of this rule is to eliminate the need to recall and record each minute of activity.

c. **Be sure that the time reported for an activity was actually spent doing the activity.** Being at the pool for 2 hours but only swimming for 15 minutes, for example, should be recorded as 15 minutes, not 2 hours. Working in the garden all day Saturday (8 hours) should mean actually working for 8 hours. **Do not record the time spent on breaks, rest periods, meals, and the like.**

4. Special Cases:

a. **If the last week was totally atypical**--for example, in the hospital or in bed, or involving a family crisis, or a work crisis, or travel--**it is permissible to go to the previous week for the survey.** Do not take this action lightly; use it only **in unusual circumstances.**

b. If a person has weekdays instead of weekends off from work--for example, Tuesday and Wednesday instead of Saturday and Sunday--ask the participant if they consider the weekdays they have off as their weekend. If they do not consider the days off as their weekend days, ask them which days are most like weekends. Some participants may only consider one day as their weekend day. Others may have three day weekends. The point here is to determine the participant's non-work days as they are likely to have a different routine than the workdays. **Make sure to count the most appropriate days of the week, as indicated by the participant, as weekend days.**

c. Weekend days should be denoted on the worksheet by drawing a light, wavy line through the activities for the days which the participant counts as weekend days.

F. Strength and Flexibility Exercises

Any reported strength and flexibility exercises performed for at least 10 minutes should be recorded on the worksheet if they are performed at the

moderate, hard, or very hard intensity level as are any other physical activities. Usually strength and flexibility exercises will be recorded as ***moderate*** physical activities, however the interviewer should be confident that these activities are performed at the same intensity as going on a brisk walk. The classification can be verified by determining the time spent in the activity and the total number of exercises (i.e., number of sit-ups, push-ups, etc.) performed during that time period.

G. Review

1. At the end of each day of recall, the interviewer should ask the participant to take a **retrospective look of the past week** as well as at the end of **each day** to determine any activities that may have been overlooked.
2. **Use cues as much as possible** to aid in the participant's recall of the past week. For example, "Did you want to add any other household, occupational, or sports activities that you participated in the past week and that we have not talked about?" "Did you take any walks we have not already covered?", "Are there any activities that you are unsure about?". However, it is important that the interviewer administer these questions consistently to all participants.

H. Other Physical Activity Questions.

1. Was this a typical week in terms of your usual pattern of activity or exercise? (YES/NO).
   a. If NO, were you more or less active in the past week than you usually are? (MORE/LESS).
2. Sitting Activities

   Sitting activities are not recorded as part of the PAR worksheet, but are of interest to ACT nonetheless. Therefore, two questions on such activities are included on page three of the Physical Activity Recall form. Such activities include sitting, watching television, working at a

desk or computer, eating or reading, etc. We are interested in the participant's usual activity over the last three months.

a. Review the time period transition and the list of sitting activities with the participant and ask them to give an average of the hours spent sitting during their work week. Some participants will be able to do this quickly as their days usually follow a routine. Remember, we are looking for a **global** estimate of sitting time over the last three months, therefore, it is not appropriate to attempt to match this answer with the previous week's recall..

b. Repeat for average weekend or non-work time spent sitting for whichever days the participant considers to be weekend days.

2. Ask about the number of flights of stairs climbed up each day and record answer. Note that 10 steps equals a flight and that we are only interested in flights climbed, not flights up and down.
3. Participant should provide an estimate of the number of minutes walked during a day and the pace at which they walk. The participant does not need to count each step, rather a general estimate of the time they spend walking during a typical day.
4. Ask the participant the three questions regarding strength and flexibility exercises. Remember the time frame for these activities is over the last three months.
5. Thank the participant for their time and participation. The interview is concluded.

I. Summarizing The Worksheet

1. After the interview, data from the completed worksheet is entered into the ACT 7-day Energy Expenditure Calculation Software. The computer program calculates summaries of the intensity categories necessary to give a kilocalorie per day estimate of physical activity for each participant. Before entry into the computer, the interviewer must summarize the daily hours of

sleep. The daily hours of sleep for the last seven days will be entered into the energy expenditure calculation computer program.

2. Prior to data entry the interviewer should visually review each form and ensure completeness and correctness of each entry. Questionable intensities of reported physical activities should be verified using the Compendium of Physical Activities or with Laura Becker at the Dallas Clinic.
3. Prior to data entry, each interviewer should be thoroughly familiar with procedures and protocols for use of the ACT 7-day Energy Expenditure Calculation Software.

J. Manual Calculation of the 7 Day Recall Form

Calculation of the kilocalorie expenditure for the 7 Day Recall Form should be performed using the ACT PAR Scoring Application software installed at each clinical site. If the data collection site is different from the location of the ACT data entry computer with the scoring software installed, computer calculation is still possible via faxing and telephone relay between the two sites. In cases of power failure or computer failure, the following manual calculation may be used to score the ACT Physical Activity Recall form. However, due to the increased likelihood of mathematical error the manual calculation should be used only when all other options fail. As soon as possible, PAR forms that have been hand calculated should be entered into the ACT PAR Scoring Application software to confirm the PAR score.

The following example refers to the responses for the 7 Day Recall Certification audio tape which was administered at each site. Very hard intensity activity has been added that was not part of the audio tape.

1. Sum the seven nights of sleep. Example:

6:00
5:30
7:15
5:30
9:45
7:00
5:30
46:30 = total hours of sleep

2. Sum the daily hours/minutes spent in moderate intensity activity for each line of the recall. Example:

Thurs. morning		:17	
Wed. morning	:17		
Tues. morning	:17		17 x 3 = 51 minutes
Sun. morning	:20		+ 20 minutes = 1 hour, 11 minutes
Sat. morning	:16		+ 16 minutes = 1 hour, 27 minutes
Fri. morning	:15		+ 15 minutes = 1 hour, 42 minutes
Thurs. afternoon		:15	
Mon. afternoon		1:15	afternoon totals = 1 hour, 30 minutes

Total moderate intensity activity = 3 hours, 12 minutes

3. Sum the daily hours/minutes spent in hard intensity activity for each line of the recall. Example:

Thurs. afternoon	:45
Wed. afternoon	:30
Fri. afternoon	:36

Total hard intensity activity = 1 hour, 51 minutes

4. Sum the daily hours/minutes spent in very hard intensity activity for each line of the recall. In this example there was no very hard intensity activity.

Tues. evening :42

Total very hard intensity activity = 0:42

6. Subtract total obtained in step 5 from 168 to get time spent in light activity. Example:

168:00
- 53:15
114:45 = total hours of light activity.

7. Divide the minutes portion of each of the categories by 60 to obtain the fraction of each hour spent in activity. Example:

Sleep = 46:30 (30/60 = .5), total sleep = 46.5
Light = 114:45 (45/60 = .75), total light = 114.75
Moderate = 3:12 (12/60 = .20), total moderate = 3.20
Hard = 1:51 (51/60 = .85), total hard = 1.85
Very Hard = :42 (42/60 = .70), total very hard = .70

8. Use the following table to perform the next calculation:

Activity	Total Time	Multiply by:	Total
Sleep	46.5	1	46.5
Light	114.75	1.5	172.125
Moderate	3.20	4.0	12.8
Hard	1.85	6.0	11.1
Very Hard	1.70	10.0	17.0
	168.00	Grand Total	259.525

9. Divide grand total by 7 to obtain energy expenditure to determine eligibility. Example:

259.525/7 = 37.075

Because the energy expenditure is greater than 35 kcal/kg/wt, this person is ineligible.

K. Evaluation Of The Interview By The Interviewer

In some cases it may be important for the interviewer to give a subjective evaluation of the quality of the interview once it has been completed. Please attach the PAR Interview Evaluation Form to the Worksheet once completed. Although these data will not be entered into the computer, the subjective opinion of the interviewer is important to evaluate data quality.

1. Were there any problems with this survey?
   a. Yes
   b. No
   c. Explain
2. Do you think this was a valid interview?
   a. Yes
   b. Maybe
   c. No
3. Please list any activities reported by the participant which you **don't** know how to classify.

   Procedures for dealing with data from interviews determined to be invalid will be handled on a case-by-case basis. Interviewers are requested to discuss such cases with Laura Becker at the Dallas Clinic.

L. Important Procedures The Interviewer Often Overlooks

1. Ask about each day in turn starting with yesterday and working backwards. "Okay, today is Tuesday, yesterday was Monday." Also make sure to label the worksheet with the appropriate days of the week. This makes logging the participant's activities much easier. Also connecting activities to specific days of the week aids the participant in recall of events.
2. Before asking about activities, it might help to ask the participant what he or she did that day, in general. "Where did you go and what did you do on that day?" Again, this helps them recall activities specific to that day.

3. Ask separately about each segment of the day. "What activities did you do in the morning; in the afternoon; in the evening?" Again, this helps the participant to remember more clearly.
4. Several times during the interview, remind the participant to think about all physical activities including work, household, and leisure/sport activities.
5. Count walking that is done for at least 10 minutes continuously. However, for the activity to be counted it must add up to at least 10 minutes in one intensity category during a limited time segment of the day.
6. At the end of the interview, ask the participant if he/she forgot any activities.
7. The interviewer should not guess what intensity an activity is. Have the participant classify all activities into intensity categories. They should use the rule: running is ***very hard***, brisk walking is ***moderate***, and ***hard*** is in between.
8. The purpose of the PAR is to estimate energy expenditure, so an activity does not have to be continuous to be coded. If their activities add up to at least 10 minutes in one intensity category (e.g., hard) for one segment of the day (e.g., Wednesday afternoon), then that activity or those activities should be counted. For example, consider 60 minutes of gardening which included both digging and planting. If the participant alternately dug and stopped to plant in five minute intervals, this activity would be recorded as 30 minutes of digging. and would qualify as ***hard*** activity. If 10 minutes of activity is spread out over two or more segments of the day, it is not counted. For example, 5 minutes of walking in the morning, 5 minutes in the afternoon and 5 minutes in the evening do not qualify. This rule allows the interviewer to code sporadic activities, but it does not force one to code every single minute of activity during the day, which would be too time consuming.
9. Weekend days should be marked with a "squiggly" line down the column.
10. If the participant offers information about sexual activities, the interviewer should offer his or her thanks, but the activity should not be recorded.

However, do not make a point with the participant that the activity won't be recorded.

M. Certification and Quality Control Monitoring

Interviewer certification and continuous quality control monitoring of PAR measurement is critical to ACT primarily due to the fact that physical activity is a primary outcome variable and as such reduction of variance is most important. It is suggested that a minimum of three certified PAR interviewers be available at each Clinical Center throughout the course of the study. There are three stages of interviewer certification and quality control monitoring used in ACT.

1. Initial interviewer certification.

Prior to conducting physical activity recall interviews for ACT, relevant staff will be required to be certified in the interview procedure. During initial training for PAR measurement, this certification will require the following steps:

a. A personal review of ACT PAR audio tape containing sample 7-day PAR interviews.

b. Attendance in a four hour training session led by a qualified individual experienced in PAR administration. This session will include practice sessions in which the interviewer has the opportunity for administering at least three practice PAR interviews under the supervision of the instructor. The instructor will provide appropriate feedback and guidance.

c. Personal review by qualified instructor.

2. Initial certification during course of study.

For those individuals unable to attend the initial PAR training sessions conducted at Bowman Gray School of Medicine in August 1995, and those who join the study team while the study is occurring, opportunities at individual

Clinical Centers will be provided for PAR interviewer certification. There are four stages to this decentralized approach to certification:

a. A personal review of ACT PAR audio tape containing sample 7-day PAR interviews.

b. Attendance in a four hour training session led by a qualified individual experienced in PAR administration. This session will include practice sessions in which the interviewer has the opportunity for administering at least three practice PAR interviews under the supervision of the instructor. The instructor will provide appropriate feedback and guidance.

c. Opportunity to view ACT PAR video tape containing initial PAR training sessions conducted at Bowman Gray School of Medicine in August 1995.

d. Personal review by qualified instructor via telephone. In this last stage of certification, a telephone appointment will be made with Laura Becker at the Dallas Clinical Center. During the phone call, the interviewer will conduct two standardized practice physical activity interviews under supervision. Feedback will be provided and, upon completion, the interviewer will be certified.

3. Recertification and monitoring.

To minimize "interviewer drift", all certified PAR interviewers will be monitored for quality control. At six month intervals, each Clinical Center will be visited by Laura Becker or equivalent for observation and monitoring of PAR interviews. Each interviewer will be observed on three separate interviews and provided feedback where necessary. Scheduling of recertification and monitoring visits will occur on a site-by-site basis. Upon successful completion of the visit, feedback will be provided and the interviewer will be recertified.

Activity Counseling Trial

7-day Physical Activity Assessment Appendix

Sample 7-day Physical Activity Recall Script

Sample Instructor's Training Outline

Interviewer Certification and Evaluation form

Interview Form

Worksheet

Ainsworth, et al. Compendium of Physical Activities: classification of energy costs of human physical activities. Medicine and Science in Sports Exercise 1993;25:71-80.

Activity Counseling Trial

7 Day Physical Activity Recall Questionnaire
Interviewer Script

Note to the interviewer: This script is provided to help in the administration of the 7 Day Physical Activity Recall for the Activity Counseling Trial (ACT). While you do not need to memorize this script word for word, you should become familiar with it to closely follow along. For the most part, this script only contains what you should say to the participant. Instructions in coding the information and recording it on the 7 Day Recall form are included in the Manual of Operations (MOP). Interviewer Tips and Probing Tips are included at the end of this script.

Instructions in parentheses ( ) are for the interviewer and are not part of the script to the participant.

(Complete participant information in the shaded area on each page and label worksheet with days of the week from yesterday to one week ago, prior to starting the interview.)

(Page 1)

"Hi, (Participant's name)_____. We're going to do a 7 day physical activity recall together. We'll go over the last seven days and what you actually did during those days."

"There are three intensity levels that we want to talk about. The first one is ***moderate*** intensity physical activity. Here are some examples of ***moderate*** intensity activities (show laminated card). These would all be about the same intensity as going on a brisk walk."

"The next level is ***hard*** intensity activity, and here are some examples of ***hard*** intensity activities (show laminated card). This would be activity that's a little harder than going on a brisk walk, but not quite as hard as running."

"The last intensity level is ***very hard*** intensity activity. Here are some examples of ***very hard*** intensity activities (show laminated card). These would all be about the same intensity as running."

"Remember, these are just examples, so some of the activities you do that are ***moderate***, ***hard***, or ***very hard*** may not be listed on these cards. If you have any questions about how to rate an activity just ask me. A lot of the activities you do are considered ***light*** intensity activities, which are less than ***moderate*** intensity activities, so you won't have to report those activities."

"We're also going to break the day up into 3 general time segments. Morning is usually considered from the time you get out of bed until the time you have lunch. Afternoon is the time after lunch, but before dinner, and evening is the time from dinner until the time you get in the bed. Remember, these are just general guidelines that work for most people."

"Let's start first with some questions about work."

"Were you employed in the last seven days? This includes paid work and volunteer work."

"How many days of the last seven did you work?"

"How many total hours did you work in the last seven days?"

"What days of the week do you consider to be your weekend or non-work days? For most people this would be Saturday and Sunday but it may be different for you."

(If work days + non-work days do not total 7) "What was the reason why you worked less days this past week?"

"For the past seven days, and thinking only about activities that are ***at least moderate*** intensity (point to cards). How many days did you do activity or exercise that added up to at least 30 minutes each day?"

(Page 2)

"Let's talk now about your sleeping habits over the last seven days. On those weeknights did you get in bed and get out of bed at the same time or did it vary?" (Remember for recording purposes, weeknights are the nights before a weekday. Example: if weekdays are Monday - Friday, the weeknights are Sunday - Thursday.)

> Participant says "About the same every night." "OK, what time was it that you got in the bed? What time did you get out of the bed? Did you have any unusual weekdays when you got in bed or out of bed earlier or later? Let's go back to (most recent weekend night). What time did you get in bed on (most recent weekend night) night? What time did you get out of bed on (weekend morning) ? How about on (next recent weekend night) ? What time did you get in bed? What time did you get out of bed on (morning of next weekend night) ?"
>
> Participant says "They vary." "OK, let's think back on last night getting up this morning. What time did you get in the bed last night? What time did you get out of the bed this morning? Let's think back on (night before last) what time was it that you got in the bed? What time did you get out of the bed (yesterday) morning? Repeat by going backwards through the last 7 nights."

"Did you take any naps or lay down for any period of time during the last 7 days?"

"Now we're going to talk about your ***moderate*** (point to card) , ***hard*** (point to card) , and ***very hard*** (point to card) activities for the last week."

"Let's think back on yesterday, which was (yesterday). On yesterday morning, from the time you got out of the bed until the time you had lunch, did you do anything you would consider ***moderate, hard*** or ***very hard***?"

"How about yesterday afternoon, from the time you had lunch until the time you had dinner?"

"What about last evening, from the time you had dinner until the time you got in the bed. Anything ***moderate, hard,*** or ***very hard***?"

(Continue working backward for each day of the week, making sure you prompt them often as to the day of the week and the segment of the day being discussed).

"Are there any activities you did during the last week that might be ***moderate, hard,*** or ***very hard*** that we've not already talked about?"

(Page 3)

"Was this a typical week in terms of your usual pattern of activity or exercise?"

(If "No") "Were you more or less active in the past week than you usually are?"

"Up to now, we've just been talking about the last 7 days. Now, I'd like you to think about your usual activities over the last three months."

"During your work week, on average, how many hours per day do you spend sitting quietly? That would be like if you sit to watch TV, work at a desk or computer, eat or read."

"During your weekend, on average, how many hours per day do you spend sitting quietly?"

"How many flights of stairs do you climb up each day? A flight is 10 steps."

"If you had to add together the total minutes you spend walking during the day, how many minutes would that be? Remember, add up your actual walking time and don't add in the time

spent just standing. Include your to and from walking and any fitness walking. Don't try to remember every step, just give a general idea of the time spent walking."

"What is your usual pace of walking? Is it casual or strolling, average or normal, fairly brisk, or brisk or striding?"

"Do you regularly do strength and flexibility exercises like sit-ups, pushups, yoga or stretching?"

"How many days per week do you do these exercises?"

"On the days that you do strength and flexibility exercises, how many minutes do you spend doing them?"

"That's the end of this questionnaire, (participant name) ." (Explain to participant what they will be doing next in the clinic visit).

Interviewer Tips:

- Participant says this wasn't a typical week, doesn't want to do recall on past week, or says information won't be valid. Tell participant there will be a question at the end of the questionnaire where we can note that it wasn't a typical week.
- If participant isn't putting effort into the recall, take a different approach. Think back on (next day of the week) what did you get up and do on (next day of the week)? When the participant starts to put more effort into the recall, switch back to asking about anything ***moderate***, ***hard*** or ***very hard*** during each segment of the day.
- Always get the participant to compare their activity to walking, running, or in between walking and running.
- If the participant asks how an activity is classified, get as much information about the activity as possible and then tell them how it is usually classified.
- Assure the participant that it is all right to change answers or add forgotten items to the recall.

- Some participants will be ashamed or embarrassed of low activity levels. Assure them that different people have different activity levels.
- Some participants will apologize profusely if the interviewer has to erase or change an answer that has been given. Tell them that's why we do the interview in pencil and it's more important to get it right.
- Use cues that the participant may have provided during the interview to prompt their memories. If the participant just can't remember, go to the next time segment and at the end of the recall ask again about the missing time segment.
- Put zeros on the worksheet to indicate that no moderate, hard, or very hard activity was performed.
- Use Probing Tips to get complete information on an activity, its intensity, and duration.

Probing Tips:

- Get as much detail about an activity, its duration and its intensity as possible without exhausting the participant or getting bogged down.
- When a participant reports an activity, ask if they consider it ***moderate***, ***hard***, or ***very hard***.
- Remember to liken ***moderate*** activity to going on a brisk walk. ***Hard*** activity is more than a brisk walk but not quite running. ***Very hard*** activity is the same intensity as running.
- Use the laminated cards to help classify activities.
- Ask "How long did you spend in that activity?", "Did you take any breaks?", "Were you working at the same intensity level for the whole time?". Try and determine as closely as possible the actual time spent in an activity.
- If you're unsure of what comprises an activity (i.e., yardwork). Ask the participant to tell you the details of the activity. Determine which activities are ***moderate***, ***hard***, or ***very hard*** and record individual times in correct intensity categories.
- If you are unsure about how to classify an activity, refer to the Compendium of Physical Activities by Ainsworth, et al. (Manual of Operations). If you need further help, call Laura Becker in Dallas at (214) 701-8001.

- The participant might report that this was a typical week for their pattern of activity. If the recall reflects some unusual activity (i.e., moving an office, cleaning the garage), ask the participant if they normally do _(unusual activity)_ or something equal to that activity every week. If they answer 'no', then the past week was not a typical week. If they say 'yes' then the past seven days were typical.
- Make sure that the participant is including all their waking time to calculate sitting time. For their work week, ask them if the answer they give includes time sitting before work and after work.
- Look for facial clues for signs of boredom, confusion, misunderstanding and adjust the interview accordingly.
- Listen attentively, things the interviewer hears at the first of the recall can be used to aid in the activity recall.
- Control the interview. It needs to be long enough to get the correct information, but not so long that time is wasted in meaningless conversation or useless details.
- Don't try to hide the recall form from the participant, but adopt a casual manner where the participant does not see the completed worksheet.
- Use a calendar to help the participant keep the days straight. If they have brought their own calendar they can use it to help them. Don't openly encourage participants to bring their calendars prior to a 7 day recall.

General techniques for interviewing

Presented below are general interviewing techniques. Specific issues regarding the 7-day PAR interview and solutions to a variety of problems are offered at the end of the Interviewer Script found in this manual.

I. HOW TO GET SATISFACTORY ANSWERS

A. ***Learn the Purpose of Each Question.*** In order to do a good job of interviewing, you need to understand the kind of information we are trying to get through each particular questions. Unless you understand its purpose, you will not be able to judge when response is adequate and when you must probe for clarification or for additional information.

B. ***Don't Attempt to Interpret/Explain the Question - Maintain Neutrality.*** If a participant does not seem to understand a question, repeat the question slowly and clearly. Give the participant time to think about the question (while simultaneously being aware of time allowed for administering the questionnaire). Unless you have other instructions about handling specific questions, the acceptable reply for a participant who wants to know what a question means is "whatever it means to you". Do not attempt to explain the purpose of a question unless the interviewer instructions specifically authorize you to do so.

C. ***Don't Leave a Question Until You Have an Adequate Answer or Have Determined That a Participant Can't Give a Clearer Answer.***

II. PROBING TECHNIQUES

The two most effective neutral probes are silence and repeating the original question.

A. ***Silence.*** The value of silence cannot be overestimated. Many people, including interviewers, react to silence as a vacuum that must be filled with constant chatter. The interviewer who can wait quietly and patiently will soon find that 15 seconds of silence is more that most participants can take, and the participant will often expand or clarify a previously inadequate answer.

B. ***Repeat the Question or Answer Categories.*** Be sure to repeat the question as stated in the questionnaire. This is particularly useful when the participant answers a question irrelevantly. In some cases it will be necessary to remind the participant of your frame of reference, I.E. to acknowledge what the participant has said and then bring the participant back to the topic by repeating the question.

C. ***Do not Accept a "Don't Know" Answer Without Probing at Least Once.*** If a response is a "don't know", probe by asking: "Well, what do you think?" or "I'd like to know your opinion" (if the question asks for an opinion rather than facts). If the question deals with facts, we prefer an approximation to no answer at all, and you might probe "what's your best guess?" or "approximately?" to convey the idea that 100% accuracy is not required.

D. ***Use Neutral Probes That Do Not Suggest Answers.*** Probes are needed to obtain more complete, accurate answers. All probes must be non-directive, i.e., the probe must not suggest any particular answer to the participant. Probes should be used whenever the participant is hesitant in answering questions; when he/she seems to have trouble expressing him/herself; when he/she seems too shy to speak at length; whenever there is any reason for the interviewer to believe that the participant has not given a complete report of his/her thoughts; and finally, reassuring probes are needed when a participant seems to lack confidence.

E. ***Examples of Other Neutral Probes***:

1. In what way?
2. What is that? Why do you feel that way?
3. How do you mean?
4. I would like your impression.
5. I would like you opinion.
6. What do you think?
7. Can you give me an example? or For example?
8. Can you explain that in a little more detail?
9. How are you using the term...?
10. How is that? or How does that work?

11. Anything at all - even little things?
12. If you had to choose, which would you say?
13. What else can you tell me about that?
14. In general, overall...

1. Generally Speaking, Some Probes are Avoided in Favor of others.
   a. Instead of "anything else?" you'll find that "what else can you tell me about that?" is more likely to elicit answers.
   b. Instead of "why?" you'll find "why do you feel that way?" or I'd be interested in your reasons" accomplishes the same purpose and is less likely to be threatening.
2. Questions Used in Ordinary Conversation Should be Avoided Because They Suggest Answers
   a. Refrain from asking "do you mean A or B". This suggests two possible answers and there may be others which may occur to the participant.

F. ***Do Not Leave a Probe Dangling.*** Always record the response to a probe even if it's only "no" or "That's all I can think of".

G. ***Always Cross Reference.*** When you probe to clarify a response, always indicate which response you are clarifying. There will be times when a participant will say something ambiguous and continue talking.
   1. If there's not enough space to record the respondent's answer, use the margin. Be sure to label these continuations clearly when you edit each completed interview.
   2. Don't ask "do you mean..." People tend to say "yes" to any suggestion either because it's easy or because they think it's the right answer.

Activity Counseling Trial

Seven-Day Physical Activity Recall Training
Instructor's Outline

I. Introduction to Seven-Day PAR Training

A. Purpose

1. To get an estimate of an individual's energy expenditure (including strength & flexibility activities) for previous week.
2. Not singling out aerobic activities, looking at activities performed at various levels of energy expenditure.
3. Most people spend majority of time doing light activity
   a) Exception: Stocking shelves at work (moderate)
4. History of PAR

II. Interviewer Preparation Guidelines

A. Explain following items before beginning interview:

1. Recall of actual activities for past week, not a history

B. Not interested in light activities

1. Have to be same intensity as walking or harder
2. Very light (sitting) is estimated separately.

C. Categorization of activity

1. ***Moderate*** - similar to how you feel when you're walking briskly
2. ***Very Hard*** - similar to how you feel when you're running
3. ***Hard*** - falls in between

III. Interview Protocol and Guidelines

A. Establishing days for recall

1. Start with yesterday and work backwards *(see manual)*
2. Label worksheet with days of the week

B. Sleep

1. Start with yesterday and work backwards *(see manual)*

a) Want an estimate of individual's hours in bed, not necessarily asleep

b) Write total hours at top in that day's column - easier to wait until later to add up totals

c) Prompt: ask if they have a regular time that they go to bed and get up, especially if they are having trouble remembering - also ask what they did that night to help them remember

C. Activity

1. Start with yesterday and work backwards *(see manual)*

D. Other Activity Questions

E. Summarization and Data Entry

F. Sample Certification Audio Tape and Review

G. Certification

Activity Counseling Trial

Seven-Day Physical Activity Recall Training
Interviewer Certification and Evaluation Form

Interviewer:_____ Reviewer:_____ Date:_____

	Interviewer Techniques	Yes	Comments
1.	Asks questions about work schedule.	___	
2.	Defines 'sleep' correctly.	___	
3.	Reviews sleep habits, beginning with previous night.	___	
4.	Queries about naps.	___	
5.	Explains intensity guidelines. Walk=mod Jog=very hard.	___	
6.	Explains that stop-and-go walking is not included if intensity is not at least moderate.	___	
7.	Asks in general what participant was doing each day using context cues for better recall.	___	
8.	Asks about activities that may have been forgotten for each day.	___	
9.	Asks which days are considered weekends.	___	
10.	Asks separately about morning, afternoon, and evening activities.	___	
11.	Prompts participant to define intensity level by referring to intensity guidelines.	___	
12.	Makes clear the length of activities.	___	
13.	Prompts for any 'breaks' taken.	___	
14.	Appropriately used rule of recording 10 min. at one intensity in one segment of the day (Did not require continuous activities for scoring).	___	
15.	Asks about any activities for the week	___	

that may have been forgotten

Scoring

1. Put times in correct places on worksheet. ___
2. Marks weekend days. ___
3. Uses correct arithmetic. ___
4. Compare scoring of interviewer and reviewer. ___

Provide additional comments below. Note reasons for discrepancies between interviewer and reviewer.

Strengths:

Needs Improvement:

Activity Counseling Trial
Interview Evaluation Form

Comments on the Worksheet:_____

Interviewer assessment:

Were there any problems with the 7-Day PAR interview? (circle one)

1. Yes
0. No

Explain: _____

_____

_____

_____

_____

Do you think this was a valid 7-Day PAR interview?

1. Yes
2. Maybe
0. No

Please list below any activities reported by the participant which you don't know how to classify.

_____

_____

_____

ACT Physical Activity Recall

ID ☐☐☐☐☐☐ Acrostic ☐☐☐☐☐☐

Date Completed ☐☐☐☐☐☐ (Mon Day Year) Visit Code ☐☐☐

Day of the week form completed : _____

1. Were you employed in the last seven days? 1☐ Yes 2☐ No

2. How many days of the last seven did you work? ☐ (round to nearest day)

3. How many total hours did you work in the last seven days? ☐☐ hours

4. What days of the week do you consider to be your weekend or non-work days? For most people this would be Saturday and Sunday but it may be different for you.

   1☐ Sunday 2☐ Monday 3☐ Tuesday 4☐ Wednesday 5☐ Thursday 6☐ Friday 7☐ Saturday

5. If you did not work your usual week, why did you work less than usual?

   _____

   _____

6. For the past seven days, and thinking only about activities that are ***at least*** of moderate intensity, how many days did you do activity or exercise that added up to at least 30 minutes each day?

   ☐ number of days (0 to 7)

Acrostic ☐☐☐☐☐☐

	Days of the Week	Yesterday HRS MIN		One Week Ago HRS MIN				
	Sleep	:	:	:	:	:	:	:
MORNING	Moderate	:	:	:	:	:	:	:
MORNING	Hard	:	:	:	:	:	:	:
MORNING	Very Hard	:	:	:	:	:	:	:
AFTER NOON	Moderate	:	:	:	:	:	:	:
AFTER NOON	Hard	:	:	:	:	:	:	:
AFTER NOON	Very Hard	:	:	:	:	:	:	:
EVENING	Moderate	:	:	:	:	:	:	:
EVENING	Hard	:	:	:	:	:	:	:
EVENING	Very Hard	:	:	:	:	:	:	:

Calculated Energy Expenditure ☐☐.☐ Kcal/kg/day

Acrostic ☐☐☐☐☐☐

7. Was this a typical week in terms of your usual pattern of activity or exercise?

1☐ Yes

2☐ No —— Were you more or less active in the past week than you usually are? 1☐ More 2☐ Less

Until now, we've just been talking about the last seven days. Now I would like you to think about your usual activities over the last three months.

8. During your work week, on average how many hours per day do you spend sitting quietly (e.g., watching TV, working at a desk or computer, eating, or reading)? ☐☐ average hours per day

During your weekend, on average how many hours per day do you spend sitting quietly (e.g., watching TV, working at a desk or computer, eating, or reading)? ☐☐ average hours per day

9. How many flights of stairs do you climb up each day? (1 flight = 10 steps) ☐☐ number of flights

10. If you had to add together the total minutes you spend walking during the day, how many minutes would that be? Remember, add up your actual walking time and don't add in the time spent just standing. Include your to and from walking and any fitness walking. Don't try to remember every step, just give a general idea of the time spent walking. ☐☐☐ total minutes per day.

11. What is your usual pace of walking? Mark **ONE** only.

1☐ Casual or strolling (less than 2 miles per hour)

2☐ Average or normal (2 to 3 miles per hour)

3☐ Fairly brisk (3 to 4 miles per hour)

4☐ Brisk or striding (4 miles per hour or faster)

12. Do you regularly do strength and flexibility exercises like sit-ups, push-ups, yoga, or stretching?

1☐ Yes —— How many days per week do you do these exercises? ☐ number of days (0-7)

2☐ No

13. On the days that you do strength and flexibility exercises, how many minutes do you spend doing them? ☐☐☐ total minutes

Form completed by ☐☐ (staff code)

Compendium of Physical Activities: classification of energy costs of human physical activities

BARBARA E. AINSWORTH, WILLIAM L. HASKELL, ARTHUR S. LEON, DAVID R. JACOBS, JR., HENRY J. MONTOYE, JAMES F. SALLIS, and RALPH S. PAFFENBARGER, JR.

Division of Epidemiology, School of Public Health (B.E.A., D.R.J., A.S.L.) and Division of Kinesiology, School of Kinesiology and Leisure Sciences (B.E.A., A.S.L.), University of Minnesota, Minneapolis, MN 55455; Stanford Center for Research in Disease Prevention, Stanford, CA 94305 (W.L.H.); Biodynamics Laboratory, Department of Physical Education, University of Wisconsin-Madison, Madison WI 53706 (H.J.M.); Child and Family Development Health Studies, Department of Pediatrics, University of California-San Diego, La Jolla, CA 92093 (J.F.S.); and School of Medicine, Stanford University, Stanford, CA 94305 (R.S.P.)

ABSTRACT

AINSWORTH, B. E., W. L. HASKELL, A. S. LEON, D. R. JACOBS, JR., H. J. MONTOYE, J. F. SALLIS, and R. S. PAFFENBARGER, JR. Compendium of Physical Activities: classification of energy costs of human physical activities. *Med. Sci. Sports Exerc.*, Vol. 25, No. 1, pp. 71–80, 1993. A coding scheme is presented for classifying physical activity by rate of energy expenditure, i.e., by intensity. Energy cost was established by a review of published and unpublished data. This coding scheme employs five digits that classify activity by purpose (i.e., sports, occupation, self-care), the specific type of activity, and its intensity as the ratio of work metabolic rate to resting metabolic rate (METs). Energy expenditure in kilocalories or kilocalories per kilogram body weight can be estimated for all activities, specific activities, or activity types. General use of this coding system would enhance the comparability of results across studies using self reports of physical activity.

EXERCISE, EXERTION, PHYSICAL ACTIVITY

The proliferation of self-report measures of physical activity reflects growing interest in the study of physical activity and its relation to various health outcomes. A common problem faced by researchers is the coding of physical activities by type and by intensity. Each researcher has devised a coding system to fit his or her purposes. While there are similarities across published systems, there are also differences that limit the comparability of results across studies and add confusion to the field. The availability of a comprehensive list of physical activities coded with a standardized system that is flexible enough to meet multiple needs of physical activity researchers would facilitate research in this area.

This Compendium of Physical Activities has been developed to facilitate the coding of physical activities and to promote comparability of coding across studies. The Compendium is designed to be useful for investigators who collect data on physical activity by diary, recall, or direct observation methods. The physical activity data may be used to describe activity patterns of populations, to study determinants of physical activity, or to investigate the relations between physical activity, health and disease. Because each activity can be coded by function, specific type, and intensity, the same compendium can be used for many different purposes and in both clinical and epidemiologic studies.

0195-9131/93/2501-0071$3.00/0
MEDICINE AND SCIENCE IN SPORTS AND EXERCISE

Submitted for publication September 1992.
Accepted for publication September 1992.

The intensity or energy cost values were derived from the best available published and unpublished data. Most sources have been used extensively by investigators in the past, but this Compendium has integrated these sources and offers a single coding system that can serve as a common source for subsequent research.

CODING SCHEME

This activity classification system was a product of a multicenter Request For Applications from the Epidemiology section of the National Heart, Lung, and Blood Institute (NHLBI) for the purpose of validating physical activity measurement techniques. It provides a comprehensive system for coding physical data on physical activity by purpose and energy cost. The energy cost of specific activities listed in this Compendium were obtained primarily from the following previously published physical activity energy expenditure lists: Tecumseh Occupational Questionnaire (13,14), Minnesota Leisure Time Physical Activity Questionnaire (LTPA) (5,10), McArdle, Katch, and Katch's physical activity list (7,9), the 7-Day Recall Physical Activity Questionnaire (2), and the American Health Foundation's physical activity list (8). Activities from the LTPA were identified by a T followed by a number (e.g., T115). By retaining the LTPA designator codes, the new list may be used to score the LTPA with its original physical activity intensity codes.

As would be expected, there was considerable overlap in energy expenditure values among the supplied lists. For example, the Minnesota LTPA, which was developed from the Tecumseh Leisure Time Questionnaire, identifies similar activities; while the list of activities from the 7-Day Physical Activity Recall questionnaire is nearly identical to that of McArdle, Katch, and Katch (9). In general, the majority of the energy expenditure lists were generated from Passmore and Durnin (11); while McArdle, Katch, and Katch (9) also used data derived from Bannister and Brown (1) and Howley and Glover (6).

The intensity assigned to activities in this publication were determined by selecting a mean energy expenditure value from the eight sources mentioned previously. The representative intensity levels were determined by consensus of the authors.

Organization

The Compendium of Physical Activities is organized to maximize flexibility in coding, data entry, and interpretation of energy cost for each class and type of activity.

Activity coding. The coding scheme for the Compendium of Activities employs a five-digit code in order to categorize activities by their major heading (first two digits on the left), specific activity (last three digits on the right), and intensity (3-digit column). The coding scheme is organized in the following way:

	00 major headings	000 specific activity	00.0 intensity
For example:	01 bicycling	009 bmx	08.5 METs

Major headings. The Compendium is organized by activity types or purpose and includes activities of daily living or self care, leisure and recreation, occupation, and rest (Table 1). The major headings explain the reason a person is engaging in a specific activity and is useful in categorizing activity types.

Identification of the proper major heading is the initial step in classifying an activity. However, it is possible that there may be more than one reason for performing an activity; thus, a specific activity may be listed under more than one major heading. For example, an individual may sit and read a book for pleasure in one situation and at another time read a document as a job requirement. These may be classified under the major headings of rest or inactivity and occupation depending on their purpose. Assumptions made for the placement of activities into major headings are listed in Appendix 2.

Specific activities. The specific activity descriptions range from a general classification of an activity (e.g., tennis, general) to a detailed description that includes the form and intensity of the activity (e.g., tennis, singles, vigorous effort) depending on the information gathered by the survey method. Activities without a specified intensity are classified as "general." More detailed descriptions of activities are preferred since an appropriate intensity can be assigned. Guidelines for coding specific activities within major headings are listed in Appendix 3.

Intensity of activities. All activities are assigned an intensity unit based on their rate of energy expenditure expressed as METs. The intensity of activities in the Compendium are classified as multiples of one MET or the ratio of the associated metabolic rate for the specific activity divided by the resting metabolic rate (RMR). For example, a 2-MET activity requires two times the metabolic energy expenditure of sitting quietly. One MET is also defined as the energy expenditure for sitting quietly, which for the average adult is approximately 3.5 ml of oxygen·kg body weight^{-1}·min^{-1} or 1 kcal·kg^{-1} body weight·h^{-1}.

A MET value was assigned to each activity in the Compendium and was based on the "best representa-

TABLE 1. Major types of activities

Bicycling	Lawn and garden	Sports
Conditioning exercises	Miscellaneous	Transportation
Dancing	Music playing	Walking
Fishing and hunting	Occupation	Water activities
Home activities	Running	Winter activities
Home repair	Self-Care	
Inactivity	Sexual activity	

tion" from published lists and selected unpublished data as was previously mentioned. For activities not in the original lists, intensity was obtained from published literature, if possible, and assigned a MET value or estimated from similar known activities (3,4,11,16).

Only data for adults were included in this Compendium. When children's games are listed in the Compendium, the intensity level is for adults participating in children's activities. Further, the Compendium is not intended to be used for adults with major neuromuscular handicaps or other conditions that would significantly alter their mechanical or metabolic efficiency.

Calculation of Energy Cost

Energy expenditure values can be expressed in kcal·kg^{-1} body weight·h^{-1}, kcal·min^{-1}, kcal·h^{-1}, or kcal·24 h^{-1}. The most accurate way to determine the kilocalorie energy cost of an activity is to measure the kcal expended during rest (i.e., the RMR) and multiply that value by the MET values listed in the Compendium. Because RMR is fairly close to 1 kcal·kg body weight^{-1}·h^{-1}, the energy cost of activities may be expressed as multiples of the RMR (15). By multiplying the body weight in kg by the MET value and duration of activity, it is possible to estimate a kcal energy expenditure that is specific to a person's body weight. For example, bicycling at a 4 MET value expends 4 kcal·kg^{-1} body weight·h−1. A 60-kg individual bicycling for 40 min expends the following: (4 METs × 60 kg body weight) × (40 min/60 min) = 160 kcal. Dividing 160 kcal by 40 min equals 4 kcal·min^{-1}. Using the same formula for an 80-kg person would yield an energy expenditure of 213 kcal or 5.3 kcal·min^{-1}. However, it is important to note that to the extent the RMR is not equal to 1 kcal·kg body weight^{-1}·h^{-1} for individuals, then estimates of energy expenditure that include weight will more closely reflect body weight than the metabolic rate (2).

Use of the Compendium for PA Records or Diaries

For records or diaries the data collection forms should be organized in a way to identify each activity's major heading, classify the intensity level, and the record the duration to ensure accurate data entry. Figure 1 shows an example of a section of a data collection form that may be used for this purpose.

It is important the participant complete all questions except the space labeled "for clinic use only." The clinic staff will use this space to record the activity code or MET value for data analysis. The space labeled "reason for activity" is to help the coder decide under which major heading to place the activity. The intensity rating is designed to help the coder in assigning the appropriate MET value. Intensity terms of light, moderate, heavy or vigorous, and very heavy or very vigorous should be used in classifying intensity. In the case of walking, the corresponding intensity terms are very slow, slow, moderate, brisk, and very brisk. If a coder does not plan to use the five digit code for data analysis, a space can be provided on the questionnaire to record the MET values to calculate kcal scores.

	Type of Activity	Reason for Activity	Subjective Intensity Level	Duration Hours:Min	Code or MET level (for clinic use only
1.					
2.					
3.					

Figure 1—Example of a section of recording form that asks participants to list the types of physical activities performed, reasons for engaging in the activities, a rating of the participants' impression of the intensity level (light, moderate, vigorous, very vigorous), and the duration of the activities in hours and minutes.

Discussion and Limitations

The Compendium of Activities is a classification system that groups physical activities by purpose and provides flexibility in determining energy cost. However, there are several factors that may limit the use of the Compendium for determining the *precise* energy cost of PA. The activity classification system was primarily based on previously published data and as such may not reflect the exact energy cost of all physical activities. Since often the values are merely averages, they do not take into account that some people perform activities more vigorously than others. In addition, the MET values of some activities were not derived from actual measurements of oxygen consumption; instead they were estimated from the energy cost of activities having similar movement patterns. Therefore, the estimates may have ill-defined confidence limits around the mean MET values. For activities in which the parameters are undefined, individual differences in energy expenditure can be large and the true energy cost for a person may or may not be close to the stated mean. This does not reduce the value of the standard intensity codes, but it is an important perspective from which to view the Compendium. Calculation of kcal energy expenditure from body weight and MET values may also affect the energy cost of activities. Therefore, use of the kcal scores in correlation analyses should be used with caution since coefficients may reflect body weight rather than the actual energy cost of activities. Expression of energy expenditure scores as kcal·kg^{-1} body weight·h^{-1} or kcal·kg^{-1} body weight·day^{-1} will eliminate this effect. Individual variation in movement patterns and differences in the way activity is reported (i.e., effort, pace, age, and gender differences) may influence the energy cost of activities also. For example, one person may rate his or her walking pace as "brisk" while another classifies the same pace as "slow." The Compendium cannot account for individual differences

in movement efficiency; however, variation in how physical activities are recorded can be reduced by providing instruction to participants on how to classify energy expenditure (i.e., 3 mph is moderate walking), standardizing data recording techniques, and having trained interviewers review the data with participants for clarity before energy costs are calculated.

SUMMARY AND CONCLUSIONS

The Compendium of Physical Activities is a unique coding system that classifies the energy cost of physical activities. Based on previously published data, it groups activities by purpose and intensity expressed as METs. The Compendium is easy to use and provides flexibility in calculating the energy cost of various types of physical activities. Despite its possible limitations, the Compendium of Physical Activities is useful for coding physical activity questionnaires or records used in physical activity research, education, and clinic settings.

We wish to thank M. Carl McNally, Mark Richardson, Terri Hartman, and Yvonne Guptill (University of Minnesota) and Martin Yee (Stanford University) for their contributions in creating and organizing the Compendium of Physical Activities. We offer a special thank you to Carl McNally for writing the SAS data analysis program to score the Compendium of Physical Activities.

This work was supported by grants NHLBI (RFA-86-90-P) to Drs Leon and Jacobs; NHLBI (5-R01-HL-37561) to Dr. Montoye; NHLBI (HL-362-72) to Dr. Haskell; and NHLBI (RFA-86-HL-9-P) to Dr. Sallis.

Dr. Barbara Ainsworth was a post-doctoral associate in the Division of Epidemiology, School of Public Health, University of Minnesota at the time of this project. Dr. Ainsworth is currently with the Applied Physiology Laboratory, Department of Physical Education, Exercise and Sport Science, University of North Carolina at Chapel Hill.

Address for correspondence: Dr. Ainsworth, Department of Physical Education, Exercise, & Sport Science, CB #8700, Fetzer Gym, University of North Carolina at Chapel Hill, Chapel Hill, NC 27599-8700

REFERENCES

1. BANNISTER, E. W. and S. R. BROWN. The relative energy requirements of physical activity. In: *Exercise Physiology*, H. B. Falls (Ed.). New York: Academic Press, 1968.
2. BLAIR, S. N., W. L. HASKELL, P. HO, et al. Assessment of habitual physical activity by a 7-day recall in a community survey and controlled experiment. *Am. J. Epidemiol* 122:794–804, 1985.
3. BURKE, E. J., J. A. AUCHINACHIE, R. HAYDEN, and J. M. LOFTIN. Energy cost of wheelchair basketball. *Physician Sportsmed.* 13:99–105.
4. FISHER, S. V. and R. P. PATTERSON. Energy cost of ambulation with crutches. *Arch Phys Med Rehabil.* 62:250–256, 1981.
5. FOLSOM, A. R., C. J. CASPERSEN, H. L. TAYLOR, et al. Leisure time physical activity and its relationship to coronary risk factors in a population-based sample: the Minnesota Heart Survey. *Am. J Epidemiol* 121:570–579, 1985.
6. HOWLEY, E. T. and M. E. GLOVER. The caloric costs of running and walking one mile for men and women. *Med. Sci. Sports Exerc.* 6:235, 1974.
7. KATCH, F. I. and W. D. MCARDLE. *Nutrition, Weight Control, and Exercise*, 3rd Ed. Philadelphia: Lea & Febiger, 1988.
8. LEON, A. S. Approximate energy expenditures and fitness values of sports and recreational and household activities. In: *The Book of Health Physical Fitness*, Chap. 5, E. L. Wynder (Ed.). 1981, pp. 283–341.
9. MCARDLE, W. D., F. I. KATCH, and V. L. KATCH. *Exercise Physiology: Energy, Nutrition, and Human Performance*, 2nd Ed. Philadelphia: Lea & Febiger, 1988, pp. 642–649.
10. MINNESOTA LEISURE TIME PHYSICAL ACTIVITY QUESTIONNAIRE MANUAL. Division of Epidemiology, School of Public Health, University of Minnesota, Minneapolis, MN 55455.
11. O'CONNELL, E. R., P. C. THOMAS, L. D. CADY, et al. Energy costs of simulated stair climbing as a job-related task in fire fighting. *J. Occup. Med.* 28:282–284, 1986.
12. PASSMORE, R. and J. V. G. A. DURNIN. Human energy expenditure. *Physiol. Rev.* 35:801–840, 1955.
13. REIFF, G. G., H. J. MONTOYE, R. D. REMINGTON, J. A. NAPIER, H. L. METZNER, and H. H. EPSTEIN. Assessment of physical activity by questionnaire and interview. In: *Physical Activity and the Heart*, M. J. Karvonen and A. J. Barry (Eds.). Springfield, IL: Charles C Thomas, 1967, pp. 336–371.
14. REIFF, G. G., H. J. MONTOYE, R. D. REMINGTON, J. A. NAPIER, H. L. METZNER, and F. H. EPSTEIN. Assessment of physical activity by questionnaire and interview. *J. Sports Med. Phys Fitness* 7:1–32, 1967.
15. TAYLOR, H., D. R. JACOBS JR., B. SHUCKER, J. KNUDSEN, A. S. LEON, and G. DEBACKER. A questionnaire for the assessment of leisure time physical activities. *J. Chronic Dis.* 31:741,755, 1978.
16. TOWN, G. P., N. SOL, and W. E. SINNING. The effect of rope skipping rate on energy expenditure of males and females. *Med Sci. Sport Exerc.* 12:295–298, 1980.

APPENDIX 1. Compendium of Physical Activities.

01009	8.5	Bicycling,	Bicycling, BMX or mountain
01010	4.0	Bicycling,	Bicycling, <10 mph, general, leisure, to work or for pleasure (T115)
01020	6.0	Bicycling,	Bicycling, 10–11.9 mph, leisure, slow, light effort
01030	8.0	Bicycling,	Bicycling, 12–13.9 mph, leisure, moderate effort
01040	10.0	Bicycling,	Bicycling, 14–15.9 mph, racing or leisure, fast, vigorous effort
01050	12.0	Bicycling,	Bicycling, 16–19 mph, racing/not drafting or >19 mph drafting, very fast, racing general
01060	16.0	Bicycling,	Bicycling, >20 mph, racing, not drafting
01070	5.0	Bicycling,	Unicycling
02010	5.0	Conditioning exercise,	Bicycling, stationary, general
02011	3.0	Conditioning exercise,	Bicycling, stationary, 50 W, very light effort
02012	5.5	Conditioning exercise,	Bicycling, stationary, 100 W, light effort
02013	7.0	Conditioning exercise,	Bicycling, stationary, 150 W, moderate effort
02014	10.5	Conditioning exercise,	Bicycling, stationary, 200 W, vigorous effort
02015	12.5	Conditioning exercise,	Bicycling, stationary, 250 W, very vigorous effort
02020	8.0	Conditioning exercise,	Calisthenics (e.g., pushups, pullups, situps), heavy, vigorous effort
02030	4.5	Conditioning exercise,	Calisthenics, home exercise, light or moderate effort, general (T 150) (example: back exercises), going up & down from floor
02040	8.0	Conditioning exercise,	Circuit training, general
02050	6.0	Conditioning exercise,	Weight lifting (free weight, nautilus or universal-type), power lifting or body building, vigorous effort (T 210)

APPENDIX 1. Continued

02060	5.5	Conditioning exercise.	Health club exercise, general (T 160)
02065	6.0	Conditioning exercise.	Stair-treadmill ergometer, general
02070	9.5	Conditioning exercise.	Rowing, stationary ergometer, general
02071	3.5	Conditioning exercise.	Rowing, stationary, 50 W, light effort
02072	7.0	Conditioning exercise.	Rowing, stationary, 100 W, moderate effort
02073	8.5	Conditioning exercise.	Rowing, stationary, 150 W, vigorous effort
02074	12.0	Conditioning exercise.	Rowing, stationary, 200 W, very vigorous effort
02080	9.5	Conditioning exercise.	Ski machine, general
02090	6.0	Conditioning exercise.	Slimnastics
02100	4.0	Conditioning exercise.	Stretching, hatha yoga
02110	6.0	Conditioning exercise.	Teaching aerobic exercise class
02120	4.0	Conditioning exercise.	Water aerobics, water calisthenics
02130	3.0	Conditioning exercise.	Weight lifting (free, nautilus or universal-type), light or moderate effort, light workout, general
02135	1.0	Conditioning exercise.	Whirlpool, sitting
03010	6.0	Dancing.	Aerobic, ballet or modern, twist
03015	6.0	Dancing	Aerobic, general
03020	5.0	Dancing.	Aerobic, low impact
03021	7.0	Dancing	Aerobic, high impact
03025	4.5	Dancing	General
03030	5.5	Dancing	Ballroom, fast (disco, folk, square) (T 125)
03040	3.0	Dancing	Ballroom, slow (e.g., waltz, foxtrot, slow dancing)
04001	4.0	Fishing and hunting	Fishing, general
04010	4.0	Fishing and hunting.	Digging worms, with shovel
04020	5.0	Fishing and hunting.	Fishing from river bank and walking
04030	2.5	Fishing and hunting.	Fishing from boat, sitting
04040	3.5	Fishing and hunting	Fishing from river bank, standing (T 660)
04050	6.0	Fishing and hunting	Fishing in stream, in waders (T 670)
04060	2.0	Fishing and hunting.	Fishing, ice, sitting
04070	2.5	Fishing and hunting.	Hunting, bow and arrow or crossbow
04080	6.0	Fishing and hunting.	Hunting, deer, elk, large game (T 710)
04090	2.5	Fishing and hunting.	Hunting, duck, wading
04100	5.0	Fishing and hunting.	Hunting, general
04110	6.0	Fishing and hunting.	Hunting, pheasants or grouse (T 680)
04120	5.0	Fishing and hunting.	Hunting, rabbit, squirrel, prairie chick, raccoon, small game (T 690)
04130	2.5	Fishing and hunting.	Pistol shooting or trap shooting, standing
05010	2.5	Home activities.	Carpet sweeping, sweeping floors
05020	4.5	Home activities.	Cleaning, heavy or major (e.g., wash car, wash windows, mop, clean garage), vigorous effort
05030	3.5	Home activities.	Cleaning, house or cabin, general
05040	2.5	Home activities	Cleaning, light (dusting, straightening up, vacuuming, changing linen, carrying out trash), moderate effort
05041	2.3	Home activities	Wash dishes-standing or in general (not broken into stand/walk components)
	2.3	Home activities	Wash dishes; cleaning dishes from table-walking
05050	2.5	Home activities.	Cooking or food preparation-standing or sitting or in general (not broken into stand/walk components)
05051	2.5	Home activities.	Serving food, setting table-implied walking or standing
05052	2.5	Home activities.	Cooking or food preparation-walking
05055	2.5	Home activities.	Putting away groceries (e.g., carrying groceries, shopping without a grocery cart)
05056	8.0	Home activities.	Carrying groceries upstairs
05060	3.5	Home activities.	Food shopping, with grocery cart
05065	2.0	Home activities	Standing-shopping (non-grocery shopping)
05066	2.3	Home activities	Walking-shopping (non-grocery shopping)
05070	2.3	Home activities	Ironing
05080	1.5	Home activities.	Sitting, knitting, sewing, light wrapping (presents)
05090	2.0	Home activities.	Implied standing-laundry, fold or hang clothes, put clothes in washer or dryer, packing suitcase
05095	2.3	Home activities.	Implied walking-putting away clothes, gathering clothes to pack, putting away laundry
05100	2.0	Home activities.	Making bed
05110	5.0	Home activities.	Maple syruping/sugar bushing (including carrying buckets, carrying wood)
05120	6.0	Home activities	Moving furniture, household
05130	5.5	Home activities.	Scrubbing floors, on hands and knees
05140	4.0	Home activities.	Sweeping garage, sidewalk or outside of house
05145	7.0	Home activities.	Moving household items, carrying boxes
05146	3.5	Home activities.	Standing-packing/unpacking boxes, occasional lifting of household items light-moderate effort
05147	3.0	Home activities.	Implied walking-putting away household items-moderate effort
05150	9.0	Home activities.	Move household items upstairs, carrying boxes or furniture
05160	2.5	Home activities.	Standing-light (pump gas, change light bulb, etc.)
05165	3.0	Home activities.	Walking-light, noncleaning (ready to leave, shut/lock doors, close windows, etc.)
05170	2.5	Home activities.	Sitting-playing with child(ren)-light
05171	2.8	Home activities.	Standing-playing with child(ren)-light
05175	4.0	Home activities.	Walk/run-playing with child(ren)-moderate
05180	5.0	Home activities.	Walk/run-playing with child(ren)-vigorous
05185	3.0	Home activities.	Child care: sitting/kneeling-dressing bathing, grooming, feeding, occasional lifting of child-light effort
05186	3.5	Home activities.	Child care: standing-undressing, bathing, grooming, feeding, occasional lifting of child-light effort
06010	3.0	Home repair.	Airplane repair
06020	4.5	Home repair.	Automobile body work
06030	3.0	Home repair.	Automobile repair
06040	3.0	Home repair.	Carpentry, general, workshop (T 620)
06050	6.0	Home repair.	Carpentry, outside house (T 640), installing rain gutters
06060	4.5	Home repair.	Carpentry, finishing or refinishing cabinets or furniture
06070	7.5	Home repair.	Carpentry, sawing hardwood
06080	5.0	Home repair.	Caulking, chinking log cabin
06090	4.5	Home repair.	Caulking, except log cabin
06100	5.0	Home repair.	Cleaning gutters
06110	5.0	Home repair.	Excavating garage
06120	5.0	Home repair.	Hanging storm windows
06130	4.5	Home repair.	Laying or removing carpet
06140	4.5	Home repair.	Laying tile or linoleum
06150	5.0	Home repair.	Painting, outside house (T 650)
06160	4.5	Home repair.	Painting, papering, plastering, scraping, inside house, hanging sheet rock, remodeling (T 630)
06170	3.0	Home repair.	Put on and removal of tarp-sailboat
06180	6.0	Home repair.	Roofing
06190	4.5	Home repair.	Sanding floors with a power sander
06200	4.5	Home repair.	Scrape and paint sailboat or powerboat
06210	5.0	Home repair.	Spreading dirt with a shovel
06220	4.5	Home repair.	Wash and wax hull of sailboat, car, powerboat, airplane
06230	4.5	Home repair.	Washing fence
06240	3.0	Home repair.	Wiring, plumbing
07010	0.9	Inactivity, quiet	Lying quietly, reclining (watch television), lying quietly in bed-awake

APPENDIX 1. Continued

07020	1.0	Inactivity, quiet:	Sitting quietly (riding in a car, listening to a lecture or music, watch television or a movie)
07030	0.9	Inactivity, quiet:	Sleeping
07040	1.2	Inactivity, quiet:	Standing quietly (standing in a line)
07050	1.0	Inactivity, light:	Recline-writing
07060	1.0	Inactivity, light:	Recline-talking or talking on phone
07070	1.0	Inactivity, light:	Recline-reading
08010	5.0	Lawn and garden,	Carrying, loading or stacking wood, loading/unloading or carrying lumber
08020	6.0	Lawn and garden,	Chopping wood, splitting logs
08030	5.0	Lawn and garden,	Cleaning land, hauling branches
08040	5.0	Lawn and garden,	Digging sandbox
08050	5.0	Lawn and garden,	Digging, spading, filling garden (T 590)
08060	6.0	Lawn and garden,	Gardening with heavy power tools, tilling a garden (see occupation, shoveling)
08080	5.0	Lawn and garden,	Laying crushed rock
08090	5.0	Lawn and garden,	Laying sod
08095	5.5	Lawn and garden,	Mowing lawn, general
08100	2.5	Lawn and garden,	Mowing lawn, riding mower (T 550)
08110	6.0	Lawn and garden	Mowing lawn, walk, hand mower (T 570)
08120	4.5	Lawn and garden	Mowing lawn, walk, power mower (T 590)
08130	4.5	Lawn and garden,	Operating snow blower, walking
08140	4.0	Lawn and garden,	Planting seedlings, shrubs
08150	4.5	Lawn and garden	Planting trees
08160	4.0	Lawn and garden,	Raking lawn (T 600)
08170	4.0	Lawn and garden,	Raking roof with snow rake
08180	3.0	Lawn and garden	Riding snow blower
08190	4.0	Lawn and garden	Sacking grass, leaves
08200	6.0	Lawn and garden	Shoveling, snow, by hand (T 610)
08210	4.5	Lawn and garden	Trimming shrubs or trees, manual cutter
08215	3.5	Lawn and garden	Trimming shrubs or trees, power cutter
08220	2.5	Lawn and garden	Walking, applying fertilizer or seeding a lawn
08230	1.5	Lawn and garden,	Watering lawn or garden, standing or walking
08240	4.5	Lawn and garden	Weeding, cultivating garden (T 580)
08245	5.0	Lawn and garden,	Gardening, general
08250	3.0	Lawn and garden,	Implied walking/standing-picking up yard, light
09010	1.5	Miscellaneous	Sitting, card playing, playing board games
09020	2.0	Miscellaneous,	Standing-drawing (writing), casino gambling
09030	1.3	Miscellaneous	Sitting-reading, book, newspaper, etc.
09040	1.8	Miscellaneous	Sitting-writing, desk work
09050	1.8	Miscellaneous	Standing-talking or talking on the phone
09055	1.5	Miscellaneous	Sitting-talking or talking on the phone
09060	1.8	Miscellaneous	Sitting-studying, general, including reading and/or writing
09065	1.8	Miscellaneous,	Sitting-in class, general, including note-taking or class discussion
09070	1.8	Miscellaneous,	Standing-reading
10010	1.8	Music playing,	Accordion
10020	2.0	Music playing	Cello
10030	2.5	Music playing,	Conducting
10040	4.0	Music playing,	Drums
10050	2.0	Music playing,	Flute (sitting)
10060	2.0	Music playing,	Horn
10070	2.5	Music playing	Piano or organ
10080	3.5	Music playing	Trombone
10090	2.5	Music playing	Trumpet
10100	2.5	Music playing	Violin
10110	2.0	Music playing	Woodwind
10120	2.0	Music playing,	Guitar, classical, folk (sitting)
10125	3.0	Music playing	Guitar, rock and roll band (standing)
10130	4.0	Music playing	Marching band, playing an instrument, baton twirling (walking)
10135	3.5	Music playing	Marching band, drum major (walking)
11010	4.0	Occupation	Bakery, general
11020	2.3	Occupation,	Bookbinding
11030	6.0	Occupation,	Building road (including hauling debris, driving heavy machinery)
11035	2.0	Occupation,	Building road, directing traffic (standing)
11040	3.5	Occupation	Carpentry, general
11050	8.0	Occupation,	Carrying heavy loads, such as bricks
11060	8.0	Occupation	Carrying moderate loads up stairs, moving boxes (16–40 pounds)
11070	2.5	Occupation,	Chambermaid
11080	6.5	Occupation,	Coal mining, drilling coal, rock
11090	6.5	Occupation,	Coal mining, erecting supports
11100	6.0	Occupation,	Coal mining, general
11110	7.0	Occupation,	Coal mining, shoveling coal
11120	5.5	Occupation,	Construction, outside, remodeling
11130	3.5	Occupation,	Electrical work, plumbing
11140	8.0	Occupation,	Farming, baling hay, cleaning barn, poultry work
11150	3.5	Occupation,	Farming, chasing cattle, nonstrenuous
11160	2.5	Occupation	Farming, driving harvester
11170	2.5	Occupation,	Farming, driving tractor
11180	4.0	Occupation,	Farming, feeding small animals
11190	4.5	Occupation,	Farming, feeding cattle
11200	8.0	Occupation,	Farming, forking straw bales
11210	3.0	Occupation,	Farming, milking by hand
11220	1.5	Occupation,	Farming, milking by machine
11230	5.5	Occupation,	Farming, shoveling grain
11240	12.0	Occupation,	Fire fighter, general
11245	11.0	Occupation,	Fire fighter, climbing ladder with full gear
11246	8.0	Occupation,	Fire fighter, hauling hoses on ground
11250	17.0	Occupation	Forestry, ax chopping, fast
11260	5.0	Occupation,	Forestry, ax chopping, slow
11270	7.0	Occupation,	Forestry, barking trees
11280	11.0	Occupation,	Forestry, carrying logs
11290	8.0	Occupation,	Forestry, felling trees
11300	8.0	Occupation,	Forestry, general
11310	5.0	Occupation,	Forestry, hoeing
11320	6.0	Occupation,	Forestry, planting by hand
11330	7.0	Occupation,	Forestry, sawing by hand
11340	4.5	Occupation,	Forestry, sawing, power
11350	9.0	Occupation,	Forestry, trimming trees
11360	4.0	Occupation,	Forestry, weeding
11370	4.5	Occupation,	Furnery
11380	6.0	Occupation,	Horse grooming
11390	8.0	Occupation,	Horse racing, galloping
11400	6.5	Occupation,	Horse racing, trotting
11410	2.6	Occupation,	Horse racing, walking
11420	3.5	Occupation,	Locksmith
11430	2.5	Occupation	Machine tooling, machining, working sheet metal
11440	3.0	Occupation	Machine tooling, operating lathe
11450	5.0	Occupation,	Machine tooling, operating punch press
11460	4.0	Occupation,	Machine tooling, tapping and drilling
11470	3.0	Occupation,	Machine tooling, welding
11480	7.0	Occupation,	Masonry, concrete
11485	4.0	Occupation,	Masseur, masseuse (standing)
11490	7.0	Occupation,	Moving, pushing heavy objects, 75 lbs or more (desks, moving van work)
11500	2.5	Occupation,	Operating heavy duty equipment/automated, not driving
11510	4.5	Occupation,	Orange grove work
11520	2.3	Occupation,	Printing (standing)
11525	2.5	Occupation,	Police, directing traffic (standing)
11526	2.0	Occupation,	Police, driving a squad car (sitting)
11527	1.3	Occupation,	Police, riding in a squad car (sitting)
11528	8.0	Occupation,	Police, making an arrest (standing)
11530	2.5	Occupation,	Shoe repair, general
11540	8.5	Occupation,	Shoveling, digging ditches
11550	9.0	Occupation,	Shoveling, heavy (more than 16 lbs · min^{-1})
11560	6.0	Occupation,	Shoveling, light (less than 10 lbs · min^{-1})
11570	7.0	Occupation,	Shoveling, moderate (10–15 lbs · min^{-1})

APPENDIX 1. Continued

11580	1.5	Occupation.	Sitting-light office work, in general (chemistry lab work, light use of handtools, watch repair or micro-assembly, light assembly/repair)
11585	1.5	Occupation.	Sitting-meetings, general, and/or with talking involved
11590	2.5	Occupation.	Sitting; moderate (heavy levers, riding mower/forklift, crane operation)
11600	2.5	Occupation.	Standing; light (bartending, store clerk, assembling, filing, xeroxing, put up Christmas tree)
11610	3.0	Occupation.	Standing; light/moderate (assemble/repair heavy parts, welding, stocking, auto repair, pack boxes for moving, etc.), patient care (as in nursing)
11620	3.5	Occupation.	Standing, moderate (assembling at fast rate, lifting 50 lbs, hitch/twisting ropes)
11630	4.0	Occupation.	Standing, moderate/heavy (lifting more than 50 lb, masonry, painting, paper hanging)
11640	5.0	Occupation.	Steel mill, fettling
11650	5.5	Occupation.	Steel mill, forging
11660	8.0	Occupation.	Steel mill, hand rolling
11670	8.0	Occupation.	Steel mill, merchant mill rolling
11680	11.0	Occupation.	Steel mill, removing slag
11690	7.5	Occupation.	Steel mill, tending furnace
11700	5.5	Occupation.	Steel mill, tipping molds
11710	8.0	Occupation.	Steel mill, working in general
11720	2.5	Occupation.	Tailoring, cutting
11730	2.5	Occupation.	Tailoring, general
11740	2.0	Occupation.	Tailoring, hand sewing
11750	2.5	Occupation.	Tailoring, machine sewing
11760	4.0	Occupation.	Tailoring, pressing
11766	6.5	Occupation	Truck driving, loading and unloading truck (standing)
11770	1.5	Occupation.	Typing, electric, manual or computer
11780	6.0	Occupation.	Using heavy power tools such pneumatic tools (jackhammers, drills, etc.)
11790	8.0	Occupation.	Using heavy tools (not power) such as shovel, pick, tunnel bar, spade
11791	2.0	Occupation.	Walking on job, less than 2.0 mph (in office or lab area), very slow
11792	3.5	Occupation.	Walking on job, 3.0 mph, in office, moderate speed, not carrying anything
11793	4.0	Occupation	Walking on job, 3.5 mph, in office, brisk speed, not carrying anything
11795	3.0	Occupation.	Walking, 2.5 mph, slowly and carrying light objects less than 25 lbs
11800	4.0	Occupation.	Walking, 3.0 mph, moderately and carrying light objects less than 25 lbs
11810	4.5	Occupation.	Walking, 3.5 mph, briskly and carrying objects less than 25 lbs
11820	5.0	Occupation.	Walking or walk downstairs or standing, carrying objects about 25–49 lbs
11830	6.5	Occupation.	Walking or walk downstairs or standing, carrying objects about 50–74 lbs
11840	7.5	Occupation.	Walking or walk downstairs or standing, carrying objects about 75–99 lbs
11850	8.5	Occupation.	Walking or walk downstairs or standing, carrying objects about 100 lbs and over
11870	3.0	Occupation.	Working in scene shop, theater actor, backstage, employee
12010	6.0	Running.	Job/walk combination (jobbing component of less than 10 min) (T 180)
12020	7.0	Running	Jogging, general
12030	8.0	Running.	Running, 5 mph (12 min·mile^{-1})
12040	9.0	Running.	Running, 5.2 mph (11.5 min·mile^{-1})
12050	10.0	Running.	Running, 6 mph (10 min·mile^{-1})
12060	11.0	Running.	Running, 6.7 mph (9 min·mile^{-1})
12070	11.5	Running.	Running, 7 mph (8.5 min·mile^{-1})
12080	12.5	Running.	Running, 7.5 mph (8 min·mile^{-1})
12090	13.5	Running.	Running, 8 mph (7.5 min·mile^{-1})
12100	14.0	Running.	Running, 8.6 mph (7 min·mile^{-1})
12110	15.0	Running.	Running, 9 mph (6.5 min·mile^{-1})
12120	16.0	Running.	Running, 10 mph (6 min·mile^{-1})
12130	18.0	Running.	Running, 10.9 mph (5.5 min·mile^{-1})
12140	9.0	Running.	Running, cross-country
12150	8.0	Running.	Running, general (T 200)
12160	8.0	Running.	Running, in place
12170	15.0	Running.	Running, stairs, up
12180	10.0	Running.	Running, on a track, team practice
12190	8.0	Running.	Running, training, pushing wheelchair, marathon wheeling
12195	3.0	Running.	Running, wheeling, general
13000	2.5	Self-care.	Standing-getting ready for bed, in general
13009	1.0	Self-care.	Sitting on toilet
13010	2.0	Self-care.	Bathing (sitting)
13020	2.5	Self-care.	Dressing, undressing (standing or sitting)
13030	1.5	Self-care.	Eating (sitting)
13035	2.0	Self-care.	Talking and eating or eating only (standing)
13040	2.5	Self-care.	Sitting or standing-grooming (washing, shaving, brushing teeth, urinating, washing hands, put on make-up)
13050	4.0	Self-care.	Showering, toweling off (standing)
14010	1.5	Sexual activity.	Active, vigorous effort
14020	1.3	Sexual activity.	General, moderate effort
14030	1.0	Sexual activity.	Passive, light effort, kissing, hugging
15010	3.5	Sports.	Archery (nonhunting)
15020	7.0	Sports.	Badminton, competitive (T 450)
15030	4.5	Sports.	Badminton, social singles and doubles, general
15040	8.0	Sports.	Basketball, game (T 490)
15050	6.0	Sports.	Basketball, nongame, general (T 480)
15060	7.0	Sports.	Basketball, officiating (T 500)
15070	4.5	Sports.	Basketball, shooting baskets
15075	6.5	Sports.	Basketball, wheelchair
15080	2.5	Sports.	Billiards
15090	3.0	Sports.	Bowling (T 390)
15100	12.0	Sports.	Boxing, in ring, general
15110	6.0	Sports.	Boxing, punching bag
15120	9.0	Sports.	Boxing, sparring
15130	7.0	Sports.	Broomball
15135	5.0	Sports.	Children's games (hopscotch, 4-square, dodgeball, playground apparatus, t-ball, tetherball, marbles, jacks, arcade games)
15140	4.0	Sports	Coaching: football, soccer, basketball, baseball, swimming, etc.
15150	5.0	Sports.	Cricket (batting, bowling)
15160	2.5	Sports.	Croquet
15170	4.0	Sports.	Curling
15180	2.5	Sports.	Darts, wall or lawn
15190	6.0	Sports.	Drag racing, pushing or driving a car
15200	6.0	Sports.	Fencing
15210	9.0	Sports.	Football, competitive
15230	8.0	Sports.	Football, touch, flag, general (T 510)
15235	2.5	Sports.	Football or baseball, playing catch
15240	3.0	Sports.	Frisbee playing, general
15250	3.5	Sports.	Frisbee, ultimate
15255	4.5	Sports.	Golf, general
15260	5.5	Sports.	Golf, carrying clubs (T 090)
15270	3.0	Sports.	Golf, miniature, driving range
15280	5.0	Sports.	Golf, pulling clubs (T 080)
15290	3.5	Sports.	Golf, using power cart (T 070)
15300	4.0	Sports.	Gymnastics, general
15310	4.0	Sports.	Hacky sack
15320	12.0	Sports.	Handball general (T 520)
15330	8.0	Sports.	Handball, team
15340	3.5	Sports.	Hang gliding
15350	8.0	Sports.	Hockey, field
15360	8.0	Sports.	Hockey, ice

APPENDIX 1. Continued

15370	4.0	Sports.	Horseback riding, general
15380	3.5	Sports.	Horseback riding, saddling horse
15390	6.5	Sports.	Horseback riding, trotting
15400	2.5	Sports.	Horseback riding, walking
15410	3.0	Sports.	Horseshoe pitching, quoits
15420	12.0	Sports.	Jai alai
15430	10.0	Sports.	Judo, jujitsu, karate, kick boxing, tae kwan do
15440	4.0	Sports.	Juggling
15450	7.0	Sports	Kickball
15460	8.0	Sports.	Lacrosse
15470	4.0	Sports.	Moto-cross
15480	9.0	Sports.	Orienteering
15490	10.0	Sports.	Paddleball, competitive
15500	6.0	Sports.	Paddleball, casual, general (T 460)
15510	8.0	Sports.	Polo
15520	10.0	Sports.	Racketball, competitive
15530	7.0	Sports.	Racketball, casual, general (T 470)
15535	11.0	Sports.	Rock climbing, ascending rock
15540	8.0	Sports.	Rock climbing, rappelling
15550	12.0	Sports.	Rope jumping, fast
15551	10.0	Sports.	Rope jumping, moderate, general
15552	8.0	Sports.	Rope jumping, slow
15560	10.0	Sports	Rugby
15570	3.0	Sports	Shuffleboard, lawn bowling
15580	5.0	Sports.	Skateboarding
15590	7.0	Sports.	Skating, roller (T 360)
15600	3.5	Sports.	Sky diving
15605	10.0	Sports.	Soccer, competitive
15610	7.0	Sports.	Soccer, casual, general (T 540)
15620	5.0	Sports	Softball or baseball, fast or slow pitch, general (T 440)
15630	4.0	Sports.	Softball, officiating
15640	6.0	Sports.	Softball, pitching
15650	12.0	Sports.	Squash (T 530)
15660	4.0	Sports	Table tennis, ping pong (T 410)
15670	4.0	Sports	Tai chi
15675	7.0	Sports	Tennis, general
15680	6.0	Sports.	Tennis, doubles (T 430)
15690	8.0	Sports.	Tennis, singles (T 420)
15700	3.5	Sports.	Trampoline
15710	4.0	Sports.	Volleyball, competitive, in gymnasium (T 400)
15720	3.0	Sports.	Volleyball, noncompetitive; 6–9 member team, general
15725	8.0	Sports.	Volleyball, beach
15730	6.0	Sports.	Wrestling (one match = 5 min)
15731	7.0	Sports.	Wallyball, general
16010	2.0	Transportation.	Automobile or light truck (not a semi) driving
16020	2.0	Transportation.	Flying airplane
16030	2.5	Transportation	Motor scooter, motor cycle
16040	6.0	Transportation.	Pushing plane in and out of hangar
16050	3.0	Transportation.	Driving heavy truck, tractor, bus
17010	7.0	Walking	Backpacking, general (T 050)
17020	3.5	Walking.	Carrying infant or 15-lb load (e.g., suitcase), level ground or downstairs
17025	9.0	Walking.	Carrying load upstairs, general
17026	5.0	Walking.	Carrying 1- to 15-lb load, upstairs
17027	6.0	Walking.	Carrying 16- to 24-lb load, upstairs
17028	8.0	Walking.	Carrying 25- to 49-lb load, upstairs
17029	10.0	Walking.	Carrying 50- to 74-lb load, upstairs
17030	12.0	Walking.	Carrying 74+-lb load, upstairs
17035	7.0	Walking.	Climbing hills with 0- to 9-lb load
17040	7.5	Walking.	Climbing hills with 10- to 20-lb load
17050	8.0	Walking.	Climbing hills with 21- to 42-lb load
17060	9.0	Walking.	Climbing hills with 42+-lb load
17070	3.0	Walking.	Downstairs
17080	6.0	Walking.	Hiking, cross country (T 040)
17090	6.5	Walking.	Marching, rapidly, military
17100	2.5	Walking.	Pushing or pulling stroller with child
17110	6.5	Walking	Race walking
17120	8.0	Walking	Rock or mountain climbing (T 060)
17130	8.0	Walking.	Up stairs, using or climbing up ladder (T 030)
17140	4.0	Walking.	Using crutches
17150	2.0	Walking.	Walking, less than 2.0 mph, level ground, strolling, household walking, very slow
17160	2.5	Walking.	Walking, 2.0 mph, level, slow pace, firm surface
17170	3.0	Walking.	Walking, 2.5 mph, firm surface
17180	3.0	Walking.	Walking, 2.5 mph, downhill
17190	3.5	Walking.	Walking, 3.0 mph, level, moderate pace, firm surface
17200	4.0	Walking.	Walking, 3.5 mph, level, brisk, firm surface
17210	6.0	Walking.	Walking, 3.5 mph, uphill
17220	4.0	Walking.	Walking, 4.0 mph, level, firm surface, very brisk pace
17230	4.5	Walking.	Walking, 4.5 mph, level, firm surface, very, very brisk
17250	3.5	Walking.	Walking, for pleasure, work break, walking the dog.
17260	5.0	Walking.	Walking, grass track
17270	4.0	Walking	Walking, to work or class (T 015)
18010	2.5	Water activities.	Boating, power
18020	4.0	Water activities.	Canoeing, on camping trip (T 270)
18030	7.0	Water activities.	Canoeing, portaging
18040	3.0	Water activities.	Canoeing, rowing, 2.0–3.9 mph, light effort
18050	7.0	Water activities.	Canoeing, rowing, 4.0–5.9 mph, moderate effort
18060	12.0	Water activities.	Canoeing, rowing, >6 mph, vigorous effort
18070	3.5	Water activities.	Canoeing, rowing, for pleasure, general (T 250)
18080	12.0	Water activities.	Canoeing, rowing, in competition, or crew or sculling (T 260)
18090	3.0	Water activities.	Diving, springboard or platform
18100	5.0	Water activities.	Kayaking
18110	4.0	Water activities.	Paddleboat
18120	3.0	Water activities.	Sailing, boat and board sailing, windsurfing, ice sailing, general (T 235)
18130	5.0	Water activities.	Sailing, in competition
18140	3.0	Water activities.	Sailing, Sunfish/Laser/Hobby Cat, keel boats, ocean sailing, yachting
18150	6.0	Water activities.	Skiing, water (T 220)
18160	7.0	Water activities.	Skimobiling
18170	12.0	Water activities.	Skindiving or scuba diving as frogman
18180	16.0	Water activities.	Skindiving, fast
18190	12.5	Water activities.	Skindiving, moderate
18200	7.0	Water activities	Skindiving, scuba diving, general (T 310)
18210	5.0	Water activities.	Snorkeling (T 320)
18220	3.0	Water activities.	Surfing, body or board
18230	10.0	Water activities.	Swimming laps, freestyle, fast, vigorous effort
18240	8.0	Water activities.	Swimming laps, freestyle, slow, moderate or light effort
18250	8.0	Water activities.	Swimming, backstroke, general
18260	10.0	Water activities.	Swimming, breaststroke, general
18270	11.0	Water activities.	Swimming, butterfly, general
18280	11.0	Water activities.	Swimming, crawl, fast (75 yards · min^{-1}), vigorous effort
18290	8.0	Water activities.	Swimming, crawl, slow (50 yards · min^{-1}), moderate or light effort
18300	6.0	Water activities.	Swimming, lake, ocean, river (T 280, T 295)
18310	6.0	Water activities.	Swimming, leisurely, not lap swimming, general
18320	8.0	Water activities.	Swimming, sidestroke, general
18330	8.0	Water activities.	Swimming, synchronized
18340	10.0	Water activities.	Swimming, treading water, fast vigorous effort

APPENDIX 1. Continued

18350	4.0	Water activities,	Swimming, treading water, moderate effort, general
18360	10.0	Water activities,	Water polo
18365	3.0	Water activities,	Water volleyball
18370	5.0	Water activities,	Whitewater rafting, kayaking, or canoeing
19010	6.0	Winter activities,	Moving ice house (set up/drill holes, etc.)
19020	5.5	Winter activities,	Skating, ice, 9 mph or less
19030	7.0	Winter activities,	Skating, ice, general (T 360)
19040	9.0	Winter activities,	Skating, ice, rapidly, more than 9 mph
19050	15.0	Winter activities,	Skating, speed, competitive
19060	7.0	Winter activities,	Ski jumping (climb up carrying skis)
19075	7.0	Winter activities,	Skiing, general
19080	7.0	Winter activities,	Skiing, cross-country, 2.5 mph, slow or light effort, ski walking
19090	8.0	Winter activities,	Skiing, cross-country, 4.0–4.9 mph, moderate speed and effort, general
19100	9.0	Winter activities,	Skiing, cross-country, 5.0–7.9 mph, brisk speed, vigorous effort
19110	14.0	Winter activities,	Skiing, cross-country, >8.0 mph, racing
19130	16.5	Winter activities,	Skiing, cross-country, hard snow, uphill, maximum
19150	5.0	Winter activities,	Skiing, downhill, light effort
19160	6.0	Winter activities,	Skiing, downhill, moderate effort, general
19170	8.0	Winter activities,	Skiing, downhill, vigorous effort, racing
19180	7.0	Winter activities,	Sledding, tobogganing, bobsledding, luge (T 370)
19190	8.0	Winter activities,	Snow shoeing
19200	3.5	Winter activities,	Snowmobiling

APPENDIX 2. Guidelines for assigning activities by major purpose or intent.

1. Conditioning exercises include activities with the intent of improving physical condition. This includes stationary ergometers (bicycling, rowing machines, treadmills, etc.) health club exercise, calisthenics, and aerobics.
2. Home repair includes all activity associated with the repair of a house and does not include housework. This is not an occupational task.
3. Sleeping, lying, sitting, and standing are classified as inactivity.
4. Home activities include all activities associated with maintaining the inside of a house and includes house cleaning, laundry, grocery shopping, and cooking.
5. Lawn and garden includes all activity associated with maintaining the yard and includes yard work, gardening, and snow removal.
6. Occupation includes all job-related physical activity where one is paid (gainful employment). Specific activities may be cross-referenced in other categories (such as reading, writing, driving a car, walking) and should be coded in this major heading if related to employment. Housework is occupational only if the person is earning money for the task.
7. Self-care includes all activity related to grooming, eating, bathing, etc.
8. Transportation includes energy expended for the primary purpose of going somewhere in a motorized vehicle.

APPENDIX 3. Guidelines for coding specific activities

A. General guidelines. All activities should be coded as "general" if no other information about the activity is given. This applies primarily to intensity ratings. If any additional information is given, activities should be coded accordingly.

B. Specific guidelines

1. Bicycling
   a. Stationary cycling using cycle ergometers (all types), wind trainers, or other conditioning devices should be classified under the major heading of Conditioning Exercise, stationary cycling specific activities (codes 02010 to 02015).
   b. The list does not account for differences in wind conditions.
   c. If bicycling is performed in a race, classify it as general racing if no descriptions are given about drafting (code 01050). If information is given about the speed or drafting code as 01050 (bicycling, 16–19 mph, racing/not drafting or >19 mph drafting, very fast) or 01060 (bicycling, ≥20 mph, racing, not drafting).
   d. Using a mountain bike in the city should be classified as bicycling, general (code 01010). Cycling on mountain trails or on a BMX course is coded 01009.
2. Conditioning Exercises
   a. If a calisthenics program is described as a light or moderate type of activity (e.g., performing back exercises) but indicates a vigorous effort on the part of the participant, code the activity as calisthenics, general (code 02030).
   b. Exercise performed at a health club that is not described should be classified as health club, general (code 02060). Other activities performed at a health club (e.g., weight lifting, aerobic dance, circuit training, treadmill running, etc. at a health club) should be classified under separate major headings.
   c. Regardless of whether aerobic dance, conditioning, circuit training, or water calisthenics programs are described by their component parts (i.e., 10 min jogging in place, 10 min sit-ups, 10 min stretching, etc.), code the activity as one activity (e.g., water aerobics, code 02120).
   d. Effort, speed, or intensity breakdowns for the specific activities of stair-treadmill ergometer (code 02065), ski machine (code 02080), water aerobics or water calisthenics (code 02120), circuit training (code 02040), and slimnastics (code 02090) are not given. Code these as general, even though effort or intensities may vary in the descriptions of the activity.
3. Dancing
   a. If the type of dancing performed is not described, code it as dancing, general (code 03025).
4. Home Activities
   a. House cleaning should be coded as light (code 05040) or heavy (code 05020). Examples for each are given in the description of the specific activities.
   b. Making the bed on a daily basis is coded 05100. Changing the bed sheets is coded as cleaning, light (code 05040).
5. Home Repair
   a. Any painting outside of the house (i.e., fence, the house, barn) is coded, painting, outside house (code 60150).
6. Inactivity
   a. Sitting and reading a book or newspaper is listed under the major heading of Miscellaneous, reading, book, newspaper, etc. (code 09030).
   b. Sitting and writing is listed under the major heading of Miscellaneous, writing (code 09040).
7. Lawn and Garden
   a. Working in the garden with a specific type of tool (e.g., hoe, spade) is coded as digging, spading, filling garden (code 08050).
   b. Removing snow may be done by one of three methods: shoveling snow by hand (code 08200), walking and operating a snow blower (code 08130), or riding a snow blower (code 08180).
8. Music Playing
   a. Most variation in music playing will be according to the setting (i.e., rock and roll band, orchestra, marching band, concert band, standing on the stage, performance, practice, in a church etc.). The compendium does not consider differences in the setting (except for marching band and guitar playing).
9. Occupation
   a. Types of occupational activities not listed separately under specific activities (e.g., chemistry laboratory experiments), should be placed into the types of energy expenditure classifications best describing the activity. See sitting: light (code 11580), sitting: moderate (code 11590), standing: light (code 11600), standing: light to moderate (code 11610), standing: moderate (code 11620), standing: moderate to heavy code 11630)

APPENDIX 3. Continued

b. Driving an automobile or a light truck for employment (taxi cab, salesman, contractor, ambulance driver, bus driver), should be listed under the major heading of Transportation, automobile or light truck (not a semi) driving (code 06010).
c. Performing skin or SCUBA diving as an occupation is listed under the major heading of Water Activities and the specific activity of skindiving or SCUBA diving as a frogman (code 18170).

10. Running
a. Running is not classified as treadmill or outdoor running. Running on a treadmill or outdoors should be coded by the speed of the run (codes 12030 to 12130). If speed is not given, code it as running, general (code 12150).

11. Self-care
a. The compendium does not account for effort ratings. All items are considered to be general.

12. Transportation
a. Being a passenger in an automobile is coded under the major heading of inactivity, sitting quietly (code 07020).

13. Walking
a. Household walking is coded 17150, regardless if the subject identified a walking speed.
b. If the walking speed is unidentified, use 3.0 mph, level, moderate, firm surface as the standard speed (code 17190). This should not be used for household walking.
c. Walking during a household move, shopping, or for household work is coded under the major heading of Home Activities. Walking for job-related activities is coded under Occupational Activities.
d. If a subject is backpacking, regardless of descriptors attached, the code is backpacking, general (code 17010).
e. The compendium does not account for variations in speed or effort while carrying luggage or a child.
f. Mountain climbing should be classified as general (rock or mountain climbing, code 17120) if no descriptors are given. If the weight of the load is described, code the activity as climbing hills with the appropriate load (codes 17030 to 17060).
g. Walking on a grassy area (golf course, in a park, etc.) should be coded as walking, grass track (code 17260). The compendium does not account for variations in walking speed on a grassy area, so ignore recordings of walking speed or effort. If the walking is not on a grassy area, code the activity according to the walking speed (codes 17150 to 17230).
h. Walking to work or to class should be coded as 17270. The compendium does not account for walking speed or effort in this activity. Even though a speed or effort is given for the walking, do not code walking to work or to class in any other walking category.
i. Hiking and cross-country walking (code 17080) should be used only if the walking activity lasted 3 h or more. Do not use this category for backpacking, but for day hikes.

14. Water Activities
a. Swimming should be coded as leisurely, not lap swimming, general (code 18310) if descriptors about stroke, speed, or swimming location are not given.
b. Lap swimming should be coded as swimming laps, freestyle, slow (code 18240) if the activity is described as lap swimming, light or moderate effort, but stroke or speed are not indicated. Swimming laps should be coded as swimming, laps, freestyle, fast (code 18.30) if the activity is described as lap swimming, vigorous effort, but stroke or speed are not indicated given.
c. Swimming crawl should be coded as swimming, crawl, slow (50 yards $\cdot$ min^{-1}) if speed is not given and the effort is rated light or moderate (code 18290). Swimming crawl should be coded as swimming, crawl, fast (75 yards $\cdot$ min^{-1}) if speed is not given, but the effort is rated as vigorous (code 18280).
d. The swimming strokes of backstroke (code 18250), breaststroke (code 18260), butterfly (code 18270), and sidestroke (code 18230) are coded as general for speed and intensity.
e. If a swimming activity is not identified as lake, ocean, or river swimming (code 18300), assume that the swimming was performed in a swimming pool.
f. If canoeing is related to a canoe trip, code as canoeing, on a camping trip (code 18020). Otherwise, code it according to the speed and effort listed.

APPENDIX D
PROCEDURES FOR SELF-ADMINISTERED QUESTIONNAIRES

D.1 General Considerations 2

D.2 Diet 7

Appendix 1 Administering the Diet Questionnaire by Interview 13

Appendix 2 Modifications to the original Health History and Habits Questionnaire 15

Appendix 3 Specific Coding Rules 16

Appendix 4 Checklist for Review of Completed Questionnaires 21

Diet Questionnaire Form . . . . .

D.3 HRQL Outcomes with Physical Activity and Psychosocial Mediators (IFA) 22

Health-Related Quality of Life/Influences on Activity Forms . . . . .

D.4 Medical History 34

Demographics/Medical History Form . . . . .

D.5 Physical Exam 37

Physical Exam Form . . . . .

ACT Physical Exam Data Collection Form . . . . .

APPENDIX D

PROCEDURES FOR SELF-ADMINISTERED QUESTIONNAIRES

D.1 General Considerations

Overview Self-administered questionnaires can offer several advantages: a) **ease of administration**, with items that have long or complex response categories, b) **privacy**, the respondent does not have to immediately share his/her response with the study staff person, c) and **flexibility** in mode of distribution and designated place for completion. A tradeoff is that the a staff person is not present to appropriately guide the participant in completing the questionnaire, monitor quality, and collect each questionnaire distributed.

Distributing and Introducing the Questionnaires

A few general guidelines can help insure that high quality data are returned by participants with self-administered forms:

1) The staff person should be familiar with instructions for all self-administered forms, items and meanings, and the general purpose of each measure.

2) A general description of each instrument and the response format should be provided to the participant, noting any sections or items in the questionnaire with unusual features or changes in instructions. An example of each response format should be reviewed with the participant. As an introduction, a general explanation about the types of responses sought can be very helpful. For example, the staff person may say "Let me tell you a little bit about these questionnaires. For these questions (point to HRQL and Mediators questionnaires) you are given a set of answers, and are you are supposed to choose the one answer that best fits you, or your view. Do not worry if the choice of answers does not fit your feelings or views exactly, just choose the one answer that is closest to your view. In this way, we can combine the answers from everyone in the study."

3) The staff person should emphasize the importance of completing the questionnaire without interruption during a convenient time. This is particularly important in ACT, where the questionnaires are taken home and completed. There are three self-administered questionnaires in ACT: Diet, HRQL, and Mediators (see appendix D). To facilitate and encourage effective time management, it is often

helpful to provide the participant with the estimated time needed to complete each section so that he/she may budget enough time to complete each questionnaire. The participant may complete the separate questionnaires on different days, or times of day, depending on convenience. However, it should be emphasized that it is ideal to complete an entire questionnaire at one sitting.

4) Staff should emphasize that the responses to the questions are about the participant's views, feelings, or behaviors only. Other persons, such as family or friends, should not be consulted about how they would respond, or what they feel is true for the participant.

5) Staff should emphasize that, as stated in the informed consent, all of the participant's answers will be kept in strict confidence, and not shared with anyone in a way which will reveal their identity.

6) Staff should inform the participant that they should bring the completed questionnaires with them to the next scheduled screening visit. In this regard, it is often beneficial to help participants develop an organization plan for storage and retrieval of study materials and information at home. Some tips include: " choose a location in your home to keep the newsletters, appointment schedules, questionnaires, and other materials that you will receive in the coming months as you participate in ACT", "mark on your calendar your next visit date(s), and make a note of any special study activities that you may need to do - such as completing the take-home questionnaires for the SV2 visit", and "make a note to yourself about the things you need to do for ACT and place it in the location you usually use to post reminders and messages". Encourage the participant to think of other ways that may be effective for them to "keep up" with appointments and scheduled activities.

7) Participant's should be informed that if they have a question about an item which prevents them from selecting the best or closest answer to their views or behaviors, to circle the item and note it with a '?' in the margin.

Reminder to Return the Questionnaires During the SV2 reminder telephone call, the participant should be reminded of the take-home questionnaire packet, and told to be sure to bring the completed questionnaires with them to the upcoming visit. If the participant indicates that he/she has not yet completed the questionnaire, the caller should stress the importance of having a completed

questionnaire in order to complete screening. Any help, or assistance needed in completing specific items in the questionnaire can be provided either by the caller, or by the staff reviewer at the upcoming screening visit (see Appendix D: Diet, HRQL, Mediators for specific instructions).

Review of the Completed Questionnaires. Upon the participant's return visit (SV2 or others), a trained staff person, ideally the person who instructed the participant on how the complete the questionnaire, should review the pages of the questionnaire for items not completed, or comments about the items noted by the participant. It is important the questionnaire review take place in a location which affords privacy, so that the participant's questions or responses may not be overheard by other staff or non-staff persons in the area.

The demeanor of the reviewer should be casual, yet professional. In reviewing the items, the reviewer should strive to be neutral, and should not show surprise, curiosity, pleasure, disapproval or other expressions of value judgement toward any response given, or any question raised about a questionnaire or an item. The participant should be encouraged to feel proper or correct, and not embarrassed about skipping an item that was unclear, or asking a question about an item for clarification.

In the event the reviewer is asked a question by the participant about how to complete an item in the questionnaire, the reviewer should follow specific guidelines described for that questionnaire (see specific sections in Appendix D). As a general guideline, for attitudinal or self-appraisal items, the reviewer should use a natural, or conversational voice tone, and repeat the questionnaire verbatim. Emphasize that there are no right or wrong answers, and that what a participant thinks is what really counts. An opinion can never be wrong.

Probing In some cases, in response to a participant's question about an item, the reviewer may have to probe for an appropriate response. Neutral questions or comments are frequently used to obtain clearer responses which may more closely correspond to the response choices. Examples of these are: How do you mean? Could you tell me more about your thinking on that? Would you tell me what you

have in mind? Why do you feel that way? Which would be closer to the way you feel? The reviewer must remember that the balance between probing and directing responses is difficult one to maintain. The reviewer must be sure that sure that she/he is merely eliciting clarification and not pushing the patient to respond in a particular manner. Also, the reviewer must judge when to stop probing. Care should be taken that the participant does not feel pressure to respond to a question or item, or feel inadequate for not understanding a word or phrase used. A participant is not required to answer a question he/she would prefer not to answer. A refusal to answer a question should be treated politely and respectfully by the reviewer.

Ending the Review After each questionnaire has been identified and carefully reviewed for completeness, the participant should be thanked for his/her time and effort needed to complete the questionnaires. The questionnaire(s) should now be forwarded for data entry. A local tracking form may be useful to record the completion and receipt of the self-administered questionnaires.

Lost or Missing Questionnaires Since the self-administered forms are being sent home at SV1, for collection at SV2, without preventative steps, a small percentage of participants can be expected to return to SV2 without the requested questionnaires. Several strategies can be implemented to reduce or rectify this problem of missing data: 1) to prevent lost or misplaced questionnaires in the home, the questionnaires can be hole-punched and placed in thin, brightly colored binders with the ACT logo, along with a brief instruction pages(s); 2) use an SV2 appointment schedule card, or notice to includes a reminder stating: "please remember to complete the take-home questionnaire before you arrive for your next visit on date. For a replacement copy (if lost or damaged) please call nnn-nnnn, we will gladly mail you another packet of questionnaires." 3) Conduct the reminder telephone call approximately two to three days prior to the next scheduled visit date to allow ample time to complete the questionnaires. This strategy may be helpful because many persons may wait until the last day to complete the forms. Providing a "next visit" reminder more than one day in advance allows the person more opportunity to find time to complete the questionnaires; and 4) provide the participant with a peel-off sticker to place on a calendar or refrigerator, or a photocopied calendar page showing the participant's ACT activities

for the next month.

If a participant shows up for the scheduled visit without the requested questionnaires completed the reviewer should administer a new packet of questionnaires either by handing them to the participant for self administration before the close of the measurement visit, or by interview administering the questionnaire. Please see Appendix D.3, Section II, for instructions on interview administration. If a participant is unable to extend the time he/she allotted for the measurement/screening visit that day, then the reviewer or staff should make an agreement with the participant for a strategy to obtain questionnaire data. These may include: a) arranging a time at which a telephone interview can be conducted within the next week; or b) a follow-up call to verify that the individual has completed the forms and mailed them back to the clinic using a mailer and postage provided by the clinic.

D.2 DIET

Diet Questionnaire Instructions

Rationale

The purpose of the Diet Questionnaire is to assess usual dietary intake of nutrients which might change over time, particularly among intervention participants, and which could affect the secondary outcome measures of blood pressure and lipids. The diet questionnaire to be used in ACT is a self-administered questionnaire based on the National Cancer Institute Health History and Habits Questionnaire and its associated software package (HHHQ-DIETSYS Analysis Software, Version 3.0, NCI, 1993). Modifications made to the original instrument are taken largely from the Insulin Resistance Atherosclerosis Study, including the addition of ethnic foods to the questionnaire (total number of items on the ACT food frequency, 99) and the addition of several nutrients to the underlying nutrient database. In addition, the format and wording of the questionnaire were modified in order to lower the level of literacy needed to appropriately complete the form. Including the foods list, the grade level is estimated at 8 years. The instructions are estimated at 7 years of educational achievement need for full comprehension. These modifications are summarized in Appendix 2 of this chapter.

Overview

The Diet Questionnaire contains the following components:

- The front page contains general instructions, study ID, name, visit date, age, gender and whether the participant is following a special diet.
- The main body of the questionnaire begins on page 2 and ends on page 8. This section asks the participant to indicate the frequency with which he or she consumes selected food items which are ordered by category. An open-ended question on page 9 asks the participant to report on other foods that are consumed at least once per week.
- Pages 10-12 contain questions on how foods are prepared and frequency of consumption of special foods, food groups, and vitamin/mineral supplements. The final question on page 13 allows space for comments.

For ACT, the time frame specified for recall of usual diet is one month. The time period of one month is used because we wish to evaluate the extent to which health habits tend to correlate and change concurrently (i.e., the phenomenon of "health lifestyle"). In ACT, we will serially assess usual dietary habits which may change concurrently with the changes in physical activity behavior that we expect in the physical activity intervention groups. We also wish to assess any change in intake occurring in the standard care group. Therefore, since there is only a 6-month interval between the baseline and first post-randomization data collection visit, the time frame for assessment of dietary habits is one month.

The ACT diet questionnaire relies on reporting of frequency of consumption of food items (or

food groups). Most variability in nutrient intake is captured by reporting of frequency of intake, but enhanced precision is achieved by inclusion of portion size. Because of participant and staff burden, we will not query portion size in ACT. Instead, we will use the NCI-HHHQ option of incorporating age- and gender-specific portion size estimates, assuming a medium portion size for all participants on all items.

The ACT Diet Questionnaire is self-administered but requires verbal instructions to the participant prior to their completing the instrument. **The adequacy of these instructions is critical to the quality of the data obtained with the instrument.** The instrument also requires a review for adequacy upon return of the completed questionnaire, and may require conferring with the participant for clarifications or corrections. Rarely (less than 5% of participants), it is necessary to administer the questionnaire in an interview format. Specific guidelines for administration of the ACT diet questionnaire follow.

Methods

Distribution, Data Management, and Quality Control for the Diet Questionnaire

The Coordinating Center will mail sufficient quantities of the final questionnaire to each clinical center.

The Clinical Centers are responsible for administering the questionnaires, reviewing them for completeness and accuracy after they are returned by the participants, and coding responses to the open-ended foods question. Clinical Center staff will enter the questionnaires into the database prepared by the Coordinating Center. **All forms must be double-entered to ensure accuracy.** This is a specific requirement of the NCI-HHHQ software system. Follow Coordinating Center guidelines for mailing back a copy of the form.

The Coordinating Center will run data quality check programs and will request clarification and/or corrections by the Clinical Center staff as needed. The Coordinating Center will run programs necessary to estimate food and nutrient intake.

Because dietary factors are secondary outcomes in ACT, formal certification of Clinical Center staff is not required. It is expected that each Clinical Center staff member who will be administering the ACT Diet Questionnaire will be familiar with the material presented in this document. A checklist (Appendix 4) will be provided to Clinical Center staff as a reminder of what to look for in reviewing completed forms prior to data entry. The NCI-HHHQ DietSys quality control checks will be reviewed periodically according to Clinical Center and clinical staff and any unusual occurrences of potential errors will be addressed. Clinical Center staff are encouraged to call Beth Mayer with any questions they may have as the study progresses.

Clinic Procedures for Distributing the Diet Questionnaire

Participants will be instructed on completion of the Diet Questionnaire at SV1. They will be

asked to complete the questionnaire at home and to return the questionnaire at SV2, at which time the information will be reviewed and corrections/clarifications can be obtained. At SV1, carefully write identifying information in the upper part of the form. Make sure that all the information is written in the appropriate space.

Review the questionnaire with the participant as detailed in the instructions below, answer any questions, and give the participant the questionnaire.

Completed questionnaires should be returned and reviewed by clinic personnel at SV2. If participants are called to remind them of the SV2 visit, the caller should include a reminder to bring in the questionnaire.

If a participant forgets to return the questionnaire at SV2, encourage the participant to fill out the questionnaire while they are in the clinic. If this is not possible, provide a stamped, addressed envelope for them to use and ask them to return the completed questionnaire as soon as possible. Mailed questionnaires should also be reviewed by clinic staff, and clarifications can be obtained over the telephone.

If it is determined at SV1 that the participant will require administration of the questionnaire as an interview, schedule time for the interview either later that day or at SV2. Appendix 1 gives the procedures for administering the questionnaire by interview.

Instructions for the Participant

A clear, positive introduction and explanation of the Diet Questionnaire is extremely important to obtaining valid information from the questionnaire. Importantly, this information will allow the participant to complete the form with minimal frustration. Use the following guidelines for introducing and instructing the participant on completing the questionnaire.

Do not overwhelm the participant with too much detail! Keep it simple. The entire explanation should take an average of 10 minutes.

This is the time to identify the small number of participants likely to have significant difficulty completing the form at home. Alternatives are:

1. Have the participant complete the form while they are in clinic (during SV1, or if they arrive back for SV2 without the form completed) so that they can ask questions while they are working on the form. Also, you can observe the participant and ask them if they have questions if you see that they are puzzling over the form for an unreasonably long time.
2. Conduct the assessment as an interview (see Appendix 2 for specifics). This will occur only rarely.

Remember, as you go over the form, the vast majority of participants will be able to complete the form. Again, your job is to be clear, positive, and supportive; and most important, provide the directions at a level that is easily understood by the individual participant. Specifically:

1. Inform the participant that we are interested in their overall pattern of eating over the past month (past 30 days). If he/she is concerned about not remembering what they ate, acknowledge their concerns and encourage them to simply estimate to the best of their ability. Later in your explanation, you can reinforce this by emphasizing the text on page 2, *"We don't expect you to remember exactly what you ate. The first answer that comes to mind is usually the best choice."*
2. Show the participant the first page of the questionnaire. Inform the participant that on average it takes about 20 minutes to complete the questionnaire. Ask the participant to return the completed questionnaire at SV2.
3. Next, "walk through" the rest of the questionnaire with the participant, as follows.
   a. (page 2). Review the instructions given on the form, point-by-point, noting that you will go through an example with the participant. As you talk, watch the participant to see if they have questions, look confused, or look like they understand. Even if they seem to be understanding clearly, go through the example given at the bottom of the page.
   Read through and point out (with a pencil) the specific possible responses for frequency. Encourage the participant to be careful to check the appropriate box.
   b. Go through the first item on the food frequency list. If there is any difficulty,clarify the point and do the second item as another example to confirm understanding.

If you suspect that the participant may be having difficulty reading the form, either because of vision or literacy, simply ask the participant directly if they are having trouble. You can blame the print size or something about the form if the participant is uncomfortable acknowledging their difficulty, whatever the reason. In this case, if the participant volunteers that they have someone at home who can help them, this is fine. However, do not ask the participant to burden a family member or friend; instead, if necessary, schedule an interview if you feel the participant's difficulty with the form is significant.

To help the participant feel oriented to the form, tell them that the items are grouped by type of food (e.g., fruits, vegetables, meats). Note that some foods may be unfamiliar to the participant, due to inclusion of a variety of foods consumed by an ethnically diverse study population.

Remind the participant to think of foods eaten at home and also away from home. Remind them to include both meals and snacks.

Emphasize completeness and that no line should remain blank. The participant should check "None" or "Never or less than 1 per month" rather than simply skip foods he rarely or never eats.

c. (go to page 8). **The frequency responses for beverages are different than those for foods.** Show the new possible responses to the participant, emphasizing the last few (going up to 6+ per day).

d. (go to page 9). Note briefly that there is a page to write down any foods that the participant eats often which may have been missed earlier.

e. (go to page 10). Note briefly that the next few pages ask general questions about eating habits and how food is prepared. If the participant indicates that they do not prepare the food, reassure them that they can just answer to the best of their ability.

f. (go to page 13). Show the participant that there is space for them write down anything else they would like us to know about their eating habits.

g. Ask if there are any questions. In a positive manner, give the form to the participant to take home. Let them know they may call anytime if questions arise.

Encourage the participant to complete the questionnaire without a lot of distractions. However, if the participant becomes fatigued, they can feel free to take a break about halfway through the questionnaire and come back to it later that day. (Avoid excessive discontinuous filling out of the form--this will hurt the quality of the information).

Checking the Questionnaire When It is Returned

When the questionnaire is returned spend a few minutes (usually 2-5 min) checking over the questionnaire while the study participant is still there. **The goal is to identify omissions or errors, NOT to judge the quality of the participant's diet.**

1. Make sure the ID number is correct.

2. Check for omissions--skipped foods, missing information. Prevent skipped foods by careful instruction beforehand that the participant should check "none", rather than skipping foods they rarely or never eat. If there are any omissions, attempt to fill out the blank spaces with the participant's help.

3. Check for unlikely frequencies such as liver twice a day.

It is not necessary to try to make the foods add up to something that seems "right", like seven dinners a week. In many cases the foods will not add up to what we consider a "typical" diet. Identifying differences **between** participants in their usual diets is critical. Errors can occur when we assume too much about what seems "right".

4. Roughly compare the summary frequency questions (Q. 12-14, page 12) responses to the appropriate specific line-items (e.g., fruits) to be sure they are reasonably consistent. Over-reporting on the specific line items is more common than under-reporting. Do not worry about small inconsistencies, only large discrepancies. For example, if on page 12, intake of fruit is

reported to be 1/week but the fruit line items add up to more than 1/day, ask the participant to clarify the line items. The questions on page 12 are used as a data quality check only. The nutrient estimates come from the specific line items--these need to be reasonably accurate.

5. Check "open-ended" foods section (page 9) and be sure that there is no "double reporting" of foods here and on the previous pages. For example, if the participant writes in "plain yogurt", be sure that they did not also report this under "flavored yogurt" within the food items. Code the item where it best fits--in this case, remove what the participant meant as plain yogurt from the "flavored yogurt" line and include it in the open-ended page. Other items can just as accurately be reported either place (e.g., liver). Just be sure they only occur once. **If you are not sure, ask the participant to clarify.**

6. **Coding of "open-ended" foods.** Each food reported on the "open-ended" page must be assigned a two-digit code or must be coded within the main body of the questionnaire (the specific line items). Use Appendix 3 to look up the codes.

Coding questions. Sometimes a question will arise as to how to code a particular food. The most common example of this is use of specially modified products, e.g., fat free cream cheese. Appendix 3 gives specific coding rules that should cover most items. **If an item in question is not included in Appendix 3, call the Coordinating Center (Beth Mayer) so that an appropriate coding rule can be established.** As new coding rules accrue, an updated Appendix 3 will be circulated to the clinics to ensure that coding is standardized across the centers.

Appendix 4 is a checklist that outlines the key steps for checking the Diet Questionnaire when it is returned.

Appendix 1

Administering the ACT Diet Questionnaire by Interview.

Occasionally, you may determine that it is best to administer the questionnaire as an interview. Your introduction to the actual diet interview will depend on the reason for an interview administration over the planned self-administration. Use your general interviewing skills to establish a positive rapport and put the participant at ease. The transition from presenting the form as something for the participant to do at home to something you will go through with them in person must be made gracefully, in a non-judgmental manner. Assure the participant you are happy to administer the questionnaire.

As you go through the form, be sure the participant understands what you are asking, using the same concepts outlined in the instructions in the MOP. **The interview should be 25-35 minutes on average. It is necessary to practice administering the interview in order to learn how to present the information efficiently and to go through the food list efficiently, but without overwhelming the participant or having the participant become bored.**

Some additional, specific points to consider follow:

a. (Cover page) Special diets. We are interested in whether the participant thinks they have modified their usual diet in order to follow one or more of these special diets. These diets may have been recommended by their physician or a nutritionist, but they do not need to have been specifically recommended by a health professional. If a special diet has been recommended to the participant but they have not changed what they would otherwise eat in order to follow the diet, then the answer would be "no", they are not on the diet. It is not necessary to delve into details of compliance to a diet. Just get an assessment from the participant as to whether or not they consider themselves to be on a special diet; i.e., have they changed their food eating habits because of health concerns?

b. (page 1). Instructions for the food items. Keep in mind the reason for administering the questionnaire as an interview, and adapt your review of the instructions accordingly.

Don't get bogged down at this point--this will frustrate the participant. Instead, reassure the participant that they will "get the hang of it" after the first couple of foods.

c. (page 2). Food list. Be particularly attentive as you begin the food list. Based on conversation with the participant, ask a few questions as you go through the first page to verify the information. These "reality-check" questions can often be based on situations of eating, e.g., the fresh fruit last month was terrific, so the participant ate strawberries three times/week as

dessert.

Go through the foods efficiently to avoid the interview taking too long, but maintain a conversational tone and show interest in the participant's responses so that the participant does not become bored and give unreliable information. Throughout, watch the participants for comprehension.

Use the notes on the form placed between categories of foods as verbal cues. These provide important transitions, reminders, and a short break for both of you.

Be sure to go through each food item, even if the participant says they do not eat anything in a particular category. For example, even if a participant says they are a vegetarian, it may turn out that they eat fish occasionally. Use your judgement so as not to frustrate or alienate the participant, but at a minimum, touch on each item briefly and confirm "none".

d. (page 8). Beverage list. Go through these new responses, and read them aloud, emphasizing the last few categories, e.g., up to 6 or more times per day.

e. (page 9). Open-ended foods. Show the participant the list of foods on the page. Emphasize that we are interested in foods consumed **at least once per week** (not less often).

f. Remainder of the form. Based on the participant's style, you may either read responses aloud or sit beside the participant and show them the responses. Either way, be sure the participant understands the range of possible responses. For example, for the fats used in cooking, be sure the participant knows that they may report up to two types of fat, not just one.

On the last page, after noting any other information the participant would like us to know, be sure to thank them for their time.

g. Reviewing the form. Even though you have administered the form in person, you must still review the form according to the guidelines given for the self-administered form. If feasible, it is best to have a different clinic staff person conduct this review. If not, try to give yourself a few minutes break before reviewing the form. Obtain any necessary clarifications/corrections before the participant leaves.

Appendix 2

Summary of Modifications to the original NCI-Health History and Habits Questionnaire

Note: Modifications were taken from the Insulin Resistance Atherosclerosis Study, with goals of facilitating self-administration with minimal staff burden in a diverse study population. "Diverse" here encompasses differences related to geography, ethnicity, and socioeconomic status including education.

1. Re-wording of instructions and questions to accommodate lower education attainment.
2. Addition of foods to the food list. The original questionnaire contained 98 "line items". The ACT Diet Questionnaire has 99 items. Additions were primarily made to enhance sensitivity to potential ethnic and geographic differences. Some original line items were combined to minimize the total number of items. These decisions were made based on similarity of nutrient content of items, prioritizing nutrients of specific importance to ACT.
3. Expansion of the type of fat used in cooking question to include canola and olive oil.
4. A question to ascertain type of fat used in cooking refried beans, useful for Hispanic populations.
5. Revision of the open-ended question designed to ascertain other foods eaten at least once per week to include food items potentially important to ethnic populations, and inclusion of some items from the original list within the line items because of the anticipated frequency of use in Hispanic and African-American populations.
6. Expansion of ascertain of salt intake, including usual use of salt added in food preparation and at the table, sodium-reduced products, and high sodium foods, condiments, and seasonings.
7. Expansion of the nutrient database to include simple and complex carbohydrates as well as several specific fatty acids (omega-3 fatty acids, stearic acid, palmitic acid, trans fatty acids). Nutrient values were obtained using NHANES II and HHANES 24-hour recall databases and the Nutrition Data System (NDS), version 2.3.

Additional information regarding modifications is available in IRAS manuals.

Appendix 3

Specific Coding Rules

For items not listed explicitly on the interview form, coding rules have been developed based on nutrient content of the item in question. Many of these have come up in earlier studies and are listed here. As new food items are encountered in ACT, coding rules will be update. On page 17 are the specific code numbers for selected open-ended foods.

Fruits

Fruits added to cereals. If there is 1/4 cup or more, include the fruit in this section. Otherwise, do not code.

Snack fruit bars, fruit roll-ups, etc. Code as dried fruit.

5-Alive. Code as orange juice.

Vegetables

Bean soup (like black bean soup): Code with "other beans".

Green salad. This codes (automatically) only for lettuce and a few slices of tomato. If a salad is usually topped with other vegetables like garbanzos, peppers, etc. then code these items in their respective lines.

Salad dressing. Remind participant to remember salad dressing on salads (including salad bars) and in items like tuna salad, pasta salad, etc.

Cole slaw. Code with cauliflower, cabbage, and salad dressing

V-8 juice. Code as tomato juice.

Snow peas. Code as peas.

Chard. Code as spinach.

Artichoke. Code as other vegetables

Garlic. Do not code.

Rice cakes. Code as plain rice.

Brown rice, white rice. Code as rice.

Margarine, butter or other fat added to vegetables. This refers to fat added at the table, after cooking. (The type of fat is taken from the question towards the end of the interview)

Unsalted butter or margarine. Code as regular butter or margarine.

Molly McButter or other calorie-free butter flavoring. Do not code.

Meats, poultry, fish, mixed dishes

Shellfish. Include from mixed dishes, including Asian.

Other fish. Include from mixed dishes, including Asian.

Spaghetti. Includes sauces with meat for flavoring and without meat. If meatballs, or a significant amount of meat is included, then add meat under the appropriate meat line.

Pesto sauce or olive oil on pasta. Code as butter on bread or rolls.

Pasta with clam sauce. Code pasta and add small serving shellfish.

Pizza rolls. Code as pizza.

Menudo. Code as beef.

Barbecue. Code as sausage - 2 times the reported frequency.

Pickled Herring. Code as tuna - ½ the reported frequency.

Caviar. Code as shellfish.

Chicarones. Code as - 2 times the reported frequency,

Lean Cuisine. Code components (e.g., chicken, rice, vegetables).

Low-fat frozen entree. Code as regular entree.

T.V. Dinner. Code components (e.g. meatloaf, potatoes, vegetables).

Jerky (beef, chicken) Code as bacon.

Lunch

If a participant reports luncheon meat, probe for some type of bread. Matzo ball soup. code as "other broth-based soup", plus "biscuits, scones, etc".

Slim Fast Cup-A-Soup. Code as broth-based soup.

Breads and snacks

Chips made with safflower or canola oil. code as regular chips.

Blue corn chips. Code as regular chips.

Low-salt chips, including low-salt blue corn chips. Code as regular chips.

Low-salt popcorn. Code as regular popcorn.

Plain popcorn. Code with open-ended foods.

Low-sodium crackers. Code as regular crackers.

Sourdough or French bread. Code as white bread.

Matzo balls. Code as biscuits, scones, etc.

Potato bread. code as white bread.

Unsalted butter or margarine on bread. Code as regular butter or margarine.

Trail mix. Code as half as "salty snacks" and half as "nuts and seeds".

Breakfast

Be sure total amount of cereal makes sense. Cereals are often over-reported by the time several different types are queried.

"Fortified" includes cereals with supplementation to 100% of the RDA for most vitamins. If a cereal is both high fiber and fortified, code as "Fortified".

Eggs. For Eggbeaters or other low-fat egg substitute, code half the reported frequency.

Egg whites only. Do not code.

Bulgur, kasha, oat bran, (cooked) etc. Code as cooked cereals.

French toast. Code as 1 egg and 1 serving bread.

Wheat-germ. Code as high fiber cereal.

Raisin bran. Code as bran cereal.

Sweets

Sugar-free "spreadable fruit". Code as "other fruit" (or add to the specific line item for that fruit if possible) and code only ½ the frequency.

Sweet dim sum. Code as cake doughnuts.

Graham crackers. Code as cookies.

Sherbet. Code as frozen yogurt/ice milk.

NutraSweet fudgesicles or other specialty dairy desserts. code as frozen yogurt/ice milk.

Granola bars, breakfast bars, Power bars. Code as cookies, cake.

"Dietetic" cookies and cakes. Code one-half the servings reported.

Sugar-free jello. Do not code.

Calorie-free candles, mints, gum, etc. Do not code.

Syrup. Code with other candy, jelly, honey, etc.

Weight Watchers Mousse Dessert. Code as frozen yogurt/ice milk.

Weight Watchers Cookies. Code as regular cookies - ½ the reported frequency.

Cracker Jack. Code on cookies/cakes/dessert line.

Non-fat pudding. Code ½ the reported frequency.

Light syrup. code ½ the reported frequency.

Dairy products

Low-fat or diet cheese, including Kraft "lite" cheese. Code ½ the reported frequency.

Low-fat (1% or 2%) cottage cheese. Code as regular cottage cheese.

Non-fat cottage cheese. Code ½ the reported frequency.

Diabetic Ice Cream. code as ½ the reported frequency.

Non-fat Ice Cream. code as frozen yogurt/ice milk.

Beverages

Hot chocolate from a mix. Code as milk (using type of milk used in the hot chocolate) plus small serving of chocolate.

Reduced-calorie hot chocolate from a mix. Code like regular hot chocolate, using skim milk, but code only half the number of servings of chocolate.

Non-alcoholic beer. Code as regular, caffeine free soft drink.

Crystal Light or other calorie-free, unfortified beverage mix. Code as diet soda.

Mocha Mix in coffee. Code as non-dairy creamer.

Evaporated milk in coffee. Code twice the reported frequency.

Other milk substitutes (like LacAid, soy milk). Specify brand and if it is low-fat; and flag for individual review.

Lactose-Free Milk. Code as type of lactose-free milk (whole, 2%,1% skim).

Optifast. Code as open ended food code #22 plus non-fat milk (or whole or 2% milk if specified by the participant.

Evaporated Milk. Code as twice the frequency of milk.

Gatorade. Code as other fortified fruit drink.

Instant Orange Cappucino Coffee (or other flavored coffee mixes). Code as regular or decaffeinated coffee - 2 times the frequency reported, plus sugar in coffee-large and non-dairy creamer-large.

Slim-fast. Code as open ended food code #22 plus non-fat milk.

Hot-chocolate made with water. Code as chocolate plus non-fat milk.

Salt (never, sometimes, always) Salt substitute. Do not code.

Type of fat question

Diet soft margarine. Code as soft margarine.

Vegetable shortening. Code as stick margarine.

If more than 2 types of fat are checked, ask the participant which two they use the most (considering both frequency and amount consumed). If they use all those originally checked about the same amount, call the Coordinating Center (Beth Mayer) for a decision of which 2 to enter (the system only allows 2).

Miscellaneous

Mustard. Do not code.

Tobasco Sauce. Do not code.

Codes for open-ended foods

See next page

01 veal, lamb	** rice cakes
29 goat, duck	
30 pate	23 pudding, rice pudding, bread pudding, custard
36 sushi	39 mellorine
10 Italian sausage, other sausage	* other dairy products
* mixed dish with meat	83 jello
* Mixed dish with chicken	83 sherbet
02 chili without meat (with beans)	** granola bars
** low-fat or low-calorie frozen entree or dinner (for example, Lean Cuisine)	26 other sweets or desserts
	84 plain popcorn (no added fats)
** TV dinner or frozen entree (not diet)	31 sour cream or dips
13 liver	27 plain non-fat yogurt
19 venison	37 olives
03 tofu	34 green chiles, jalapenos
	38 pickles
** egg whites or egg substitutes	33 catsup
** French toast	33 barbecue sauce
21 pancakes, waffles	40 cranberry sauce
** syrup	
71 bran	69 lemon, lime
22*** Instant Breakfast or other liquid meal supplement or fortified diet drinks (Slim Fast, Cambridge, Sego) made with 2% or whole mile	52 jicama
	* any other
24 milkshakes	
** hot chocolate	

* Flag for individual review. Gather as much specific information as possible (brand name, fat content, etc). Code as line item(s)

** See "Specific Interviewing and Coding Rules" and code with the appropriate line item.

***Code 22 for the mix AND add the number of servings of the appropriate type of milk in the line items. Verify that we have not double-counted servings of milk.

NOTE: Each of these codes needs to be verified with the foods programs. Some are new codes.

Appendix 4
Checklist for Review of Completed Questionnaires

Review the completed Diet Questionnaire while the participant is still in the clinic so that clarifications and corrections to the form can be made quickly. This process must be complete prior to data entry in the clinic.

The goal is to identify omissions or errors, NOT to judge the quality of the participant's diet.

1. *Check ID number* : be sure it is correct.
2. *Check for omissions*--skipped foods, missing information. If there are any omissions, attempt to fill out the blank spaces with the participant's help.
3. *Check for very unlikely frequencies*, such as liver twice a day.
4. *Compare the summary frequency questions* (Q. 12-14, page 12) responses to the appropriate of line-items (e.g., fruits) to be sure they are reasonably consistent. The nutrient estimates come from the specific line items--these need to be reasonably accurate.
5. *Check "open-ended" foods section* (page 9) and be sure that there is no "double reporting" of foods here and on the previous pages.
6. *Coding of "open-ended" foods.* Each food reported on the "open-ended" page must be assigned a two-digit code or must be coded within the main body of the questionnaire (the specific line items). Use Appendix 3 to look up the food codes and miscellaneous coding rules.
7. *For any unresolved issues*, call the Coordinating Center (Beth Mayer).

ACT Diet Questionnaire

Clinic Use Only

ID ☐☐☐☐☐☐ Acrostic ☐☐☐☐☐☐

Date Distributed ☐☐/☐☐/☐☐ (Mon/Day/Year) Date Returned ☐☐/☐☐/☐☐ (Mon/Day/Year)

Instructor ☐☐ (staff code) Visit Code ☐☐☐

Participant Name

We would like to know about the foods you most often eat. Please answer the questions at home and bring it with you to your next clinic visit. If you have any questions, please call us at _____. Thank you for your time and effort.

1. How old are you? ☐☐ years

2. Are you a 1☐ man or a 2☐ woman?

3. Are you on any special diet to:

lose weight	1☐ Yes	2☐ No
eat less fat or cholesterol	1☐ Yes	2☐ No
use less salt	1☐ Yes	2☐ No
treat diabetes	1☐ Yes	2☐ No

Acrostic ☐☐☐☐☐☐

4. **This section asks about the foods you usually eat.** We know people don't eat the same foods every day or every week, so please think about what you ate in the last month or so.

   For each food, check how often you ate the food.

   We don't expect you to remember exactly what you ate. The first answer that comes to mind is usually the best choice!

   - Please include foods eaten at home, at restaurants, at work, at homes of friends and family, or any other place.
   - Please do not skip any foods.

   - Please **be careful** which column you put your answer in.

For Example: This person ate rice about two or three times last month, ate peas about twice a week, and usually had a salad every day.

	None	1 Per Month	2-3 Per Month	1 Per Week	2 Per Week	3-4 Per Week	5-6 Per Week	1 Per Day	2+ Per Day
rice	0	1	✔ 2	3	4	5	6	7	8
peas	0	1	2	3	✔ 4	5	6	7	8
green salad	0	1	2	3	4	5	6	✔ 7	8

Acrostic

Please check how often you eat these foods.

TYPE OF FOOD	NONE	1 PER MONTH	2-3 PER MONTH	1 PER WEEK	2 PER WEEK	3-4 PER WEEK	5-6 PER WEEK	1 PER DAY	2+ PER DAY
FRUITS AND JUICES									
apples, applesauce, pears	0	1	2	3	4	5	6	7	8
bananas	0	1	2	3	4	5	6	7	8
cantaloupe, watermelon, other melon	0	1	2	3	4	5	6	7	8
oranges, grapefruit	0	1	2	3	4	5	6	7	8
peaches, apricots, nectarines (canned, frozen, or dried)	0	1	2	3	4	5	6	7	8
any other fruit (grapes, strawberries, peaches, fruit cocktail, apricots, persimmons, etc)	0	1	2	3	4	5	6	7	8
dried fruits, including raisins, prunes, figs	0	1	2	3	4	5	6	7	8
orange juice or grapefruit juice	0	1	2	3	4	5	6	7	8
other fruit juice including fortified fruit drinks, Hi-C, Kool-aid, cranberry juice, apple juice, grape juice	0	1	2	3	4	5	6	7	8
VEGETABLES AND SIDE DISHES									
string beans, green beans	0	1	2	3	4	5	6	7	8
green peas	0	1	2	3	4	5	6	7	8
refried beans (not including those in burritos, etc)	0	1	2	3	4	5	6	7	8
other beans such as pintos, black eyed peas, black beans, garbanzos, baked beans, or lentils	0	1	2	3	4	5	6	7	8
corn, posole, chicos	0	1	2	3	4	5	6	7	8
acorn or butternut squash	0	1	2	3	4	5	6	7	8
tomatoes, tomato juice, chopped tomatoes, pico de gallo	0	1	2	3	4	5	6	7	8

Acrostic

TYPE OF FOOD	NONE	1 PER MONTH	2-3 PER MONTH	1 PER WEEK	2 PER WEEK	3-4 PER WEEK	5-6 PER WEEK	1 PER DAY	2+ PER DAY
salsa picante, taco sauce	0	1	2	3	4	5	6	7	8
broccoli	0	1	2	3	4	5	6	7	8
cauliflower, brussel sprouts, cabbage, sauerkraut	0	1	2	3	4	5	6	7	8
spinach, mustard greens, turnip greens, collards, kale	0	1	2	3	4	5	6	7	8
carrots, or mixed vegetables containing carrots	0	1	2	3	4	5	6	7	8
green salad	0	1	2	3	4	5	6	7	8
diet salad dressing, diet mayonnaise (including on sandwiches)	0	1	2	3	4	5	6	7	8
regular salad dressing, mayonnaise, tartar sauce (including on sandwiches)	0	1	2	3	4	5	6	7	8
French fries, fried potatoes	0	1	2	3	4	5	6	7	8
other potatoes, such as boiled, baked, mashed, potato salad	0	1	2	3	4	5	6	7	8
any other vegetable, including cooked onions, zucchini squash, asparagus, sweet peppers, bok choy, okra, etc.	0	1	2	3	4	5	6	7	8
rice (white, brown, or wild)	0	1	2	3	4	5	6	7	8
pasta, noodles, fideo, couscous (without cheese or tomato sauce)	0	1	2	3	4	5	6	7	8
butter, margarine, or other fat on vegetables, potatoes, rice, etc. at the table	0	1	2	3	4	5	6	7	8

Acrostic

TYPE OF FOOD	NONE	1 PER MONTH	2-3 PER MONTH	1 PER WEEK	2 PER WEEK	3-4 PER WEEK	5-6 PER WEEK	1 PER DAY	2+ PER DAY
MEATS, FISH, POULTRY, AND MIXED DISHES (Reminder: Please include foods eaten at home and away from home.)									
hamburgers, cheeseburgers, meat loaf, picadillo, carne guisada (asada)	0	1	2	3	4	5	6	7	8
beef (steaks, roasts, etc. including on sandwiches)	0	1	2	3	4	5	6	7	8
beef stew or pot pie with carrots or other vegetables	0	1	2	3	4	5	6	7	8
pork, including chops, roasts or ribs	0	1	2	3	4	5	6	7	8
ham, ham hocks	0	1	2	3	4	5	6	7	8
fried chicken	0	1	2	3	4	5	6	7	8
chicken, turkey or wild fowl (roasted, broiled, or ground, including on sandwiches)	0	1	2	3	4	5	6	7	8
chicken or turkey stew or pot pie with carrots or other vegetables	0	1	2	3	4	5	6	7	8
fried fish or fish sandwich	0	1	2	3	4	5	6	7	8
canned tuna fish, salmon, sardines (including tuna salad, tuna casserole)	0	1	2	3	4	5	6	7	8
shell fish (shrimp, lobster, crab, oysters, mussels, etc.)	0	1	2	3	4	5	6	7	8
other broiled or baked fish	0	1	2	3	4	5	6	7	8
gravies made with meat drippings or white sauce	0	1	2	3	4	5	6	7	8
pizza	0	1	2	3	4	5	6	7	8
spaghetti, lasagna, other pasta with tomatoes or tomato sauce, spanish rice	0	1	2	3	4	5	6	7	8
mixed dishes with cheese (including macaroni and cheese, chile rellenos, cheese quesadillas, quiche)	0	1	2	3	4	5	6	7	8

Acrostic

TYPE OF FOOD	NONE	1 PER MONTH	2-3 PER MONTH	1 PER WEEK	2 PER WEEK	3-4 PER WEEK	5-6 PER WEEK	1 PER DAY	2+ PER DAY
burritos, including breakfast burritos, soft taco with flour tortillas	0	1	2	3	4	5	6	7	8
enchiladas, tamales, tacos, tostadas, chalupas, other mexican dishes with corn tortillas, including nachos with chili and cheese	0	1	2	3	4	5	6	7	8
red chile con carne, green chile con carne (without beans)	0	1	2	3	4	5	6	7	8
LUNCH ITEMS (Please include anytime you eat these foods, not just at lunch.)									
low fat hot dogs, bologna (include pork, beef, turkey)	0	1	2	3	4	5	6	7	8
regular hot dogs (include pork, beef, turkey)	0	1	2	3	4	5	6	7	8
regular bologna, salami, spam, other lunch meats (excluding ham)	0	1	2	3	4	5	6	7	8
vegetable and tomato soup (including vegetable beef, minestrone)	0	1	2	3	4	5	6	7	8
other broth-based soups (including caldo, tortilla soup)	0	1	2	3	4	5	6	7	8
cream soups	0	1	2	3	4	5	6	7	8
BREAD, SNACKS, SPREADS									
white bread (including sandwiches, hamburger or hotdog buns, bagels, rolls, pita bread, English muffin)	0	1	2	3	4	5	6	7	8
dark bread (including whole wheat, rye, pumpernickel, other high-fiber bread)	0	1	2	3	4	5	6	7	8
Biscuits, scones, croissants, muffins, fry bread (popover), hush puppies	0	1	2	3	4	5	6	7	8

Acrostic

TYPE OF FOOD	NONE	1 PER MONTH	2-3 PER MONTH	1 PER WEEK	2 PER WEEK	3-4 PER WEEK	5-6 PER WEEK	1 PER DAY	2+ PER DAY
flour tortilla (by itself, not in burritos, etc)	0	1	2	3	4	5	6	7	8
corn tortilla (by itself, not in enchiladas, etc)	0	1	2	3	4	5	6	7	8
corn bread, corn muffins	0	1	2	3	4	5	6	7	8
snacks such as crackers, potato chips, corn chips, tortilla chips, pretzels, popcorn	0	1	2	3	4	5	6	7	8
nuts and seeds, including peanuts, peanut butter, pine nuts, sunflower seeds	0	1	2	3	4	5	6	7	8
margarine on bread or roll	0	1	2	3	4	5	6	7	8
butter on bread or rolls	0	1	2	3	4	5	6	7	8
BREAKFAST FOODS (Please include anytime you eat these foods, not just at breakfast.)									
high fiber, bran or granola cereals, shredded wheat	0	1	2	3	4	5	6	7	8
highly fortified cereals, such as Product 19, Total, or Most	0	1	2	3	4	5	6	7	8
cold cereals such as Corn Flakes, Rice Krispies, Frosted Flakes, Fruit Loops	0	1	2	3	4	5	6	7	8
cooked cereals (including oatmeal, cream of wheat, grits)	0	1	2	3	4	5	6	7	8
eggs (include omelettes, fritatta)	0	1	2	3	4	5	6	7	8
low-fat bacon, sausage	0	1	2	3	4	5	6	7	8
bacon, sausage, chorizo	0	1	2	3	4	5	6	7	8

Acrostic

TYPE OF FOOD	NONE	1 PER MONTH	2-3 PER MONTH	1 PER WEEK	2 PER WEEK	3-4 PER WEEK	5-6 PER WEEK	1 PER DAY	2+ PER DAY
SWEETS									
ice cream	0	1	2	3	4	5	6	7	8
frozen yogurt, low-fat ice cream	0	1	2	3	4	5	6	7	8
doughnuts, cookies, cakes, pastry, brownies, sopapillas, pan dulce	0	1	2	3	4	5	6	7	8
pies	0	1	2	3	4	5	6	7	8
chocolate including Hershey's kisses, M&M'S, chocolate candy bars	0	1	2	3	4	5	6	7	8
other candy, jelly, honey, brown sugar, jams, or molasses, including on cereal, bread or crackers	0	1	2	3	4	5	6	7	8
DAIRY PRODUCTS									
cottage cheese, ricotta cheese	0	1	2	3	4	5	6	7	8
cheese (cheddar, American, cream cheese, parmesan, Velveeta, other cheeses or cheese spreads; including on sandwiches or as snacks)	0	1	2	3	4	5	6	7	8
low-fat flavored yogurt (2% or non-fat)	0	1	2	3	4	5	6	7	8
flavored yogurt (regular, from whole milk)	0	1	2	3	4	5	6	7	8

Acrostic

BEVERAGES **Note: Your choices for how often you drink these beverages are different. Please read the new choices carefully. You may report up to 6 or more times per day.**

TYPE OF BEVERAGE	NEVER OR LESS THAN 1 PER MONTH	1-3 PER MONTH	1 PER WEEK	2-4 PER WEEK	5-6 PER WEEK	1 PER DAY	2-3 PER DAY	4-5 PER DAY	6+ PER DAY
whole milk and beverages with whole milk (do not count the milk you put on your cereal)	0	1	2	3	4	5	6	7	8
2% milk and beverages with 2% milk (do not count the milk you put on your cereal)	0	1	2	3	4	5	6	7	8
skim milk, 1%, or buttermilk, and beverages made with these (do not count the milk you put on your cereal)	0	1	2	3	4	5	6	7	8
regular soft drinks (including colas, 7-up, lemonade, sweetened mineral water, etc) Do not count diet soft drinks.	0	1	2	3	4	5	6	7	8
beer	0	1	2	3	4	5	6	7	8
wine	0	1	2	3	4	5	6	7	8
liquor or mixed drinks	0	1	2	3	4	5	6	7	8
coffee or tea, regular or decaffeinated	0	1	2	3	4	5	6	7	8
sports drinks such as Gatorade, Power-Aid	0	1	2	3	4	5	6	7	8
non-dairy creamer in coffee or tea (including flavored creamers)	0	1	2	3	4	5	6	7	8
milk in coffee or tea	0	1	2	3	4	5	6	7	8
cream or half-and-half in coffee or tea	0	1	2	3	4	5	6	7	8
sugar in coffee or tea (do not count artificial sweeteners)	0	1	2	3	4	5	6	7	8

Acrostic ☐☐☐☐☐☐

5. We did not have room to list all of the different foods that people eat. On this page, please list <u>all foods that you eat at least once per week</u> that we missed. Here are some foods you can think about.

veal, lamb, goat
liver, chicken livers
game, including venison, rabbit
casseroles with meat (describe)
casseroles with chicken (describe)
chile without meat
low-fat or low-calorie frozen entree or dinner ("Lean Cuisine" type)
TV dinner or frozen entree (not diet)
fat free cheese
pancakes, waffles, French toast, syrup
Instant Breakfast supplement
fortified diet drinks (Slim Fast, Cambridge, Sego, etc.)
milkshake
hot chocolate
pudding, rice pudding, bread pudding, custard
plain, non-fat yogurt
avocado, guacamole
cole slaw
Chinese food
Thai or Vietnamese food
sour cream, dips
tofu
green chiles, jalapenos
pickles
olives
catsup or barbecue sauce
any other (describe)

FOOD (PLEASE DESCRIBE)	FOOD CODE (CLINIC USE ONLY)	AVERAGE USE LAST MONTH					
		1 PER WEEK	2 PER WEEK	3-4 PER WEEK	5-6 PER WEEK	1 PER DAY	2+ PER DAY
		3	4	5	6	7	8
		3	4	5	6	7	8
		3	4	5	6	7	8
		3	4	5	6	7	8
		3	4	5	6	7	8
		3	4	5	6	7	8
		3	4	5	6	7	8
		3	4	5	6	7	8

Acrostic ☐☐☐☐☐☐

6. These questions are about vitamin pills. Please give an answer for each kind of vitamin pill in the questions below.

	NEVER	LESS THAN ONCE PER WEEK	ONCE A WEEK OR MORE
How often do you take a "one-a-day" type vitamin pill?	0	1	2
How often do you take a "stress tab" or theragram-type vitamin pill?	0	1	2
How often do you take extra vitamin E?	0	1	2
How often do you take extra vitamin C?	0	1	2
How often do you take extra vitamin A or beta-carotene?	0	1	2
How often do you take potassium pills?	0	1	2
How often do you take any other vitamin or mineral pills? Please describe: _____	0	1	2

7. Please check (√) the answer that best describes your eating habits.

	SELDOM/ NEVER	SOMETIMES	OFTEN/ ALWAYS
How often do you eat the skin on chicken?	1	2	3
How often do you eat the fat on meat?	1	2	3
How often do you add salt, seasoned salt (garlic salt, celery salt, etc), or meat tenderizer to your food when cooking?	1	2	3
How often do you add salt to your food at the table? How many shakes do you use? ☐	1	2	3

Acrostic ☐☐☐☐☐☐

The next few questions are about the fat used in cooking the foods you eat.
If someone else usually does the cooking, please answer as best you can.

8. How often is fat or oil used in cooking the foods you eat? For example, in frying eggs, meat or vegetables?

None	1 Per Month	2-3 Per Month	1 Per Week	2 Per Week	3-4 Per Week	5-6 Per Week	1 Per Day	2+ Per Day
0	1	2	3	4	5	6	7	8

9. What kind of fat or oil is used in cooking? (You may select up to two choices)

1 ☐ Don't know 2 ☐ Soft margarine 3 ☐ Stick margarine 4 ☐ Butter 5 ☐ Lard, fatback, bacon fat
6 ☐ Pam or no oil 7 ☐ Olive oil 8 ☐ Canola oil 9 ☐ Other oil (such as corn, sunflower, or vegetable)

10. If you eat refried beans, what kind of fat or oil is used in cooking the beans? (You may select up to two choices)

1 ☐ Don't know/Don't eat beans 2 ☐ Soft margarine 3 ☐ Stick margarine 4 ☐ Butter 5 ☐ Lard, fatback, bacon fat
6 ☐ Pam or no oil 7 ☐ Olive oil 8 ☐ Canola oil 9 ☐ Other oil (such as corn, sunflower, or vegetable)

11. What kind of fat do you add to vegetables, potatoes, etc. at the table? (You may select up to two choices)

1 ☐ Don't add fat 2 ☐ Soft margarine 3 ☐ Stick margarine 4 ☐ Butter 5 ☐ Half butter, half margarine
6 ☐ Lard, fatback, bacon fat 7 ☐ Olive oil 8 ☐ Canola oil 9 ☐ Other oil (such as corn, sunflower, or vegetable)

Acrostic

	None	1 Per Month	2-3 Per Month	1 Per Week	2 Per Week	3-4 Per Week	5-6 Per Week	1 Per Day	2+ Per Day
12. Not counting salad or potatoes, about how often do you eat vegetables?	0	1	2	3	4	5	6	7	8
13. About how often do you eat cold cereal?	0	1	2	3	4	5	6	7	8
14. Not counting juices, how often do you eat fruit?	0	1	2	3	4	5	6	7	8

15. Please check whether or not you usually use low-salt foods.

	Don't Use at All	Regular Salt	Low Salt
Canned soups	0	1	2
Canned or frozen vegetables	0	1	2
Lunch meats like hotdogs, ham, bologna, etc.	0	1	2
Snacks like pretzels, potato chips, corn/tortilla chips, crackers, popcorn	0	1	2

Acrostic ☐☐☐☐☐☐

Thank you very much for answering these questions about how you eat. If there is anything else you would like us to know, please tell us in the space below.

Comments: _____

_____

_____

_____

Review required for coding food items?

1 ☐ Yes 2 ☐ No

↓

Review Completed?
1 ☐ Yes

CLINIC USE ONLY

Editor ID ☐☐☐

Data Entry ID ☐☐☐

1st Key Punch ☐☐/☐☐/☐☐ (Mon / Day / Year)

2nd Key Punch ☐☐/☐☐/☐☐ (Mon / Day / Year)

D.3 HRQL OUTCOMES WITH PHYSICAL ACTIVITY AND PSYCHOSOCIAL MEDIATORS (IFA)

I.1 Health-Related Quality of Life (HRQL)

Health-related quality of life (HRQL) is a multi-dimensional concept which includes, as its core, 1) physical health including physical functioning, symptoms, perceived health, and energy; 2) social functioning; and 3) emotional well-being, including depressive affect, self-perception. Other dimensions of HRQL of interest depend upon the nature and characteristics of the disease, syndrome, or health state, and potential effects from the intervention itself.

Beyond traditional interest in morbidity and mortality, HRQL outcomes can provide important information used to evaluate the effectiveness of health interventions on outcomes valued by participants, such as daily functioning and psychological outlook.

Social functioning refers to one's ability to maintain social relations (e.g., visiting friends, entertaining at home) and is distinct from social support and social integration in that it refers to behaviors rather than perceptions of available assistance. *Physical functioning* refers to a range of activities from the basic demands of daily living (e.g., eating, dressing, bathing), to more vigorous functioning (e.g., walking long distances, participating in sports). Emotional health of an individual is often characterized in negative terms in the HRQL literature (e.g., depression, anxiety), but can also include concepts such as hopefulness and optimism. *Personal productivity* refers to both paid (job status) and non-paid (volunteer) work. Measures of HRQL typically include an assessment of perceived health and overall life satisfaction.

The concept of Health-related Quality of Life (HRQL) is recognized by many researchers, clinicians, and the public as an important component in the assessment of the impact of various health conditions and their treatment on patients. The inclusion of HRQL in clinical research serves three important functions:

A) It allows the investigator to characterize the impact of a given condition or disease in terms of "clinically relevant human attributes."

B) HRQL data can tell us how HRQL relates, prospectively, to the progression of a condition or disease. That is, HRQL dimensions may be independent predictors of important clinical outcomes such as treatment adherence, morbidity and condition severity, and mortality.

C) HRQL provides data on how treatment impacts the daily functioning of the individual.

I.2 HRQL and Physical Exercise and Activity Interventions

While significant effects of physical activity on HRQL have been shown in controlled settings, often with highly selected subjects, substantially less is known with respect to sedentary persons

selected from general medical care settings, and of a broad age range as planned in ACT. Reports in the literature and experience among ACT investigators suggests that several benefits in well-being from increased cardiorespiratory fitness and physical activity may be achieved in ACT. These include: improved psychological mood (less depressive affect and anxiety), perceived vigor and energy, and enhanced role functioning, self-rated health, life satisfaction and outlook.

I.3 Description of HRQL Measures

The measures implemented in ACT are a combination of generic and population-specific instruments designed for particular use with general population samples, relatively free of major disease and illnesses, and for persons sedentary in lifestyle. They comprise several scales and subscales each yielding a summary score. Instruments were chosen based on the following qualities: prior use in exercise interventions, demonstrated adequate validity and reliability, brief in length, expected responsiveness to changes in physical fitness, and acceptable or relevant to persons from a wide range of age and SES or ethnic backgrounds. Based on these criteria, the ACT HRQL Working Group selected the scales shown in Table 1, below.

The time frame for recall is the 'last four weeks' for most HRQL measures except for psychological functioning scales which use a 'past week' period.

The following is a brief description of each instrument. Please refer to the HRQL Questionnaire to view the actual items included in each subscale:

Bed Days and Inactive Days (Items #1, a, b c). These states represent reduced functioning in normal activity due to feelings of malaise and illness. This aspect of functioning is measured with three items taken from the CDC Behavioral Risk Surveillance Survey. Physical and psychological benefits known to occur from exercise are expected to result in fewer inactive days due to health in ACT. past week' time frame.

Table 1

Instrument	No. Items	Prediction/Outcome	Domains Measured
CDC Bed Days and Inactive Days	3	Outcome	Reduced functioning in normal activity due to health, fatigue
MOS General Health Perceptions	2	Outcome	Physical health
Ladder of Life	1	Outcome	Global life satisfaction
Perceived Quality of Life Scale (PQOL) modified	15	Outcome	Satisfaction with: physical health, social contacts, sexual activity, work status, leisure time activities
Satisfaction with Physical Fitness	8	Outcome	Satisfaction with: muscle strength, stamina, muscle tone, energy, physical ability, shape
Cohen Psychological Stress Scale	14	Outcome	General psychological stress
MOS Pain Items	2	Outcome	Bodily pain, activity limitations
Exercise Induced Feeling States (EFI)	12	Outcome	Positive affect and mood states
Beck Depression Inventory (BDI)	21	Outcome	Level of depressive affect

General Health Measures (Items #2,3). Self-appraised general health is a standard HRQL outcome from a health intervention. These items are of scientific interest because they are known to predictors medical care use, productivity, and health complications which may interact with lifestyle-based interventions (i.e., compliance, and physical functioning).

Overall Life Satisfaction (Item #4). This item provides a global rating of how satisfied the individual is with their life. This item is used both to characterize the study sample, but also to determine the extent that the intervention may shift the level of overall life enjoyment.

The Perceived Quality of Life Scale (PQOL) (Items #5-19). The PQOL consists of 14 items measuring life satisfaction in major life domains and pursuit of activities. The PQOL was selected to describe perceived life satisfaction pre-intervention, and to assess shifts in satisfaction with daily functioning resulting from increased physical activity.

Satisfaction with Physical Fitness (Items #20-27). Satisfaction with body appearance, muscle tone, strength, energy, weight, and endurance are assessed using 9 items. This instrument was developed and tested for an exercise intervention in deconditioned adults. This scale is included to

describe the pre-intervention level of satisfaction with fitness, and to document the changes in satisfaction with fitness (separate from satisfaction with role functioning) resulting from the intervention.

Cohen Psychological Stress Scale (Items #28-41). This instrument measures current burden of psychological stress, including anxiety, lack of control over life situations, and coping with stress. While improved physical fitness and psychological affect are not expected to reduce stimuli that may produce stress (i.e., life demands) or personality traits (i.e., hostility), there is evidence that self-control and coping skills can be enhanced through lifestyle interventions which promote well-being. Reductions in total stress burden from ACT would be scientifically important since psychosocial stress is associated with hypertension and cardiovascular disease.

MOS SF-36 Pain subscale (Items #35,36). Two items assessing bodily pain were included from the widely used MOS SF-36 Health Survey. Together these items assess intensity of bodily pain and extent of interference with normal activities from pain.

Exercise Induced Feeling States (EFI) (Items #37a-l). This instrument describes a broader range of mood states than measured in depression inventories or screeners, yet is much briefer than more widely used measures such as the POMS. It includes positive feeling states such as energy, vigor, happy, and revived. Beyond mitigating depressive affect, the ACT interventions are hypothesized to increase positive feelings.

The Beck Depression Inventory (BDI) (Items #38-58). The BDI consists of 21 statements measuring the extent of depressive affect. It has been extensively used in clinical research. Its use with exercise interventions at Stanford has detected significant improvements in psychological well-being from physical activity interventions.

I.4 Description of Mediators: Influences on Activity. Act is employing a series of self-report measures to be used as mediators. These are grouped under the general title, *influences on activity*, and include, in order of appearance in the questionnaire: (a) self-efficacy (confidence), (b) processes, (c) deciding about exercise, (d) environmental factors, and (e) stages of change. The information provided in Appendix H (FORMS AND INSTRUCTIONS) apply to the completion of these measures. Further there are a series of methodological considerations pertinent to the psychological and social questionnaires. These are described in detail below.

II. Administration of the HRQL and IFA Questionnaires

In this study, the HRQL and IFA questionnaire will be completed by the participants (i.e., self-administered). However, there may be particular circumstances when interviewer administration in the clinic or by telephone is required. Although it is not anticipated that these special situations will arise often, there may be instances in which factors such as poor eyesight, poor hand-eye coordination, ill health, weather, or conflicting time commitments will necessitate a change in how the questionnaire is administered. Therefore, we include suggestions in this manual to assist the clinic staff in handling these situations, and also provide instructions for interviewer-administration of the instruments.

The HRQL and IFA questionnaires are to be completed for the SV2 and FU6 and FU24 periods. The methods used for the screening data collection point are not identical to those used for follow-up:

II.1.a SV1. After completing the SV1 visit, the participant should be handed the HRQL and Influences on Activity (IFA) questionnaires, and verbally instructed about how to complete the forms, and informed that they must be returned at the upcoming SV2 appointment. To achieve a high, if not complete, return rate of the forms, a reminder to bring in the forms should be included in the telephone call or postcard reminder to the participant.

II.1.b FU6 and FU24. For the repeat assessments of HRQL and IFA, verbal instructions on form completion will not be provided. Instead, a package containing the forms and cover letter will be mailed to the participant approximately 2-weeks prior to the scheduled follow-up measurement clinic visit. An example of the cover letter communication is provided below:

<< Date here>>

Dear << participant name>>

Enclosed in this envelope are the Quality of Life, and Influences on Activity questionnaires for you to complete in your home before your next scheduled ACT follow-up visit. Please be sure to bring the completed questionnaires with you when you come to your ACT visit, which is scheduled for << date of visit >>. Should you have any questions about this or anything else about ACT please call << name of contact person >> for help.

Thank you for taking the time to complete these questionnaires, we look forward to seeing you on your upcoming visit.

<< signed by ACT staff person>>

In addition, a reminder to bring in completed quality of life (HRQL) and influences on activity (IFA) questionnaires should be included in a telephone call or postcard appointment reminder system implemented.

II.2 Specific Guidelines

The way in which a questionnaire is administered to a study participant can affect the validity of the responses to the questionnaire items. For this reason, it is important to adhere to the following guidelines in administering study questionnaires.

Step 1: Review the Study Protocol It is important that the clinic staff person review the protocol for distributing, instructing and reviewing the HRQL and IFA questionnaires to be certain of the correct procedures to follow. This is particularly important in clinics where a small number of participants are to be recruited and/or where more than one clinic staff member will be administering the questionnaires to the study participants.

Step 2. Questionnaire Distribution at SV1. The individual distributing the questionnaire plays a critical role in the process of data collection. There is the potential for the quality of the participant's responses to be affected by the general attitudes and actions of the interviewer. A relaxed and friendly manner puts the participant at ease and conveys the message that the interviewer considers

the questionnaire an important part of the study.

Time Burden. Pilot tests of the HRQL questionnaires have revealed that approximately **10 to 12 minutes** is required to complete all the HRQL forms. An additional **15 to 20** minutes may be needed to complete the IFA questionnaire. It is helpful to inform participants of the total time commitment of approximately one-half hour so that they may plan a time to fill out these forms, and so that participants may realize that, despite a possible appearance of being lengthy, these forms are not likely to impose a substantial time burden to complete. The staff person should use neutral or positively worded communication to convey time information, such as: "on average, these forms take about 10 to 12 minutes to complete" or "in our other studies, we've found that these forms take about 10 to 12 minutes to complete". Statements like "these forms won't take as long as you think", or "these really aren't that difficult to complete" may be perceived as indifference or lack of concern by the staff person.

Purpose. Participants should be told that these questionnaires ask about their recent physical and social well-being, and mood (HRQL) as well as their past and current physical activity (IFA).

Format. Staff should review the response format with the participant, and highlight with a marking pen places on questionnaire when the format changes. This can be accomplished by highlighting the specific time reference (e.g., the phrase "in the last month" would be highlighted).

Item # 1 a-c: write in the number of days in the blank. If zero days were spent in the state specified enter '0'.

Item #4: this is a ladder format. Check the box which corresponds to the number on the scale that represents your feeling or viewpoint.

Items #5 - 43: these items refer to your life or your feelings over the past FOUR WEEKS.

Items #44 - 58: these items refer to your life or your feelings over the last WEEK only.

It is possible that for some item responses, the subjective appraisals and descriptors provided to evaluate a concept as complex as quality of life may not exactly fit the experiences or feelings of the participant. To prevent respondent confusion and potentially skipped items, participants should be

instructed to "choose the one response that most **closely** fits your view or experience." Similarly, if a respondent feels unsure about the intended meaning or definition of an item or word, he/she should use the meaning or definition they would INFER for the word or sentence in question. Thus, each respondent should interpret the items or questions from their own viewpoint, understanding, or expectations.

Completeness. Remind participants that they should respond to each question. The only time a blank or unanswered item response should occur is if the participant refuses or wishes not to answer a particular item for some reason. Point out however, that you believe that they will find the questions nonthreatening, and easy to complete.

Finally, ask participants if they have any questions about the questionnaire.

Step 3: Reviewing the Questionnaires at SV2, FU6 and FU24: An important role of the questionnaire administrator/reviewer is to examine the completed surveys when the participants hand them in upon their return visit (SV2, FU6 and SV24). If the participant has skipped questions and/or filled the questionnaire out incorrectly, the staff person needs to discuss this with the participant before he/she leaves the office. The review process should occur in an office or clinic setting which insures the privacy of the participants' responses and comments.

Strategies. Persons who have filled out the forms incorrectly should be asked to complete the questionnaires in the appropriate manner. If an item is missing or incomplete, the interviewer should ask the participant if he/she noticed the item and meant to leave it blank or simply overlooked it. If the participant declines to provide the information when it is brought to their attention, the interviewer should accept the participant's refusal without comment. There are two major strategies for reviewing the HRQL forms: a) The participant is present during the review. In this case, the reviewer should explain the purpose of this step by saying "I will need to quickly review your questionnaire to make sure that all of the marks are in the right place for our coders, and in case you had any questions about any of the items or responses." and b) while the participant is busy with other ACT activities during the visit. In this case, if any comments or questions are noted by the participant on the HRQL form, or if an item is left unanswered, the reviewer should discuss this with the participant before he/she leaves the site. The reviewer should offer " (greeting) I am supposed to quickly review all of the questionnaires as they are handed in to make sure that all of the marks are in the right place for our coders, and in case there were any questions about any of

the items or responses. I noticed that you .... ".

As with any interview technique, all communications and discussion about the HRQL forms should be conducted with a neutral voice tone quality, so as to place the participant at ease.

Staff reviewing the HRQL and IFA forms should be thoroughly familiar with the questionnaire before it is given to the participants. It is difficult to give assistance to participants without a working knowledge of the structure and content of the questionnaire. In answering questions, survey administrators must be careful not to bias the participants' responses. The data collector may read a question to a respondent, define terms, indicate where the answer is to be marked, etc., but they should not paraphrase questions unless it is absolutely necessary. It is too easy to inadvertently alter the meaning of a question in this way. In general, most of the participant's questions can be handled by reminding him/her to follow the directions on the questionnaire, or simply by rereading the statement to the respondent. The interviewer should read the statement exactly as it is written. The administrator should remind the participant that he/she should answer the question with the response that he/she believes is more true for him/her at the present time.

If a respondent tells the data collector which answer he/she has selected, the interviewer should refrain from reacting to that answer or conveying either approval or disapproval of the participant's choice. The interviewer may indicate to the participant that there are no right or wrong answers to these question, and that the choice is the respondent's as to how to respond to the statement. The survey administrator should never help the participant decide how to mark a questionnaire item.

Step 4: Thank the Participants Always remember to thank the participant for his/her time and interest in completing the questionnaire. Escort the participant back to his/her family or the waiting room, if necessary.

III. Storing the Questionnaires

Once a questionnaire has been completed by a participant and edited by the survey administrator, the questionnaire should be stored in a secure place within the measurement site or clinic. Information collected for research purposes can only be shared with other members of the research team, and the participants' privacy must be protected at all times. The data collector should never discuss any of the responses with anyone who is not directly involved in the study.

IV. Missing Data

Item Responses. When missing items responses are identified, and are permanently missing by respondent choice (i.e., refusal) the item should be coded according to protocol listed under missing data, in Appendix H of the MOP.

Forms. If a participant forgets to bring in his/her completed HRQL and IFA forms on the designated measurement clinic visit date one of three options may be used to collect the questionnaire data:

1) The ideal strategy, time permitting, is to have the participant complete the forms during the visit, before the treadmill testing. Treadmill testing may produce fatigue and potentially heighten the participants feelings regarding fitness and health, and feeling states described in the questionnaire. The HRQL/IFA questionnaire can be completed at one sitting, or during waiting periods over several procedures prior to treadmill testing.

2) Provide the participant with another copy of the HRQL/IFA questionnaire along with a postage paid envelope addressed to the ACT Measurement Clinic site. These materials should be present at each Measurement site; extra forms will be provided by the Coordinating Center for this purpose. The participant must agree to take the forms home, complete, and return them by mail within 5 days. This initial instance of a missing form should be documented.

3) A third choice may be to administer the form over the telephone or face-to-face. This may be necessary if the participant has not completed the form for reasons of physical, visual, or literacy problems.

V. Guidelines for Interviewer Administered Forms

The HRQL/IFA Questionnaire is designed to be self administered, but can also be used in an interview format if necessary. The following procedures are provided should the need to conduct an interview arise.

V.1 Interviewer Skills

The interviewer plays a critical role in the process of data collection. It is important that the interviewer does not influence the participant's response to any question. Since more than one interviewer may be administering the questionnaires, the following guidelines should be used to standardize the administration so that each interviewer administers the questionnaires in the same way. Variability in administration of the instruments introduces bias in data collection and reduces the quality of the data.

In the ideal situation, the interviewer's presence should not influence the participant's perception or response to a question, and different interviewers should be able to obtain the same responses from the same participant. Recognizing the limitations inherent in this ideal, there are methods that can enhance the neutrality of the interviewer. Interviewers should not provide either verbal or non-verbal responses that could influence the participant's responses. For example, an interviewer should not convey surprise, pleasure, or disapproval to any answer. The interviewer role is to obtain honest, uninfluenced responses to the questions.

The interviewer should be thoroughly familiar with the questionnaire before interviewing the first participant. This will ensure that the interviewer can easily address the participants' questions or concerns. Inexperienced interviewers should also practice completing an interview by practicing with someone who is pretending to be a participant. This will help to reduce the mechanical style that sometimes results from reading unfamiliar material.

It is important that the interviewer conveys a sense of impartiality. He or she should be gracious and adaptable to all participants regardless of whether their dress, appearance, style of speech, or personal preferences are consistent with the interviewer's values and preferences.

There are no right or wrong answers on the HRQL/IFA questionnaire. It is often helpful to tell this to the respondent if uncertainty or hesitation is observed. It is important to put the respondent at ease.

V.2. Specific Guidelines

Follow Steps 3-5 of the self-administration of the questionnaire above.

VI. Scoring the HRQL and IFA Questionnaires

HRQL. The HRQL subscales and items are listed above, and presented separately on the HRQL form. Subscale scores are obtained by calculating an unweighted sum of the item responses. The Beck Depression Inventory has cut points, measuring depth of depression, that have been commonly used in research. It is the only instrument in the HRQL battery for which threshold scores have been empirically established. A BDI score of $\leq$ 10 has been used to 'not depressed', 11 to 17 to indicate 'mildly depressed', 18-22 moderately depressed, and $\geq$ 23 severely depressed.

Flag. A Beck Depression Inventory (BDI) score greater than 17 (moderate depression), or if BDI item #46 (suicidal ideation) is affirmed (response 1, 2, or 3) will initiate safety monitoring procedures as described in the ACT Protocol.

Influences on Activity (IFA). Each of the IFA subscales are presented separately in the questionnaire. For each cluster of items representing the subscales, a simple summary score should be obtained.

HRQL Questionnaire

IFA Questionnaire

Data Entry Code ☐☐

ACTIVITY COUNSELING TRIAL

HEALTH RELATED QUALITY OF LIFE QUESTIONNAIRE

INFLUENCES ON ACTIVITY QUESTIONNAIRE

Clinic Use Only

ID ☐☐☐☐☐☐ Acrostic ☐☐☐☐☐☐

Date Distributed ☐☐/☐☐/☐☐ (Mon Day Year) Date Returned ☐☐/☐☐/☐☐ (Mon Day Year)

Reviewed by ☐☐ (staff code) Visit Code ☐☐☐

This booklet contains two questionnaires. One will ask your opinions about your health and daily activities, the other will ask you questions about what influences your usual activity. Please read each question carefully and answer as accurately as possible by marking with an 'X" the appropriate box or by filling in the blanks.

Please bring the completed questionnaire with you to your next scheduled ACT appointment. If you are unsure how to answer a question or need help, please skip that item, and ask an ACT staff person for help when you return to the clinic.

Acrostic: ☐☐☐☐☐☐

ACT HRQL Form

We are interested in your opinions about your health and activities. Below are several questions about experiences that people may have day to day. Please read each question carefully and mark the one box that best describes you. There are no right or wrong answers.

THE FOLLOWING QUESTIONS ASK ABOUT YOUR HEALTH AND DAILY ACTIVITIES.

1. **During the past 4 weeks, on how many days did health problems cause you to do the following (for each question, please write in the number of days in the blank. Use a '0' if your answer is no days):**

   a. Stay in bed all or most of the day? _____ Days in past 4 weeks
   b. Cut down on your usual activities all or most of the day _____ Days in past 4 weeks
   c. Feel less well than usual for all or most of the day _____ Days in past 4 weeks

2. **In general, would you say your health is:**

   ☐ Excellent ☐ Very good ☐ Good ☐ Fair ☐ Poor

3. **Compared to one year ago, how would you rate your health in general now?**

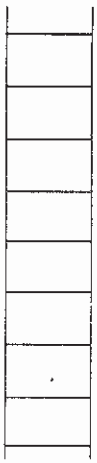
   ☐ Much better now ☐ Somewhat better now ☐ About the same ☐ Somewhat worse ☐ Much worse

Please turn to the next page.

Acrostic: | | | | | | |

THE FOLLOWING QUESTIONS ARE ABOUT YOUR QUALITY OF LIFE.

4. **Here is a picture of a ladder. At the bottom of the ladder is the worst situation you might reasonably expect to have. At the top is the best you might expect to have. The other rungs are in between. Please circle the number that best describes your overall life satisfaction during the <u>past 4 weeks</u>?**



IN THE <u>PAST 4 WEEKS</u>, HOW SATISFIED HAVE YOU BEEN WITH. .	Very Dissatisfied	Somewhat Dissatisfied	A little Dissatisfied	Neither	A Little Satisfied	Somewhat Satisfied	Very Satisfied
5. how well you think and remember?							
6. the amount of walking you do?							
7. how often you get outside the house, going into town, using public transportation or driving?							
8. how often you see or talk to your family and friends?							
9. the help you give to your family and friends?							
10. your contribution to your community, neighborhood, religious or other group?							
11. your retirement or current job?							
12. the kind and amount of recreation or leisure you have?							

Acrostic: | | | | | | |

IN THE PAST 4 WEEKS, HOW SATISFIED HAVE YOU BEEN WITH. .	Very Dissatisfied	Somewhat Dissatisfied	A little Dissatisfied	Neither	A Little Satisfied	Somewhat Satisfied	Very Satisfied
13. your level of sexual activity or lack of sexual activity?							
14. how respected you are by others?							
15. the meaning and purpose of your life?							
16. the amount of variety in your life?							
17. the amount and kind of sleep you get?							
18. how happy you are?							
19. your overall level of physical fitness?							
20. the muscle strength in your legs?							
21. your level of endurance or stamina?							
22. your muscle tone?							
23. your overall level of energy?							
24. your physical ability to do what you want or need to do?							
25. your weight?							
26. your shape?							
27. your overall physical appearance?							

BELOW ARE SOME STATEMENTS THAT PEOPLE MAY USE TO DESCRIBE THEMSELVES. FOR EACH ITEM, PLEASE CHECK THE ONE ANSWER THAT DESCRIBES HOW YOU GENERALLY FEEL.

IN THE PAST 4 WEEKS, HOW MUCH OF THE TIME HAVE YOU. . .	All of the time	Most of the time	A good bit of the time	Some of the time	A little of the time	None of the time
28. been upset because of something that happened unexpectedly?						
29. felt that you were unable to control the important things in your life?						
30. felt nervous and "stressed"?						

Please turn to the next page.

Acrostic: ☐☐☐☐☐☐

IN THE PAST 4 WEEKS, HOW MUCH OF THE TIME HAVE YOU. . .	All of the time	Most of the time	A good bit of the time	Some of the time	A little of the time	None of the time
31. dealt successfully with irritating life hassles?						
32. felt that you were effectively coping with important changes that were occurring in your life?						
33. felt confident about your ability to handle your personal problems?						
34. felt that things were going your way?						
35. found that you could not cope with all the things that you had to do?						
36. been able to control irritations in your life?						
37. felt that you are on top of things?						
38. been angered because of things that happened that were outside of your control?						
39. found yourself thinking about things that you have to accomplish?						
40. been able to control the way you spend your time?						
41. felt difficulties were piling up so high that you could not overcome them?						

THE NEXT TWO QUESTIONS ASK ABOUT ANY BODILY PAIN YOU MAY HAVE EXPERIENCED.

42. During the past four weeks, how much bodily pain have you had?

☐ None ☐ Very Mild ☐ Mild ☐ Moderate (Medium) ☐ Severe ☐ Very Severe

43. During the past four weeks, how much did pain interfere with your normal work (both outside your home and at home?)

☐ Not at all ☐ A little bit ☐ Moderately (Medium) ☐ Quite a bit ☐ Extremely

Acrostic: ☐☐☐☐☐☐

THE FOLLOWING QUESTIONS ASK ABOUT YOUR THOUGHTS AND FEELINGS.

44. Over the past WEEK to what extent have you felt each of the following moods (check one answer for each item a through l).

	All of the time	Most of the time	A good bit of the time	Some of the time	A little of the time	None of the time
a. Refreshed						
b. Calm						
c. Fatigued						
d. Enthusiastic						
e. Relaxed						
f. Energetic						
g. Happy						
h. Tired						
i. Revived						
j. Peaceful						
k. Worn-out						
l. Upbeat						

FOR EACH GROUP OF STATEMENTS BELOW, PLEASE CHECK THE BOX THAT BEST DESCRIBES YOUR FEELINGS IN THE PAST WEEK. (CHECK ONE)

45.
- ☐ I do not feel sad.
- ☐ I feel sad.
- ☐ I am sad all the time and I can't snap out of it.
- ☐ I am so sad or unhappy that I can't stand it.

46.
- ☐ I am not particularly discouraged about the future.
- ☐ I feel discouraged about the future.
- ☐ I feel I have nothing to look forward to.
- ☐ I feel that the future is hopeless and that things cannot improve.

Please turn to the next page.

Acrostic: ☐☐☐☐☐☐

47. ☐ I do not feel like a failure.
☐ I feel I have failed more than the average person.
☐ As I look back on my life, all I can see is a lot of failures.
☐ I feel I am a complete failure as a person.

48. ☐ I get as much satisfaction out of things as I used to.
☐ I don't enjoy things the way I used to.
☐ I don't get real satisfaction out of anything anymore.
☐ I am dissatisfied or bored with everything.

49. ☐ I don't feel particularly guilty.
☐ I feel guilty a good part of the time.
☐ I feel quite guilty most of the time.
☐ I feel guilty all of the time.

50. ☐ I don't feel I am being punished.
☐ I feel I may be punished.
☐ I expect to be punished.
☐ I feel I am being punished.

51. ☐ I don't feel disappointed in myself.
☐ I am disappointed in myself.
☐ I am disgusted with myself.
☐ I hate myself.

52. ☐ I don't feel I am worse than anybody else.
☐ I am critical of myself for my weaknesses or mistakes.
☐ I blame myself all the time for my faults.
☐ I blame myself for everything bad that happens.

53. ☐ I don't have any thoughts of killing myself.
☐ I have thoughts of killing myself, but I would not carry them out.
☐ I would like to kill myself.
☐ I would kill myself if I had the chance.

Acrostic: ☐☐☐☐☐☐

54. ☐ I don't cry any more than usual.
☐ I cry more now than I used to.
☐ I cry all the time now.
☐ I used to be able to cry, but now I can't cry even though I want to.

55. ☐ I am no more irritated now than I ever am.
☐ I get annoyed or irritated more easily than I used to.
☐ I feel irritated all the time now.
☐ I don't get irritated at all by the things that used to irritate me.

56. ☐ I have not lost interest in other people.
☐ I am less interested in other people than I used to be.
☐ I have lost most of my interest in other people.
☐ I have lost all of my interest in other people.

57. ☐ I make decisions about as well as I ever could.
☐ I put off making decisions more than I used to.
☐ I have greater difficulty in making decisions than before.
☐ I can't make decisions at all any more.

58. ☐ I don't feel I look any worse than I used to.
☐ I am worried that I am looking old or unattractive.
☐ I feel that there are permanent changes in my appearance that make me look unattractive.
☐ I believe that I look ugly.

59. ☐ I can work about as well as before.
☐ It takes an extra effort to get started at doing something.
☐ I have to push myself very hard to do anything.
☐ I can't do any work at all.

60. ☐ I can sleep as well as usual.
☐ I don't sleep as well as I used to.
☐ I wake up 1-2 hours earlier than usual and find it hard to get back to sleep.
☐ I wake up several hours earlier than I used to and cannot get back to sleep.

Please turn to the next page.

Acrostic: ☐☐☐☐☐☐

61. ☐ I don't get more tired than usual.
☐ I get tired more easily than I used to.
☐ I get tired from doing almost anything.
☐ I am too tired to do anything.

62. ☐ My appetite is no worse than usual.
☐ My appetite is not as good as it used to be.
☐ My appetite is much worse now.
☐ I have no appetite at all anymore.

63. ☐ I haven't lost much weight, if any, lately.
☐ I have lost more than 5 pounds.
☐ I have lost more than 10 pounds.
☐ I have lost more than 15 pounds.

I am purposely trying to lose weight by eating less. ☐ Yes ☐ No

64. ☐ I am no more worried about my health than usual.
☐ I am worried about physical problems such as aches and pains, or upset stomach, or constipation.
☐ I am very worried about physical problems and it's hard to think of much else.
☐ I am so worried about my physical problems that I cannot think about anything else.

65. ☐ I have not noticed any recent change in my interest in sex.
☐ I am less interested in sex than I used to be.
☐ I am much less interested in sex now.
☐ I have lost interest in sex completely.

Thank you, this is the end of the Health Related Quality of Life Questionnaire. Please turn to the next page and complete the Influences of Activity Questionnaire.

Please turn to the next page.

Acrostic: | | | | | | |

INFLUENCES ON ACTIVITY QUESTIONNAIRE

Many people report that it is more difficult to be physically active under some conditions than others. Please rate how confident you are that you could be physically active under EACH of the following conditions over the NEXT SIX MONTHS. (Please rate EACH one below.)

I could be physically active . .	I cannot do at all 0	1	2	3	4	Moderately Certain I can do 5	6	7	8	9	Certain that I can do 10
1. when I am tired											
2. during or following a personal crisis											
3. when I am feeling depressed											
4. when I am feeling anxious											
5. during bad weather											
6. when I am slightly sore from the last time I was physically active											
7. when I am on vacation											
8. when there are competing interests (like my favorite TV show)											
9. when I have a lot of work to do											
10. when I haven't reached my physical activity goals											
11. when I don't receive support from family or friends											
12. following complete recovery from an illness											
13. when I have no one to be physically active with											
14. when my schedule is hectic											

Please turn to the next page.

Acrostic: | | | | | | |

Please rate how confident you are at the PRESENT TIME that you could perform EACH of the following. (Please rate EACH one below.)

I could walk at a fast pace without stopping for. . .	I cannot do at all 0	1	2	3	4	Moderately certain I can do 5	6	7	8	9	Certain that I can do 10
15. 10 minutes											
16. 20 minutes											
17. 30 minutes											
18. 40 minutes											
19. 50 minutes											

Experiences Affecting Physical Activity

The following experiences can affect the physical activity habits of some people. Think of any similar experiences you may be currently having or have had during the past month, then rate how frequently the event occurs. Please check the box below the word that best describes your answer for each experience.

How frequently does this occur?	Never	Seldom	Occasionally	Often	Repeatedly
1. I put things around my home to remind me to be physically active.					
2. I tell myself that if I try hard enough I can be physically active.					
3. I make commitments to be physically active.					
4. I keep things around my place of work that remind me to be physically active.					
5. I find society changing in ways that make it easier to be physically active.					

Acrostic: | | | | | | |

How frequently does this occur?	Never	Seldom	Occasionally	Often	Repeatedly
6. Warnings about health hazards of inactivity affect me emotionally.					
7. I react emotionally to warnings about an inactive lifestyle.					
8. I read articles about exercise and physical activity in an attempt to learn more about it.					
9. I have a healthy friend that encourages me to be physically active when I don't feel up to it.					
10. When I am physically active, I tell myself that I am being good to myself by taking care of my body.					
11. I am aware of more and more people encouraging me to be more physically active.					
12. I do something nice for myself for making efforts to be more physically active.					
13. I have someone who provides feedback about my physical activity.					
14. I look for information related to exercise or physical activity.					
15. I feel I would be a better role model for others if I exercised regularly.					
16. I think about the type of person I will be if I am physically active.					
17. I realize that I might be able to influence others to be healthier if I would be more physically active.					
18. I get frustrated with myself when I am not physically active.					

Please turn to the next page.

Acrostic: | | | | | | |

How frequently does this occur?	Never	Seldom	Occasionally	Often	Repeatedly
19. When I feel tired I can make myself be physically active because I know I will feel better afterward.					
20. When I am feeling tense, I find that being physically active helps to relieve my worries.					

Deciding About Physical Activity

Please rate how important each of these statements is in your decision whether or not to be physically active. In each case, rate how you think now, not how you have thought in the past or would like to think.

	Not at all important	Slightly important	Moderately important	Very important	Extremely important
1. I think I would be too tired to do my daily work after being physically active.					
2. I would sleep better if I was regularly physically active.					
3. I would feel good about myself if I kept my promise to be more physically active.					
4. I would find it hard to find a physical activity that I enjoy that is not affected by bad weather.					
5. I would like my body better if I was regularly physically active.					
6. It would be easier for me to do routine physical tasks if I was regularly physically active.					
7. I would feel less stressed if I was regularly physically active.					
8. I feel uncomfortable when I engage in physical activity because I get out of breath and my heart beats very fast.					
9. I would feel more comfortable with my body if I was regularly physically active.					

Acrostic: | | | | | | |

	Not at all important	Slightly important	Moderately important	Very important	Extremely important
10. Regular physical activity would take too much of my time.					
11. I would have less time for my family and friends if I was regularly physically active.					
12. At the end of the day, I am too exhausted to exercise.					

Environment

Please indicate below which items you have in your home, yard, or apartment complex.

	No	Yes
1. stationary aerobic equipment (e.g., cycle, rowing machine, treadmill, Nordictrac, stairmaster)		
2. bicycle		
3. a dog you can walk		
4. trampoline for jogging in place		
5. running shoes		
6. swimming pool		
7. weight lifting equipment (e.g., free weights, Nautilus, Universal)		
8. toning devices (e.g., heavy hands, ankle weights, dyna-bands, thighmaster)		
9. aerobic workout videotapes or audio tapes		
10. step aerobics, slide aerobics		

Please turn to the next page.

Acrostic: | | | | | | |

	No	Yes
11. skates (roller, in line, or ice)		
12. sports equipment (balls, racquets)		
13. canoe, row boat, kayak		
14. skis (snow or water)		

Please indicate which of the following apply to your neighborhood.

	No	Yes
15 sidewalks		
16. heavy traffic		
17. hills		
18. street lights		
19. dogs that are unattended or roaming free		
20. enjoyable scenery		
21. frequently see people walking or exercising		
22. high crime		

23. Are you a member of a health club or gym?

☐ No ☐ Yes

24. How safe do you feel walking in your neighborhood during the day?

☐ Very unsafe ☐ Somewhat unsafe ☐ Somewhat safe ☐ Very safe

25. Is your neighborhood (please check one box):

☐ homes ☐ mixed homes and businesses ☐ mainly businesses

26. What is the household income in your neighborhood?

☐ low ☐ medium ☐ medium high ☐ high

Acrostic: ☐☐☐☐☐☐

These questions have to do with work outside the home.

27. Are there exercise facilities at your work? (e.g., workout room/gym, exercise equipment, walking path/PAR course)

☐ Yes ☐ No ☐ Not applicable

28. Are there regular exercise programs at your work? (e.g., aerobic classes, team sports, walking groups, etc.)

☐ Yes ☐ No ☐ Not applicable

29. Are there shower facilities at your work?

☐ Yes ☐ No ☐ Not applicable

30. Is an exercise specialist/activity coordinator available for employees at your work?

☐ Yes ☐ No ☐ Not applicable

31. Are there any policies at your work that encourage exercise or biking?

☐ Yes ☐ No ☐ Not applicable

32. Does your employer provide any paid time for you to exercise?

☐ Yes ☐ No ☐ Not applicable

Please turn to the next page.

Acrostic: | | | | | | |

Social Support

Below is a list of things people might do or say to someone who is trying to be physically active. If you are not trying to be physically active, then some of the questions may not apply to you. However, please read and give an answer to every question.

Please rate each question *twice*. Under "FAMILY", rate how often anyone living in your household has said or done what is described during the last week. Under "FRIENDS", rate how often your friends, acquaintances, or coworkers have said or done what is described during the last week.

Please use the scale below when rating each of the questions.

0 Does not apply	1 None	2 Rarely	3 A few times	4 Often	5 Very often

During the last week, my family (or members of my household) or friends:

	FAMILY						FRIENDS					
	0	1	2	3	4	5	0	1	2	3	4	5
1. Were physically active with me.												
2. Offered to be physically active with me.												
3. Gave me helpful reminders to be physically active ("Are you going for a walk?")												
4. Gave me encouragement to become more physically active.												
5. Changed their schedule so we could be physically active together.												
6. Discussed physical activity with me.												
7. Complained about the time I spent being physically active.												
8. Criticized me or made fun of me for being physically active.												
9. Gave me rewards for being physically active (bought me something or gave me something I like).												

Acrostic:						

Please use the scale below when rating each of the questions.					
0 Does not apply	1 None	2 Rarely	3 A few times	4 Often	5 Very often

During the last week, my family (or members of my household) or friends:

	FAMILY						FRIENDS					
	0	1	2	3	4	5	0	1	2	3	4	5
10. Planned for physical activity on recreational outings.												
11. Helped plan other activities around my physical activity.												
12. Asked me for ideas on how *they* can be more physically active.												
13. Talked about how much they liked being physically active.												

Please answer each question below, by marking "Yes" or "No". Answer the questions for hard or very hard activity then answer the questions about moderate activity.

Hard or very hard physical activity or exercise includes hard activities such as jogging, aerobics, swimming, and biking. For hard or very hard activity to be regular, it must last at least 20 minutes each time, and be done at least 3 days per week.

	No	Yes
1. I currently participate in hard or very hard physical activity.		
2. I intend to increase my participation in hard or very hard physical activity in the next 6 months.		
3. I currently participate in regular hard or very hard physical activity.		
4. I have been participating in hard or very hard physical activity regularly for the past 6 months.		
5. In the past, I have been regularly physically active in hard or very hard activities for a period of at least 3 months.		

Please turn to the next page.

Acrostic: | | | | | | |

Moderate physical activity or exercise includes such activities as brisk walking, gardening, and heavy housecleaning. For moderate activity to be regular it must add up to a total of 30 or more minutes per day, and be done at least 5 days per week. For example, you could take a 30 minute walk or take a 10 minute walk, rake leaves for 10 minutes, and mop the floor for 10 minutes.

	No	Yes
1. I currently participate in moderate physical activity.		
2. I intend to increase my participation in moderate physical activity in the next 6 months.		
3. I currently participate in regular moderate physical activity.		
4. I have been participating in moderate physical activity regularly for the past 6 months.		
5. In the past, I have been regularly physically active in moderate activities for a period of at least 3 months.		

Thank you!

D.4 MEDICAL HISTORY

ACT Manual of Operations and Procedures: Medical History/Demographics Form

Overview

The purpose of the Medical History/Demographics Form is to provide, in a self administered format, a means of collecting health and demographic information on potential study participants for the Activity Counseling Trial (ACT). This form serves two major purposes in addition to that served by a standard medical history questionnaire. First, the Form will be used as a standardized tool to collect health status and demographic data that pertain to important outcome measures of interest in this study. Second, this evaluation will be used to determine each study participant's eligibility for participation in ACT based on inclusion and exclusion criterial defined in the ACT Protocol.

Exclusion Criteria

Coronary Heart Disease: diagnosis of angina and treatment by antianginal medications, of history of myocardial infarction, angioplasty or bypass surgery;

Cerebral Vascular Disease: history of stroke or transient ischemic attack;

Peripheral Vascular Disease: diagnosis of peripheral vascular disease;

Arrhythmias: diagnosis of atrial fibrillation, complex ventricular arrhythmias, or second or third-degree heart block;

Valvular Heart Disease: diagnosis of heart valve replacement or significant valvular heart disease;

Cancer: diagnosis of cancer or receiving active treatment for cancer, including melanoma but excluding other forms of skin cancer, during the past five years;

Diabetes Mellitus: diagnosis of insulin-requiring diabetes;

Pulmonary Disease: active treatment in the last six months for asthma, or a diagnosis of chronic obstructive pulmonary disease, emphysema or restrictive lung disease;

Psychiatric Illness: treatment in the last five years for a diagnosis of depression, schizophrenia or mood disorder. Also defined as currently receiving treatment with lithium, neuroleptics, major

antidepressant medications (tricyclics, serotonin re-uptake inhibitors, monamine oxidase inhibitors or antipsychotics);

Severe Systemic Disease: diagnosis of Parkinson's disease, chronic liver disease (cirrhosis, chronic hepatitis, etc.), systemic rheumatic condition (rheumatoid arthritis, psoriatic arthritis, Reiter's disease, systemic lupus erythematosus, etc), kidney failure or other systemic diseases or abnormal laboratory values which would preclude the participant from safely participating in the protocol or impair ability to complete the study;

Blood Pressure: Resting diastolic BP >100 mmHg or resting systolic BP >180 mmHg that would preclude an exercise treadmill test;

Hearing or Sight Impairments: significant visual or hearing impairment resulting in inability to use the telephone, hear normal conversation or read forms;

Impaired Cognitive Function: dementia, delirium or impaired cognitive function;

Alcohol Intake: consuming more than 21 alcoholic drinks per week or alcoholism; and

English Illiteracy: unable to speak or read English.

Administration

The Medical History/Demographics Form will be administered at SV0. The Form is self-administered and is designed to be completed with minimal supervision. Upon arrival at SV0, potential study participants will be asked to complete the Form. The importance of responding to each question should be emphasized to each participant. For questions requiring a number response, participants should be instructed to record the numbers legibly and in the appropriate boxes. On binary (Yes/No) response inquiries, the participant should be instructed to check the appropriate response in the box provided. For open-ended inquiries (where respondent is asked to provide more information), responses should be succinct but sufficient to allow evaluation by study personnel. The final two pages (pages 7 and 8) of the Form contain inquiries regarding women's health. Men should be reminded to stop after completion of page seven. The completed Form will be reviewed individually with each participant by study personnel at SV0.

Quality Control

The primary responsibility of study personnel administering the Medical History/Demographics Form will be to review the completed Form item by item with each participant to ensure that all questions are legible and complete. Clarification of unclear responses will be obtained at this time. Responses or questions that relate to exclusion criteria and/or specific disease processes that can not be clarified during the review will be collected and referred to the appropriate medical personnel.

Demographics/Medical History Form

(Revised form)

ACTIVITY COUNSELING TRIAL

DEMOGRAPHICS AND MEDICAL HISTORY

Participant Name

The questions that follow will ask for some information about your general background as well as your health history. Please answer them as completely as possible. It should take 15 to 20 minutes to finish. After you have completed the questionnaire, a clinic staff member will go over it with you. If you have any questions or concerns about your answers, please share them with the staff member at that time.

CLINIC USE ONLY

ID ☐☐☐☐☐☐ Acrostic ☐☐☐☐☐☐

Date Completed ☐☐ Mon ☐☐ Day ☐☐ Year

Reviewed by ☐☐ (staff code)

1. What is your date of birth? ☐☐ Mon ☐☐ Day ☐☐ Year

2. What is your current marital status?

1☐ never married
2☐ presently married
3☐ living in a marriage-like relationship
4☐ divorced or separated
5☐ widowed

3. What is the **highest** grade of school that you completed?

1☐ 8th grade or less
2☐ 9th- 11th grade
3☐ High school graduate
4☐ Some college (including junior or technical college)
5☐ College graduate
6☐ Post graduate

4. Has a doctor ever told you that you have diabetes?

1☐ Yes — Are you taking insulin? 1☐ Yes 2☐ No
2☐ No

5. Has a doctor ever told you that you have high blood pressure?

1☐ Yes — Do you take any medication for your high blood pressure?
- 1☐ Yes — Have you been taking the same medications **and** the same dosage for the last 3 months? 1☐ Yes 2☐ No
- 2☐ No

2☐ No

6. Have you ever been diagnosed or treated for skin cancer?

1☐ Yes — Was it melanoma?
- 1☐ Yes — Was this within the last 5 years? 1☐ Yes 2☐ No
- 2☐ No

2☐ No

Acrostic

7. Have you ever been diagnosed or treated for any types of cancer other than skin cancer?

1☐ Yes — "What kind of cancer?" _____

"Was this within the last 5 years?" 1☐ Yes 2☐ No

2☐ No

8. Has a doctor ever told you that you have had a heart attack? 1☐ Yes 2☐ No

9. Has a doctor ever told you that you have any of the following conditions?

a) Angina (chest pain from a heart problem) requiring treatment with medications 1☐ Yes 2☐ No

b) Heart failure or congestive heart failure 1☐ Yes 2☐ No

c) Heart rhythm problem (irregular heartbeat) 1☐ Yes 2☐ No

d) Heart conduction problem (heart block) 1☐ Yes 2☐ No

e) Heart valve problem

1☐ Yes — Specify type of valve problem: _____

_____

2☐ No

10. Have you ever had any of the following surgical procedures?

a) Surgery for blocked or clogged arteries in your heart 1☐ Yes 2☐ No

b) Balloon angioplasty for your heart (opening the arteries of the heart with a balloon or other device, sometimes called a PTCA) 1☐ Yes 2☐ No

c) Heart valve replacement 1☐ Yes 2☐ No

11. Has a doctor ever told you that you have had a stroke or TIA (mini-stroke)? 1☐ Yes 2☐ No

12. Are you currently taking any of the following medications:

a) Heparin or Coumadin? 1☐ Yes 2☐ No

b) Steroids by mouth? 1☐ Yes 2☐ No

Acrostic

13. Has a doctor ever told you that you have high cholesterol or an abnormally high level of fats in your blood?

1☐ Yes — Are you now taking any medications to treat it? 1☐ Yes 2☐ No

2☐ No

14. Has a doctor ever told you that you have a blood circulation problem in any of the following areas?

a) In your head or neck? 1☐ Yes 2☐ No

b) In your legs or feet? 1☐ Yes 2☐ No

c) In any other area of your body?

1☐ Yes — Specify area: _____

2☐ No

15. Has a doctor ever told you that you have asthma? #15-Yes = automatic exclusion

1☐ Yes — Do you currently take medications for your asthma on a daily basis?
1☐ Yes 2☐ No

Do physical activities such as walking, running, swimming and playing sports cause you to have asthma attacks?
1☐ Yes 2☐ No

2☐ No

16. Do you have any of the following problems?

a) Rheumatoid arthritis 1☐ Yes 2☐ No

b) Psoriatic arthritis 1☐ Yes 2☐ No

c) Reiter's Disease 1☐ Yes 2☐ No

d) Lupus or SLE 1☐ Yes 2☐ No

e) Parkinson's Disease 1☐ Yes 2☐ No

f) Emphysema 1☐ Yes 2☐ No

g) Chronic obstructive lung disease 1☐ Yes 2☐ No

17. Has a doctor ever told you that you have kidney disease?

1☐ Yes — Please specify what kind: _____

2☐ No

Acrostic

18. Has a doctor ever told you that you have liver disease?

1☐ Yes — Please specify what kind: _____

2☐ No

19. Have you been treated in the last 5 years by a health care professional for any of the following?

a) Major depression 1☐ Yes 2☐ No

b) Manic depressive illness 1☐ Yes 2☐ No

c) Schizophrenia 1☐ Yes 2☐ No

20. Are you currently taking any of the following medications for depression or other psychiatric illness?

a) Antimanic drugs, such as lithium? 1☐ Yes 2☐ No

b) Antipsychotic drugs or tranquilizers, such as thorazine or haldol? 1☐ Yes 2☐ No

c) Antidepressants, such as prozac or elavil? 1☐ Yes 2☐ No

21. Have you been hospitalized in the last 5 years for major depression? #21 - automatic exclusion 1☐ Yes 2☐ No

22. Are you currently under a doctor's care for any medical problems not listed on the previous pages?

1☐ Yes — Please describe those problems in the space below:

_____

_____

_____

_____

_____

2☐ No

23. The following questions are about your weight. [**WOMEN:** We are interested in your weight at times other than when you were pregnant.]

(a) Is your current weight 5 or more pounds different (*lighter or heavier*) from what it was **6 months ago?**

1☐ Yes, **gained** more than 5 pounds.

(i) How many pounds have you gained? ☐☐ pounds

(ii) Did you try to gain this weight? 1☐ Yes 2☐ No

2☐ Yes, **lost** more than 5 pounds.

(i) How many pounds have you lost? ☐☐ pounds

(ii) Did you try to lose this weight? 1☐ Yes 2☐ No

3☐ No 9☐ Don't know

(b) How many times in your life have you lost at least 10 pounds and then gained it back? If you have never lost and gained back 10 pounds, enter zero ("00"). (**WOMEN:** do not include times when you were pregnant.)

☐☐ times

24. The following questions are about alcohol use.

(a) In **any one year,** have you ever had 12 or more drinks containing alcohol?

1☐ Yes 2☐ No (please skip to question 25)

(b) In **the last 12 months,** have you had 12 or more drinks containing alcohol?

1☐ Yes (please answer parts c, d, and e below)

2☐ No (please skip to question 25)

(c) During a typical week, how many cans or bottles of beer do you drink? (Remember to include weekends.)

☐☐ bottles per week

(d) During a typical week, how many glasses of wine do you drink? (Remember to include weekends.)

☐☐ glasses per week

(e) During a typical week, how many mixed drinks or shots of liquor do you drink? (Remember to include weekends.)

☐☐ shots per week

Acrostic ☐☐☐☐☐☐

25. The following questions are about cigarette smoking.

(a) Have you ever smoked cigarettes regularly?

1☐ Yes (please answer parts b and c below)
2☐ No (please skip to part (d) below)

(b) How old were you when you began smoking cigarettes regularly?

☐☐ years old

(c) Do you currently smoke cigarettes?

1☐ Yes → On an average day, how many cigarettes do you smoke?
☐☐ cigarettes per day

2☐ No → When you were smoking, on an average day, how many cigarettes did you smoke?
☐☐ cigarettes per day

How old were you when you quit smoking?
☐☐ years old

(d) Do you presently use any forms of tobacco other than cigarettes?

1☐ Yes → What other forms of tobacco do you use?

Cigars	1☐ Yes	2☐ No
Cigarillos	1☐ Yes	2☐ No
Pipe tobacco	1☐ Yes	2☐ No
Chewing tobacco	1☐ Yes	2☐ No
Snuff	1☐ Yes	2☐ No
Other	1☐ Yes	2☐ No

Specify: _____

2☐ No

Acrostic ☐☐☐☐☐☐

26. What is your current employment status?
(please indicate the **one** that best describes you now)

1☐Unemployed
2☐Full-time homemaker
3☐Employed full-time or part-time
4☐Permanently disabled
5☐Retired
6☐Full-time or part-time student
7☐On temporary medical leave

27. In the spaces provided below, please write your current **job title** and **briefly describe your occupation.** (If you are retired or currently unemployed, please give the title and description of your most recent job. If you are a full-time homemaker who has never been employed outside the home, please write "homemaker" in both spaces.)

Example

A fourth grade teacher of an elementary public school might respond:

Job Title: *teacher*

Occupation: *teach fourth grade in public elementary school*

Job Title: _____

Occupation: _____

How many years have you worked (or did you work) at this job? ☐☐ years

28. Which of the following categories best describes your annual **household income? (Please select only one category.)**

1☐ Less than $5,000
2☐ $5,000 to $9,999
3☐ $10,000 to $14,999
4☐ $15,000 to $19,999
5☐ $20,000 to $24,999
6☐ $25,000 to $29,999
7☐ $30,000 to $34,999
8☐ $35,000 to $45,999
9☐ $46,000 to $49,999
10☐ $50,000 to $74,999
11☐ $75,000 to $99,999
12☐ $100,000 or more

Is your response based on the take home amount? 1☐ Yes 2☐ No

How many people are currently living in your household (including yourself)? ☐☐

Acrostic

29. Which of the following categories best describes your annual **personal income? (Please select only one category.)**

1☐ Less than $5,000	5☐ $20,000 to $24,999	9☐ $46,000 to $49,999
2☐ $5,000 to $9,999	6☐ $25,000 to $29,999	10☐ $50,000 to $74,999
3☐ $10,000 to $14,999	7☐ $30,000 to $34,999	11☐ $75,000 to $99,999
4☐ $15,000 to $19,999	8☐ $35,000 to $45,999	12☐ $100,000 or more

Is your response based on the take home amount? 1☐ Yes 2☐ No

30. Please indicate below the source(s) of **your own personal income** (not household income) by marking the primary source with a "1". If you have more than one source of income, mark the second source with a "2", the third source with a "3", and so on.

- ☐ Employment (as listed above in question 26)
- ☐ Governmental (Older Americans Supplemental Disability Income (OASDI), Railroad Retirement, Social Secruity Benefits, Supplemental Security Income (SSI), Veterans Benefits, Aid to Families with Dependent Children (AFDC), or General Assistance from Local or State governments)
- ☐ Retirement (pensions, annuities, etc.)
- ☐ Unemployment Compensation
- ☐ Interest and Dividends
- ☐ Other (alimony, child support, etc.)

MEN: **Please stop here.** Thank you for taking time to complete the form. If you have any questions or concerns about any of your answers, please tell the clinic staff person when you return the questionnaire.

Women: Please answer the questions on the following pages.

Acrostic ☐☐☐☐☐☐

31. Are you pregnant or currently trying to get pregnant? 1☐ Yes 2☐ No

32. Do you plan to try to get pregnant during the next 2 years? 1☐ Yes 2☐ No

33. The following questions are about your menstrual cycles.

(a) Have you undergone menopause (change of life)?

1☐ Yes

2☐ No ☐ Unsure

Were you pregnant or breast feeding within the last year?

1☐ Yes

Are you currently pregnant? 1☐ Yes 2☐ No

Are you currently breastfeeding? 1☐ Yes 2☐ No

2☐ No

(b) When was the first day of your last menstrual period? ☐☐/☐☐/☐☐
Mon Day Year

If your last menstrual period was less than 12 months ago, please answer the questions in the box below.

How many periods have you had in the last 12 months? ☐☐ periods

About how many days apart are your periods? ☐☐☐ days

Are your periods usually regular or irregular? 1☐ regular 2☐ irregular

(c) Have you had a hysterectomy or surgery to remove your uterus or womb?

1☐ Yes — At what age? ☐☐ years

2☐ No ☐ Unsure

(d) Have you had surgery to remove your ovaries?

1☐ Yes

How many ovaries were removed? 1☐ one 2☐ both ☐ unsure

At what age? ☐☐ years

2☐ No ☐ Unsure

Acrostic ☐☐☐☐☐☐

33. Menstrual history (continued, **women only**).

(e) Have you had any other condition or treatment that caused your menstrual periods to permanently stop, other than the surgeries listed above or natural menopause?

1☐ Yes

Please specify the condition or treatment:

_____

_____

How old were you when this occurred? ☐☐ years

2☐ No

Thank you for taking time to complete this form. If you have any questions or concerns about any of your answers, please tell the clinic staff person when you return the questionnaire.

D.5 PHYSICAL EXAM

Physical Examination

1. Purpose

The purpose of the physical examination is to provide a limited evaluation of some body systems, primarily to find medical problems that have not yet become apparent from the medical history, but which would exclude the potential participant from the study. This examination is not a comprehensive examination to evaluate overall health. The specific systems to be examined are on the attached form.

2. Administration

The physical examination will be administered during SV1. The examination should be done only after a careful review of the medical history. It should be done in a systematic way to which the examiner is accustomed. Findings should be recorded immediately on the medical examination form, rather than at a later time. Because the limited physical examination is carried out with the specific purpose of finding abnormalities that might be a sign of one or more conditions that would exclude the patient from the study, the examiner, to be most effective, should have these exclusion criterial in mind as he or she conducts the physical examination.

Needs:

Personnel

1. Physician, physicians assistant, or nurse practitioner/
2. Chaperon (if the professional and the patient are of opposite sex).
3. Equipment
   - A. Private examination room
   - B. Examination table
   - C. Otoscope with disposable ear pieces
   - D. Tongue blades
   - E. Stethoscope

F. Drape for female patients

Conducting the examination

The attached table lists the systems to be examined, the scope of the examination of each system, and specific exclusionary abnormalities to look for in connection with that particular system

After completing the examination, the examiner marks the bottom of the form "yes" or "no", according to findings that would or would not exclude the patient from the study.

3. Quality Control Considerations

Only experienced, well qualified professionals with proper credentials should conduct the physical examination. As mentioned above, each examination should be carried out in a systematic way, so that some part of the exam is not inadvertently forgotten. The examiner should have in mind the exclusionary criteria and target the exam and his/her thoughts towards finding those conditions if present.

If borderline or questionable findings are present, it is recommended that the examiner discuss those findings with a study colleague before making a final decision to exclude the patient.

Any significant abnormal findings, including those that would exclude the potential participant from the study, should be discussed with the patient and a letter should be prepared to communicate the abnormal findings to the patient's personal physician.

ACT PHYSICAL EXAM FORM

SYSTEM	SCOPE OF EXAMINATION	SPECIFIC ABNORMALITIES TO BE IDENTIFIED
General Appearance	General conduct Speech Gross musculoskeletal disorders Cooperation Affect	Conduct suggestive of drug or alcohol abuse Behavior or affect disorder suggestive of psychiatric illness Unhealthy appearance Difficulty cooperating
Skin	Color Evidence of infection Evidence of cancer	Jaundice Palor Melanoma Rash suggestive of systemic illness
Neck (including thyroid)	Mobility of neck Evaluation of neck veins Thyroid palpation Carotid palpation Carotid auscultation Palpation of anterior and posterior neck	Unexplained mass Thyroid nodule Thyroid enlargement Absence of one or more carotid pulses Carotid bruits Venous distention, suggestive of congestive heart failure
Head-Eyes-Ears-Nose-Throat	Visual inspection of the head Otoscopic examination of the canals and tympanic membranes Examination of the anterior and pharynx with the tongue blade and the otoscope	Unexplained mass Nystagmus Deformities of the nose or ear throat that would affect breathing and thus exercise Scleral jaundice or other abnormalities of the head, eyes, ears, nose and throat

ACT PHYSICAL EXAM FORM (cont)

SYSTEM	SCOPE OF EXAMINATION	SPECIFIC ABNORMALITIES TO BE IDENTIFIED
Head-Eyes-Ears-Nose-Throat (cont'd)	Evaluation of extraocular movements Pupil equality and reactivity to light and accommodation	that might suggest systemic disease
Lungs	Evaluation of bony thorax Ausculation of lungs for breath sounds, rales, rhonchi, or rubs	Asthma Chronic bronchitis Emphysema Scar from bypass or lung surgery
Heart	Evaluate rhythm and rate Palpate the PMI for location and prominence Palpate sternum and left chest for lifts or heaves Auscultate for murmurs, gallops, clicks or rubs	Significant murmur Arrhythmia Excessively prominent PMI, suggestive of cardiomegaly S3 or S4 gallops Auscultory evidence suggestive of artificial valve
Abdomen	Auscultation and palpation of all quadrants to look for masses, tenderness, and bruits	Enlargement of liver, spleen or kidneys Abdominal bruits Abdominal aneurysms Unexplained masses
Extremities	Evaluate range of motion of arms and legs Overall muscle development and strength Check radial, posterior tibialis, and dorsalis pedis pulses	Any bony tenderness or deformity Any gross muscular deformity Cyanosis, clubbing or edema Joint swelling or deformity Unexplained mass Absent pulses

ACT PHYSICAL EXAM FORM (cont)

SYSTEM	SCOPE OF EXAMINATION	SPECIFIC ABNORMALITIES TO BE IDENTIFIED
Gait	Observe the patient walking	Motor abnormalities consistent with a history of stroke Parkinsonism Arthritis which would affect mobility

ACT Physical Exam Form

ID ☐☐☐☐☐☐ Acrostic ☐☐☐☐☐☐

Today's Date ☐☐☐☐☐☐ (Mon Day Year) Completed by ☐☐ (staff code)

		Specify Abnormality
1. General Appearance	☐ Normal ☐ Abnormal →	
2. Skin	☐ Normal ☐ Abnormal →	
3. Neck (Including Thyroid)	☐ Normal ☐ Abnormal →	
4. Head, ears, nose, throat	☐ Normal ☐ Abnormal →	
5. Lungs	☐ Normal ☐ Abnormal →	
6. Heart	☐ Normal ☐ Abnormal →	
7. Abdomen	☐ Normal ☐ Abnormal →	
8. Extremities	☐ Normal ☐ Abnormal →	
9. Gait	☐ Normal ☐ Abnormal →	

Comments: _____

Should this patient be excluded as a result of physical problems? ☐ Yes ☐ No

APPENDIX E

PROCEDURES FOR INTERVIEWING PARTICIPANTS

General Considerations 2

E.1 Developing a Good Interviewing Relationship 2

E.2 The Two Main Kinds of Questions 3

E.3 Interviewer-Administered Questionnaires 3

E.4 How to Get Satisfactory Answers 4

E.5 Probing Techniques 5

E.6 How to Record the Interviews 8

E.7 Following the Centralized Training Session 8

E.8 Procedures for Administration of Medications Form 9

E.9 Baseline Medications Form . . . . .

E.10 Anti-Hypertensive Agents . . . . .

APPENDIX E
PROCEDURES FOR INTERVIEWING PARTICIPANTS

GENERAL CONSIDERATIONS

This section provides some general information concerning interviewing skills, which will be important in conducting the pre-screen contacts as well as for collecting interviewer-administered and interviewer-assisted study data.

Interviewing, in part, is a science: there are concrete rules that produce valid results. Interviewing is also an art: frequently there are only general guidelines to follow and much depends on the sensitivity of the interviewer. The procedures and techniques that follow will help you to conduct interviews that will yield valid data.

E.1. Developing a Good Interviewing Relationship

Interviewing is one of the major parts of the ACT study and therefore it is crucial that interviewers present questions appropriately, record the participants' replies precisely and accurately, and probe meaningfully. In order to maintain an objective information-gathering atmosphere, the interviewer must convey that she/he is an understanding person capable of accepting information in a non-judgmental manner, and convey an interest in what the participant is saying. The participant must find satisfaction in talking to a receptive person without the fear of appearing inadequate.

It will be the interviewer's responsibility to obtain full and accurate information by eliciting cooperation from participants, establishing and maintaining rapport, and encouraging participants, in a strictly neutral way, to answer the questions. Interviewers are skilled professionals. Their skills make it possible for participants to give frank, complete, relevant answers.

In general, you will find that the majority of participants are willing to be interviewed. A confident, enthusiastic approach that assumes people are willing to be interviewed is a most effective technique.

Previous studies have identified several factors that often increase the respondent's receptiveness:

1. Be prepared and know your material. Participants need to feel that you are interested in the study and interested in their opinions. Be an active listener and establish comfortable eye contact with the participant.

2. Offer convincing statements about the purpose of the study.

3. Discuss how the respondent was selected.

4. Describe how the research findings will benefit both the respondent and the community.

E.2. The Two Main Kinds of Questions

Precoded Questions With precoded questions, you circle the appropriate code number (or check the right answer box). In addition to checking a box or circling the right answer, it is very important that you record the participant's verbatim response whenever there is any question about which code is appropriate.

Open-ended Questions With open-ended questions, the question is followed by a blank space for you to record the participant's answer word for word. This kind of question suggests no possible answers, so it is your job to fill in that blank space with the participant's own words and to encourage her/him to express ideas as fully and as clearly as possible.

E.3. Interviewer-Administered Questionnaires

There are several standard procedures for reading questions. Read in a natural conversation rhythm and in a normal tone of voice, as if you are speaking. Be cautious about reading questions too rapidly: the participant may not feel comfortable asking you to repeat questions and consequently the answer will not reflect her/his true thoughts on the issue. Be aware of the participant's facial expressions, e.g., puzzled, confused. Repeat the question if it is answered inappropriately, but repeat it exactly as written. Show no impatience when being asked to repeat a question.

Each question must be asked of each participant in the same way, and in the same order to ensure that comparable information is being obtained from all the respondents in the study.

Interview instructions are provided throughout the interview. These instructions are not to be read to participants but are intended to let you know what to do at each point. The interviewer instructions appear in all bolded letters.

Read only those code categories that appear in the question and that you are instructed to read **UNLESS**:

1. You have special instructions to the contrary.

2. There is an instruction to "READ CHOICES", or

3. A question ends with a dash or colon and it is obvious that the codes must be read. Do NOT read any codes that do not appear in the question.

Ask the questions exactly as worded and in the same order as they appear in the questionnaires. Minor changes in wording can completely change the meaning of a question. Unless each interviewer asks the questions exactly as shown, the answers are difficult to interpret. Similarly, you must follow the sequence of questions. Do not ask questions out of order unless you are given special instructions to do so.

It is the interviewer's responsibility to ask every question. Often a previous statement by the participant will partially answer another question, but rarely does it answer that question completely. Do not omit questions and do not assume that you know the answer to the question.

E.4. How To Get Satisfactory Answers

Learn the Purpose of Each Question. In order to do a good job of interviewing, you need to understand the kind of information we are trying to get through each particular question. Unless you understand its purpose, you will not be able to judge when a response is adequate and when you must probe for clarification or for additional information.

Don't Attempt to Interpret/Explain the Question - Maintain Neutrality. If a participant does not seem to understand a question, repeat the question slowly and clearly. Give the participant time to think about the question (while simultaneously being aware of time allowed for administering the questionnaire). Unless you have other instructions about handling specific questions, the acceptable reply for a participant who wants to know what a question means is "whatever it means to you". Do

not attempt to explain the purpose of a question unless the interviewer instructions specifically authorize you to do so.

Defining Terms Used in Questions. Some participants may ask what is meant by a word used in a question. If it relates to a particular medical term, efforts should be made to clarify the term (for example, balloon angioplasty refers to a procedure involving opening the arteries of the heart with a balloon or other device). On the other hand, for questions related to psychosocial issues ("how tired have you been feeling lately"), the interviewer should leave the matter of definition to the participant, suggesting "whatever you think tired means" or "however you use the term tired," if the participant asks "what do you mean by tired?"

Don't Leave a Question Until You Have an Adequate Answer or Have Determined That a Participant Can't Give a Clearer Answer.

E.5. Probing Techniques

The two most effective neutral probes are silence and repeating the original question.

Silence. Silence can be a very valuable tool. Many people, including interviewers, react to silence as a vacuum that must be filled with constant chatter. The interviewer who can wait quietly and patiently will soon find that 15 seconds of silence is more than most participants can take, and the participant will often expand or clarify a previously inadequate answer.

Repeating the Question or Answer Categories. Be sure to repeat the question as stated in the questionnaire. This is particularly useful when the participant answers a question irrelevantly. In some cases it will be necessary to remind the participant of your frame of reference, i.e., to acknowledge what the participant has said and then bring the participant back to the topic by repeating the question.

Do not Accept a "Don't Know" Answer Without Probing at Least Once. If a response is a "don't know", probe by asking: "Well, what do you think?" or "I'd like to know your opinion" (if the question asks for an opinion rather than facts). If the question deals with facts, we prefer an approximation to no answer at all, and you might probe "what's your best guess?" or "approximately?" to convey the idea that 100% accuracy is not required.

Use Neutral Probes That Do Not Suggest Answers Probes are needed to obtain more complete, accurate answers. All probes must be non-directive, i.e., the probe must not suggest any particular answer to the participant. Probes should be used whenever the participant is hesitant in answering questions; when she/he seems to have trouble expressing herself/him; when she/he seems too shy to speak at length; whenever there is any reason for the interviewer to believe that the participant has not given a complete report of her/his thoughts; and finally, reassuring probes are needed when a participant seems to lack confidence.

Examples of Other Neutral Probes:

1. In what way?
2. What is that? Why do you feel that way?
3. How do you mean?
4. I would like your impression.
5. I would like your opinion.
6. What do you think?
7. Can you give me an example? or For example?
8. Can you explain that in a little more detail?
9. How are you using the term. . .?
10. How is that? or How does that work?
11. Anything at all - even little things?
12. If you had to choose, which would you stay?
13. What else can you tell me about that?
14. In general, overall. . .

Generally Speaking, Some Probes are Avoided in Favor of others. Instead of "anything else?" you'll find that "what else can you tell me about that?" is more likely to elicit answers. Instead of

"why?" you'll find "why do you feel that way?" or "I'd be interested in your reasons" accomplishes the same purpose and is less likely to be threatening.

Questions Used in Ordinary Conversation Should Be Avoided Because They Suggest Answers. Refrain from asking "do you mean A or B". This suggests two possible answers and there may be others that may occur to the participant.

Do Not Leave a Probe Dangling. Always record the response to a probe even if it's only "no" or "That's all I can think of".

Always Cross Reference. When you probe to clarify a response, always indicate which response you are clarifying. There will be times when a participant will say something ambiguous and continue talking.

1. If there's not enough space to record the respondent's answer, use the margin. Be sure to label these continuations clearly when you edit each completed interview.

2. Don't ask "do you mean . . .". People tend to say "yes" to any suggestion either because it's easy or because they think it's the right answer.

Make Probes Consistent with the Purpose of the Question. The importance of choosing a probe that is appropriate for the particular kind of inadequate answer given cannot be stressed enough. Think through each response, evaluate it for relevance and clarity and choose the right kind of probe. Any probe that does not suggest answers and that is non-threatening is acceptable provided it is appropriate to the particular interviewing problem.

Watch for Irrelevant Answers. Irrelevant answers can be interesting, but interviewers must bear in mind what information is being sought. Acknowledge the response and make it clear that you have been listening; also make clear your frame of reference before repeating the question. Repeat the question word-for-word, but preface it in such a way that you now need additional information.

Watch for Vague, Incomplete Answers. A probe such as "tell me more about. . ." is effective.

Avoid "Depends" or "Qualified" Answers. When the participant gives a response of this nature, it is advisable to use probes such as repeating the question; preface the question with a phrase such as "well, in general. . .".

Record and Document Fully and Clearly.

E.6. How To Record The Interviews

The following suggestions are recommended:

1. Be prepared to write.
2. Periodically establish eye contact with the participant while you are writing.
3. Use abbreviations to help you get down as much as possible.
4. Always report a response using the participant's exact words.
5. Always record verbatim the response to a probe.
6. If you question whether you circled the correct code, be sure to record the participant's verbatim response.
7. If you make a recording mistake, cross out the wrong part instead of erasing: it is faster and easier to read. Then circle and initial the correct answer. If an answer is skipped, circle both spaces and write "NA".

Enter "PM", permanently missing, for a month, day or year if unknown. Unknown values are NOT acceptable for birthdates, visits/examination dates.

E.7. Following The Centralized Training Session

Become familiar with the questionnaires. Read instructions carefully. Administer questionnaires to yourself just as you would a participant and probe yourself if an answer to a question is uncodable or otherwise inadequate. We recommend completing the interview with a friend. Re-read the instructions watching for any errors you made so that you do not repeat them on subsequent interviews. Study the instructions thoroughly so that you understand the purpose of the questions.

You may wish to re-read this section of the MOP following the conduct of interviews: it may provide a different perspective and reinforce what you have experienced.

E.8 Procedures for Administration of Medications Form

Overview

The intent of the medications form is to gather information about all prescription medicines currently used by the participant, as well as regular use of selected over-the-counter medications. At the end of SV0, eligible participants should be given written instructions to bring all medications that they take on a regular basis with them when they return to the clinic for SV1. "Medications taken regularly" are defined as any medication (prescription or over-the-counter) that the participant takes at least once per week and that he/she expects to continue taking unless otherwise advised by a physician. The patient should be instructed ***not*** to bring in any eye drops, nose drops, or vitamin supplements. Upon the participant's return to the clinic at SV1, a clinic staff member will examine the medications with the participant, list the generic or trade name of the medication on the form, and indicate on the form by placing and "X" in the appropirate box if the participant is taking any of the following medications: (1) any compound prescribed or taken because of a medical exclusion, including agents prescribed to treat angina or heart disease, medications for treatment of exclusionary psychological conditions, or insulin to treat diabetes mellitus; (2) medications prescribed for treatment of hypertension; (3) medications prescribed for treatment of hyperlipidemia; (4) oral hypoglycemics; and (5) in female participants, any estrogens prescribed.

Each clinic will be provided with an ACT Medications Dictionary that lists medications currently prescribed to treat hypertension and hyperlipidemia. The list will also include currently prescribed estrogens and oral hypoglycemics. This dictionary will list both trade and generic names of compounds alphabetically within classification (i.e., Anti-hypertensive, Anti-hyperlipidemic, Insulin/Oral Hypoglycemics, and Estrogens). Also provided in the dictionary will be a list of medications that can be considered exclusive of participation in ACT. Any persons taking one or more of those medications due to an active medical condition that is exclusionary will not be enrolled in the study (see "Exclusionary Medications" at end of Appendix E). If the participant forgets to bring medications with him/her when returning for SV1, each Clinical Center will be responsible for developing a mechanism to obtain and/or verify this information prior to SV2.

Instructions for Review and Completion of Specific Items

Distinct versions of the form will be used for SV1 and follow-up visits. The screening or "Baseline" form will not include a prompt for insulin use since diabetes requiring treatment with insulin is an exclusion criterion. The "Follow-up" form will include insulin with the prompt for oral

hypoglycemics. Thus participants who initiate insulin therapy for treatment of diabetes during the study will be asked to provide more detail about its usage **but will not** be excluded from the study; whereas, persons on insulin at SV1 will be excluded from study participation.

Following is an item-by-item list of the form contents with instructions for their completion or review.

ID -- Clearly enter the six-digit ID Number that has been previously assigned, and check carefully to make sure that it is copied correctly.

Acrostic -- Clearly enter the six-digit Acrostic and check carefully to make sure that it is copied correctly.

Date Completed -- Clearly enter the date of the SV1 visit in the boxes provided, using leading zeros (e.g., | 0 | 9 | 1 | 1 | 9 | 5 | represents the date of September 11, 1995).

Completed by -- Clearly enter your staff identification code number in the boxes provided.

If participant does not take any medications on a regular basis check here -- If the participant indicates that he/she does not take *any* medications on a regular basis, place an "X" in the box provided on the form to indicate so.

Medication Name -- Use a separate line for each medication. Clearly write out the complete name (generic or trade) of the medication being taken in the space provided.

Dose -- Write the dose taken *and* the units in which the medication is dispensed (e.g., "10 mg" or "25 mL") in the space provided.

Times per Day -- Write the number of times *per day* that the medication is taken in the space provided. If the medication is taken fewer than once per day, give the average number of doses. For example, if someone takes a medication every other day, the daily dose would be "0.5".

Anti-hypertensive -- Mark an "X" in the space provided if the medication on this line is listed in the dictionary as an anti-hypertensive agent.

Lipid-Lowering -- Mark an "X" in the space provided if the medication on this line is listed in

the dictionary as a lipid-lowering agent.

Hypoglycemic -- Mark an "**X**" in the space provided if the medication on this line is listed in the dictionary as an oral hypoglycemic agent.

Estrogen -- Mark an "**X**" in the space provided if the medication on this line is listed in the dictionary as an estrogen.

Any EXCLUSIONARY MEDICATIONS? -- Indicate by marking the boxes provided whether any of the medications listed are taken to treat a medical condition that excludes the subject from participation in ACT (see Exclusionary Medications).

Review and completion of the form at the follow-up visits (6 and 24): Completion of the form during follow-up will be essentially the same as that at SV1 except that initiation of insulin usage should be documented by completing a line for insulin including dosage and frequency taken and marking an "**X**" in the "**Insulin/Hypoglycemic**" column.

Exclusionary Medications

There are several medical conditions that exclude patients from participation in ACT that are linked to medication use. Those conditions are the following:

(1) Use of any medication to treat asthma ***within the last 6 months***.

(2) Diabetes mellitus requiring treatment with insulin.

(3) Angina requiring treatment with medication. (Note: the patient should be excluded if he or she has a current prescription to treat the condition even if he or she has not had a recent attack of angina.)

(4) A mental condition requiring treatment with anti-psychotic or psychotropic medications.

Medications used to treat each of these conditions are listed in the dictionary. If a patient is taking one of the calcium channel-blockers or beta-blockers included in the list of anti-angina agents, be careful to ***confirm whether or not the medication is prescribed for angina***. If a calcium channel-blocker or beta-blocker is prescribed for hypertension and the patient has been on the same dose for

three months or more, or if it is prescribed for any condition other than angina or hypertension, then the patient is eligible for participation. In this circumstance, use of the calcium channel-blocker or beta-blocker should be documented on the medications form and the appropriate box under the "Anti-Hypertensive" column should be marked.

E.9 Baseline Medication Form

E.10 Anti-Hypertensive Agents

ACT Baseline Medications Form

Clinic Use Only

ID ☐☐☐☐☐☐ Acrostic ☐☐☐☐☐☐

Date Completed ☐☐/☐☐/☐☐ Mon Day Year

Completed by ☐☐ (staff code)

If participant does not take *any* medications on a regular basis, check here: ☐

MEDICATION NAME	DOSE	TIMES PER DAY	ANTI-HYPERTENSIVE	LIPID-LOWERING	HYPOGLY-CEMIC	ESTROGEN
1.						
2.						
3.						
4.						
5.						
6.						
7.						
8.						
9.						
10.						
11.						
12.						
13.						
14.						
15.						
16.						
17.						
18.						
19.						
20.						

Any EXCLUSIONARY MEDICATIONS? 1☐ Yes 2☐ No

ANTI-HYPERTENSIVE AGENTS

Listed by GENERIC name.

Generic Name	Trade Name
acebutolol	Sectral
amiloride	Midamor
amlodipine	Norvasc
atenolol	Tenormin
bendroflumethiazide	Naturetin
benezepril	Lotensin
benzthiazide	Exna
betaxolol	Kerlone
bisoprolol	Zebeta
bumetanide	Bumex
captopril	Capoten
carteolol	Cartrol
chlorothiazide	Esidrix
chlorthalidone	Hygroton
clonidine	Catapres
clonidine transdermal	Catapres TTS
diltiazem	Cardizem SR
diltiazem	Cardizem CD
diltiazem	Dilacor XR
doxazosin	Cardura
enalapril	Vasotec
felodipine	Plendil
fosinopril	Monopril
furosemide	Lasix
guanabenz	Wytensin
guanadrel	Hylorel
guanethidine	Ismelin
guanfacine	Tenex
hydralazine	Apresoline
hydrochlorothiazide/amiloride	Moduretic
hydrochlorothiazide/spironolactone	Aldactazide
hydrochlorothiazide/triamterene	Dyazide
hydrochlorothiazide/triamterene	Maxzide
hydroflumethiazide	Saluron
hydroflumethiazide	Diucardin
indapamide	Lozol
isradipine	DynaCirc
labetalol	Normodyne
labetalol	Trandate
lisinopril	Prinivil
lisinopril	Zestril
losartan	Cozaar
methyclothiazide	Enduron
methyldopa	Aldomet
metolazone	Zaroxolyn
metolazone	Mykrox
metoprolol	Lopressor
metroprolol	Toprol XL
minoxidil	Loniten
nadolol	Corgard

Listed by GENERIC name.

Generic Name	Trade Name
nicardipine	Cardene
nicardipine	Cardene SR
nifedipine	Adalat CC
nifedipine	Procardia XL
penbutolol	Levatol
pindolol	Visken
polythiazide	Renese
prazosin	Minipress
propranolol	Inderal
propranolol	Inderal-LA
quinapril	Accupril
ramiprill	Altace
reserpine	Reserpine
spironolactone	Aldactone
terazosin	Hytrin
timolol	Blocadren
torsemide	Demadex
triamterene	Dyrenium
trichlormethiazide	Naqua
trichlormethiazide	Metahydrin
verapamil	Calan
verapamil	Isoptin
verapamil	Calan SR
verapamil	Isoptin SR
verapamil	Verelan

Listed by TRADE name.

Trade Name	Generic Name
Accupril	quinapril
Adalat CC	nifedipine
Aldactazide	hydrochlorothiazide/spironolactone
Aldactone	spironolactone
Aldomet	methyldopa
Altace	ramiprill
Apresoline	hydralazine
Blocadren	timolol
Bumex	bumetanide
Calan	verapamil
Calan SR	verapamil
Capoten	captopril
Cardene	nicardipine
Cardene SR	nicardipine
Cardizem CD	diltiazem
Cardizem SR	diltiazem
Cardura	doxazosin
Cartrol	carteolol
Catapres	clonidine
Catapres TTS	clonidine transdermal
Corgard	nadolol
Cozaar	losartan
Demadex	torsemide
Dilacor XR	diltiazem
Diucardin	hydroflumethiazide
Dyazide	hydrochlorothiazide/triamterene
DynaCirc	isradipine
Dyrenium	triamterene
Enduron	methyclothiazide
Esidrix	chlorothiazide
Exna	benzthiazide
Hygroton	chlorthalidone
Hylorel	guanadrel
Hytrin	terazosin
Inderal	propranolol
Inderal-LA	propranolol
Ismelin	guanethidine
Isoptin	verapamil
Isoptin SR	verapamil
Kerlone	betaxolol
Lasix	furosemide
Levatol	penbutolol
Loniten	minoxidil
Lopressor	metoprolol
Lotensin	benezepril
Lozol	indapamide
Maxzide	hydrochlorothiazide/triamterene
Metahydrin	trichlormethiazide
Midamor	amiloride
Minipress	prazosin

Listed by TRADE name.

Trade Name	Generic Name
Moduretic	hydrochlorothiazide/amiloride
Monopril	fosinopril
Mykrox	metolazone
Naqua	trichlormethiazide
Naturetin	bendroflumethiazide
Normodyne	labetalol
Norvasc	amlodipine
Plendil	felodipine
Prinivil	lisinopril
Procardia XL	nifedipine
Renese	polythiazide
Reserpine	reserpine
Saluron	hydroflumethiazide
Sectral	acebutolol
Tenex	guanfacine
Tenormin	atenolol
Toprol XL	metroprolol
Trandate	labetalol
Vasotec	enalapril
Verelan	verapamil
Visken	pindolol
Wytensin	guanabenz
Zaroxolyn	metolazone
Zebeta	bisoprolol
Zestril	lisinopril

Listed by GENERIC name.

Generic Name	Trade Name
cholestipol	Colestid
cholestyramine	Questran Light
cholestyramine	Questran
clofibrate	Atromid-S
clofibrate	Clofibrate
dextrothyroxin	Choloxin
fluvastatin	Lescol
gemfibrozil	Lopid
lovastatin	Mevacor
nicotinic acid	Nia-Bid
nicotinic acid	Niacels
nicotinic acid	Niacin
nicotinic acid	Nica
nicotinic acid	Nicobid Tempul
nicotinic acid	Nicolar
nicotinic acid	Nicor
nicotinic acid	Nicotinex
nicotinic acid	Slo-Niacin
pravastatin	Pravachol
probucol	Lorelco
simvastatin	Zocor

LIPID LOWERING AGENTS

Listed by TRADE name.

Trade Name	Generic Name
Atromid-S	clofibrate
Choloxin	dextrothyroxin
Clofibrate	clofibrate
Colestid	cholestipol
Lescol	fluvastatin
Lopid	gemfibrozil
Lorelco	probucol
Mevacor	lovastatin
Nia-Bid	nicotinic acid
Niacels	nicotinic acid
Niacin	nicotinic acid
Nica	nicotinic acid
Nicobid Tempul	nicotinic acid
Nicolar	nicotinic acid
Nicor	nicotinic acid
Nicotinex	nicotinic acid
Pravachol	pravastatin
Questran	cholestyramine
Questran Light	cholestyramine
Slo-Niacin	nicotinic acid
Zocor	simvastatin

Listed by GENERIC name.

Generic Name	Trade Name
acetohexamide	Dymelor
chlorpropmide	Diabinese
glipizide	Glucotrol
glipizide	Glucotorol XL
glyburide	DiaBeta
glyburide	Micronase
glyburide	Glynase Prestab
metformin	Glucophage
tolazamide	Tolinase
tolbutamide	Orinase

ORAL HYPOGLYCEMICS

Listed by TRADE name.

Trade Name	Generic Name
DiaBeta	glyburide
Diabinese	chlorpropmide
Dymelor	acetohexamide
Glucophage	metformin
Glucotorol XL	glipizide
Glucotrol	glipizide
Glynase Prestab	glyburide
Micronase	glyburide
Orinase	tolbutamide
Tolinase	tolazamide

Listed by GENERIC name.

Generic Name	Trade Name
chlorotrianisene	Tace
conjugated estrogens	Premarin
conjugated estrogens	Premarin Vaginal Cream
conjugated estrogens plus meprobamate	PMB 200
conjugated estrogens plus meprobamate	Milprem 400
conjugated estrogens plus meprobamate	PMB 400
dienestrol	Ortho Dienestrol Vaginal Cream
dienestrol	DV Vaginal Cream
diethylstilbestrol	DES
esterified estrogens plus chlordiazepoxide	Menrium 5-2
esterified estrogens plus chlordiazepoxide	Menrium 5-4
esterified estrogens plus chlordiazepoxide	Menrium 10-4
estradiol	Estrace Vaginal Cream
estradiol cypionate in oil	Dep Gynogen
estradiol cypionate in oil	Depo-Estradiol Cypionate
estradiol cypionate in oil	Depogen
estradiol cypionate in oil	Dura-Estrin
estradiol cypionate in oil	Estra-D
estradiol cypionate in oil	Estra-Cyp
estradiol cypionate in oil	Estroject-LA
estradiol valerate in oil	Delestrogen
estradiol valerate in oil	Valergen 10
estradiol valerate in oil	Dioval XX
estradiol valerate in oil	Duragen 20
estradiol valerate in oil	Estra-L 20
estradiol valerate in oil	Gynogen LA 20
estradiol valerate in oil	Valergen 20
estradiol valerate in oil	Deladiol 40
estradiol valerate in oil	Dioval 40
estradiol valerate in oil	Duragen 40
estradiol valerate in oil	Estra-L 40
estradiol valerate in oil	Gynogen LA 40
estradiol valerate in oil	Valergen 40
estrified estrogens	Estratab
estrified estrogens	Menest
estropipate	Ogen
estropipate	Ortho-Est
estropipate	Ogen Vaginal Cream
estrovis	Quinestrol
ethinyl estradiol	Estinyl

NOTE: INCLUDE ALL BIRTH CONTROL PILLS AS ESTROGENS.

Listed by TRADE name.

Trade Name	Generic Name
DES	diethylstilbestrol
DV Vaginal Cream	dienestrol
Deladiol 40	estradiol valerate in oil
Delestrogen	estradiol valerate in oil
Dep Gynogen	estradiol cypionate in oil
Depo-Estradiol Cypionate	estradiol cypionate in oil
Depogen	estradiol cypionate in oil
Dioval 40	estradiol valerate in oil
Dioval XX	estradiol valerate in oil
Dura-Estrin	estradiol cypionate in oil
Duragen 20	estradiol valerate in oil
Duragen 40	estradiol valerate in oil
Estinyl	ethinyl estradiol
Estra-Cyp	estradiol cypionate in oil
Estra-D	estradiol cypionate in oil
Estra-L 20	estradiol valerate in oil
Estra-L 40	estradiol valerate in oil
Estrace Vaginal Cream	estradiol
Estratab	estrified estrogens
Estroject-LA	estradiol cypionate in oil
Gynogen LA 20	estradiol valerate in oil
Gynogen LA 40	estradiol valerate in oil
Menest	estrified estrogens
Menrium 10-4	esterified estrogens plus chlordiazepoxide
Menrium 5-2	esterified estrogens plus chlordiazepoxide
Menrium 5-4	esterified estrogens plus chlordiazepoxide
Milprem 400	conjugated estrogens plus meprobamate
Ogen	estropipate
Ogen Vaginal Cream	estropipate
Ortho Dienestrol Vaginal Cream	dienestrol
Ortho-Est	estropipate
PMB 200	conjugated estrogens plus meprobamate
PMB 400	conjugated estrogens plus meprobamate
Premarin	conjugated estrogens
Premarin Vaginal Cream	conjugated estrogens
Quinestrol	estrovis
Tace	chlorotrianisene
Valergen 10	estradiol valerate in oil
Valergen 20	estradiol valerate in oil
Valergen 40	estradiol valerate in oil

NOTE: INCLUDE ALL BIRTH CONTROL PILLS AS ESTROGENS.

Listed by GENERIC name.

Generic Name	Trade Name
albuterol	Proventil
albuterol	Ventolin
beclamethasone	Beclovent
beclamethasone	Becanase
flunisolide	Aerobid
ipratropium	Atrovent
isoetharine	Bronkosol
metaproterenol	Alupent
pirbuterol	Maxair
terbutaline	Brethine
theophylline	Theo-Dur
triamcinolone	Azmacort

Listed by TRADE name.

Trade Name	Generic Name
Aerobid	flunisolide
Alupent	metaproterenol
Atrovent	ipratropium
Azmacort	triamcinolone
Becanase	beclamethasone
Beclovent	beclamethasone
Brethine	terbutaline
Bronkosol	isoetharine
Maxair	pirbuterol
Proventil	albuterol
Theo-Dur	theophylline
Ventolin	albuterol

Listed by GENERIC name.

Generic Name	Trade Name
beef and pork insulin	Regular Iletin I
beef and pork insulin NPH	NPH Ilentin I
beef and pork insulin zinc	Lente Ilenti I
beef insulin NPH	NPH Insulin
beef insulin zinc	Lente Insulin
beef insulin zinc	Ultralente U
human insulin	Humulin R
human insulin	Novolin R
human insulin	Velosulin Human
human insulin NPH	Humulin N
human insulin NPH	Novolin N
human insulin NPH/regular	Humulin 70/30
human insulin NPH/regular	Novolin 70/30
human insulin NPH/regular	Humulin 50/50
human insulin zinc	Humulin L
human insulin zinc	Novolin L
pork insulin	Regular Insulin
pork insulin	Pork Insulin Iletin
pork insulin	Regular Purified Pork Insulin
pork insulin NPH	NPH-N
pork insulin NPH	Pork NPH Ilenti II
pork insulin zinc	Lente Insulin II
pork insulin zinc	Lente L

NOTE: INSULIN USE IS AN EXCLUSION AT BASELINE.
INSULIN USE DURING FOLLOW-UP SHOULD BE
DOCUMENTED ON THE FORM WITH HYPGLYCEMICS.

INSULINS

Listed by TRADE name.

Trade Name	Generic Name
Humulin 50/50	human insulin NPH/regular
Humulin 70/30	human insulin NPH/regular
Humulin L	human insulin zinc
Humulin N	human insulin NPH
Humulin R	human insulin
Lente Ilenti I	beef and pork insulin zinc
Lente Insulin	beef insulin zinc
Lente Insulin II	pork insulin zinc
Lente L	pork insulin zinc
NPH Ilentin I	beef and pork insulin NPH
NPH Insulin	beef insulin NPH
NPH-N	pork insulin NPH
Novolin 70/30	human insulin NPH/regular
Novolin L	human insulin zinc
Novolin N	human insulin NPH
Novolin R	human insulin
Pork Insulin Iletin	pork insulin
Pork NPH Ilenti II	pork insulin NPH
Regular Iletin I	beef and pork insulin
Regular Insulin	pork insulin
Regular Purified Pork Insulin	pork insulin
Ultralente U	beef insulin zinc
Velosulin Human	human insulin

NOTE: INSULIN USE IS AN EXCLUSION AT BASELINE.
INSULIN USE DURING FOLLOW-UP SHOULD BE
DOCUMENTED ON THE FORM WITH HYPGLYCEMICS.

Listed by GENERIC name.

---------- TYPE=beta-blocker ----------

Generic Name	Trade Name
acebutolol	Sectral
atenolol	Tenormin
betaxolol	Kerlone
labetalol	Normodyne
metoprolol tartrate	Lopressor
nadolol	Corgard
pindolol	Visken
propranolol	Inderal
timolol	Blocardren

---------- TYPE=calcium channel-blocker ----------

Generic Name	Trade Name
diltiazem	Cardizem
isradipine	DynaCirc
nicardipene	Cardene
nifedipine	Procardia
nimodipine	Nimotop
verapamil	Calan
verapamil	Isoptin

Listed by TRADE name.

---------- TYPE=beta-blocker ----------

Trade Name	Generic Name
Blocardren	timolol
Corgard	nadolol
Inderal	propranolol
Kerlone	betaxolol
Lopressor	metoprolol tartrate
Normodyne	labetalol
Sectral	acebutolol
Tenormin	atenolol
Visken	pindolol

---------- TYPE=calcium channel-blocker ----------

Trade Name	Generic Name
Calan	verapamil
Cardene	nicardipene
Cardizem	diltiazem
DynaCirc	isradipine
Isoptin	verapamil
Nimotop	nimodipine
Procardia	nifedipine

Listed by type.

---------- Nitrate Type=capsule ----------

Trade Name
Dilatrate
Ismo
Isordil
Isosorbide
Nitro-Bid
Nitrogard
Nitroglycerin
Nitroglyn
Nitrospan
Peritrate
Sorbitrate

---------- Nitrate Type=lingual aerosol ----------

Trade Name
Nitolingual Spray

---------- Nitrate Type=ointment ----------

Trade Name
Nitrobid
Nitrol
Nitrong

---------- Nitrate Type=sublingual ----------

Trade Name
Cardilate
Erythrityl Tetranitrate
Isordil
Isosorbide
Nitrogara
Nitrostat

---------- Nitrate Type=transdermal ----------

Trade Name
Deponit NTG Film
Minitran
Nitro-Dur
Nitrodisc

Listed by GENERIC name.

Generic Name	Trade Name
isocarboxazid	Marplan
phenelzine	Nardil
tranylcypromine	Parnate
lithium	Eskalith
lithium	Lithobid
chlorpromazine	Thorazine
clozapine	Clozaril
fluphenazine	Prolixin
haloperidol	Haldol
perphenazine	Trilafon
thioridazine	Mellaril
thiothixene	Navane
trifluoperazine	Stelazine
doxepin	Sinequan
doxepin	Adapin
fluoxetine	Prozac
trazodone	Desyrel
amitryptilene	Elavil
desiparamine	
imipramine	Tofranil
nortriptyline	

Listed by TRADE name.

Trade Name	Generic Name
Marplan	isocarboxazid
Nardil	phenelzine
Parnate	tranylcypromine
Eskalith	lithium
Lithobid	lithium
Clozaril	clozapine
Haldol	haloperidol
Mellaril	thioridazine
Navane	thiothixene
Prolixin	fluphenazine
Stelazine	trifluoperazine
Thorazine	chlorpromazine
Trilafon	perphenazine
Adapin	doxepin
Desyrel	trazodone
Prozac	fluoxetine
Sinequan	doxepin
	desiparamine
	nortriptyline
Elavil	amitryptilene
Tofranil	imipramine

APPENDIX F
MEASUREMENT OF PHYSICAL PARAMETERS

F.1 Anthropometric Measurements 2
Height 2
Weight 3
Circumference and Skinfolds 4
General Technique 5
Specific Procedures 7
Equipment Calibration and Maintenance 11
Training and Certification 11
Figure 1 General Description of Skinfold and Placement of Calipers 13
Figure 2 Waist Circumference 14
Figure 3 Hip Circumference 14
Figures 4-11 Skinfold Measurement Sites 15-17
ACT Clinical Measures Data Collection Form 18
Protocol for Testing and Certification of Anthropometric Personnel 19

F.2 Measurement of Blood Pressure 21
Blood Pressure Alert Values 21
Overview 22
Specific Instructions 24
Summary of Korotkoff Phases and Auscultatory Gaps 28
Blood Pressure Certification 29
References 29
Protocol for Testing and Certification of Blood Pressure Personnel 31
SV1 Blood Pressure Form . . . . .
Clinical Measures Form (see page 2, Blood Pressure in Anthropometric Section F.1) . . . . .

F.1 MEASUREMENT OF PHYSICAL PARAMETERS

Anthropometric Measurements

Anthropometric measures are secondary outcomes in ACT because they are related to cardiovascular disease risk and may be favorably influenced by physical activity. Measurements of height, weight, skinfolds, and circumferences will be taken by trained and certified staff. As height and weight are measured and recorded in metric units (cm, kg), examiners should be prepared to tell participants their height and weight in English units (in, lb). A conversion table is a useful aid.

Overview of Height and Weight Measurements

Because of their generally high reliability and low variability, height and weight measurements will be taken once. To facilitate standardization and reduce the potential for recording errors, a fixed order for taking these measurements is used: first height, then weight.

Height (at SV1 only)

Equipment: Wall-mounted stadiometer (floor and backboard unit attached together), in centimeters
Headboard (a right triangle with an angle brace)

[CENTERS TO INDICATE MANUFACTURER'S NAME, MODEL, CITY, STATE FOR EACH]

Procedure:

1. The stadiometer should be placed on a firm, level surface, against a vertical wall. If the floor is carpeted a sheet of wood or hard plastic should be placed beneath the floor board.

2. The participant should remove shoes, thick socks, headgear, hair ornaments, etc., and stand erect on the floor board of the stadiometer with his/her back to the vertical back board. The buttocks, heels, and shoulder blades should be in contact with the back board. Both arms should hang freely by the sides of the trunk with palms facing the thighs. The participant should look straight ahead with his/her head in the Frankfort (horizontal) plane. The participant's weight should be distributed evenly on both feet, with heels together and both feet pointed slightly outward.

3. The examiner should be at eye level of the measurement.

4. Ask the participant to take a full inspiration. Place the headboard over the crown of the head with the headboard forming a right angle with the tape measure.

5. Ask the participant to step out from under the headboard, and record the height to the nearest tenth of a centimeter (0.1 cm).

Weight (at SV1, 6- and 24-months follow-up visits)

Equipment: Balance beam scale, in kg

[CENTERS TO INDICATE MANUFACTURER'S NAME, MODEL, CITY, STATE]

Procedure:

1. The scale should be placed on a firm, level surface. If the floor is carpeted, a sheet of wood or hard plastic should be placed under the scale.

2. Confirm that the scale is balanced (zeroed), and balance if necessary. Before each weight is measured, the sliding scale weights must be moved to zero.

3. The participant should remove shoes, headgear, outer clothing, and items from the pockets in order to be weighed in light indoor clothing, such as T-shirt and shorts.

4. Ask the participant to stand in the center of the scale platform, with head erect and eyes looking straight ahead.

5. Adjust the weight on the indicator until it is balanced, and carefully record the result to the nearest tenth of a kilogram (0.1 kg). Use care in adding the lower beam weight to the upper beam weight, as they have different increments.

6. After weighing a subject, the weights should be left in place to prevent jarring which can occur if the indicator floats at zero.

Circumferences and Skinfolds (at SV1, 6 and 24 months follow-up visits)

Overview of Circumferences and Skinfolds

To improve precision, two readings of circumferences and skinfolds will be taken. If the two measurements differ by more than the amount listed below, a third measurement should be taken. The complete set of circumferences and skinfolds will be done once before doing the second set of circumferences and skinfolds. Marking the triceps, abdominal, and thigh sites need be done only once. To facilitate standardization and reduce the potential for recording errors, the order of circumference and skinfold measurements should be: waist, hip, chest (men only), triceps, subscapular, suprailiac, abdominal, and thigh.

Tolerance Limits to Initiate a Third Reading:

Waist: >1.0 cm

Hip: >1.0 cm

Skinfolds: >3.0 mm

Although it is strongly recommended to have a recorder, it is not required. In the absence of a recorder, it is helpful to have a mirror so that the examiner can see if the tape measure is horizontal when measuring circumferences.

Equipment: Nonstretchable (e.g., steel or fiberglass) tape

Lange Calipers

Marking pen or eyebrow pencil

[CENTERS TO INDICATE MANUFACTURER'S NAME, MODEL, CITY, STATE FOR TAPE AND LANGE CALIPERS]

General Technique:

Circumferences: In general, participants will be wearing light indoor clothing, such as a T-shirt and shorts. Waist circumference measurements should be taken on the bare skin. Hip circumference measurements may be taken over light indoor clothing.

When making the waist and hip circumference measurements, preferably with the help of a recorder, always make sure the tape is horizontal all around the body.

The tension applied to the tape by the examiner affects the validity and reliability of the measurements. The tape should be held snugly around the body part, but not so tight as to compress the subcutaneous adipose tissue. The examiner should check to ensure that the tape is not indenting the skin. For some circumferences there may be gaps between the tape and the skin in some individuals. If the gap is large, a note should be made in the participant's record, but in most instances, this gap is small and of little concern. The examiner should not attempt to reduce the gap by increasing the tension of the tape.

Skinfolds: Skinfolds are taken on the right side of the participant's body on bare skin. However, if measurements can't be taken on the right side because of a prosthesis, cast, or other reason, take the measurement on the left side and make a note of this in the comment area at the bottom of the form. In general, to make a skinfold measurement a double fold of skin and subcutaneous adipose tissue is lifted by grasping firmly the fold between the thumb and index finger of the left hand (assuming the examiner is right-handed) 1 cm above the site to which the calipers will be applied. This 1 cm distance is necessary so that pressure from the fingers does not affect the measured value.

The width of the skin that is enclosed between the fingers is an important factor, but cannot be easily standardized for all sites of the body. For a given site the width of the skin should be minimal, still yielding a well-defined fold. In general, place the thumb and index finger on the skin about 8 cm apart, on a line perpendicular to the long axis of the skinfold that will be measured. The thumb and index finger are drawn towards each other, and a fold is grasped firmly between them. The basic principle is that the long axis be parallel to the natural cleavage lines of the body in the region of the measurement. The amount of tissue elevated must be sufficient to form a fold with approximately parallel sides. Care must be exercised so that only skin and adipose tissue are elevated. The fold is kept elevated until the measurement has been completed. (See Figure 1.)

The caliper is held in the right hand while a skinfold is elevated with the left hand. To make a measurement, pressure is exerted to separate the caliper jaws, and the caliper is slipped over the skinfold so that the fixed arm of the caliper is positioned on one side of the skinfold. (See Figure 1.) The measurement is made where the sides of the skinfold are approximately parallel. This is approximately midway between the base of the the site and the crest of the skinfold. As the skinfold is narrower near the crest and larger toward the base, if the calipers are placed at the base the resulting measurement is too large. The correct distance from the crest is defined as the minimal distance from the crest at which a true fold, with surfaces approximately parallel to each other and to the contact surfaces of the calipers, is obtained upon application of the calipers to the skin. The jaws of the caliper are placed so that the thickness of the skinfold is measured perpendicular to its long axis when the pressure on the caliper is released and the caliper jaws come towards each other. The skinfold should not be let go by the fingers while applying the caliper and taking a reading. The release of pressure should be gradual to avoid discomfort.

The needle of the calipers may creep a little when applied to the skinfold, as the pressure of the instrument compresses the tissue. Take the reading 1-2 seconds after the calipers are applied. Thus, while holding the skinfold gently with the left hand, apply the calipers with the right, count 1-2 seconds, and take the reading. The reading should be taken to the nearest millimeter (1.0 mm). Release the calipers from the skinfold before letting go with the left hand to avoid scratching or pinching the participant with the calipers.

Do not handle the skinfolds any more than is necessary to make the measurements, both because it may cause discomfort and because repeated manipulation may alter the local fluid content of the tissue and yield progressively lower measurements.

In some participants at some sites the skinfold is larger than the capacity of the caliper. If the skinfold thickness is greater than 65, the examiner should check the box at the bottom of the form which indicates the thickness is greater than 65. In some subjects at some sites it is simply impossible to raise a discrete fold of subcutaneous fat tissue. This should be noted by checking the box at the bottom of the form indicating that a skinfold could not be measured. If a participant refuses to have his/her skinfolds measured, this should be noted by checking the box at the bottom of the form indicating the participant refused. Any other cmments, such as the measurement was taken on the left side, should be noted as well at the bottom of the form.

Specific Procedures:

Waist Circumference (Figure 2):

1. The participant stands erect, feet together, with arms hanging relaxed at the sides.

2. The examiner should face the participant and over bare skin palpate the hip area along the participant's sides for the right iliac crest. If necessary, adjust the clothing so that the waistband or other piece of clothing is not compressing the skin. The high point of the iliac crest is the landmark for the circumference and is usually although not always at the level of the umbilicus.

3. The examiner then stands on the participant's right side and places the measuring tape around the trunk in a horizontal plane at the level marked on the right side of the trunk. The tape is held snug against the skin without compressing the tissues. The examiner should take care that the tape is along a horizontal plane parallel to the floor. A reading is taken at the end of a normal expiration to the nearest tenth of a centimeter (0.1 cm).

Hip Circumference (Figure 3):

1. The participant stands erect, feet together, arms hanging relaxed at the sides.

2. The examiner squats at the side of the participant so that the level of maximum extension of the buttocks can be seen. The tape is placed around the buttocks in a horizontal plane at this level without compressing the skin. The examiner should take care that the tape is along a horizontal plane parallel to the floor on the other side of the body as well. The tape is in contact with the skin but does not indent the soft tissues. The examiner takes the measurement from the right side of the participant, recording to the nearest tenth of a centimeter (0.1 cm).

Marking the Triceps Skinfold Site (Figure 4):

1. To locate the midpoint of the upper arm, the participant's right elbow is flexed at 90 degrees with the palm facing up. The examiner stands behind the participant and locates the lateral tip of the acromion by palpating laterally along the superior surface of the spinous process of the scapula. The zero point of the tape is placed at the acromion process (bony process of the shoulder) and the rest of the tape is extended down to the tip of the olecranon (elbow). The midpoint of the distance between these two landmarks is marked with a long horizontal line.

2. To mark the skinfold site, have the participant stand erect, feet together, with arms hanging relaxed at the sides, palms facing the thighs. Determine the midline of the back of the arm by visual inspection and place a vertical mark to cross the horizontal mark just taken. This cross mark (+) will be the location for the triceps skinfold.

Marking the Abdominal Skinfold Site (Figure 5):

1. The participant stands erect, with body weight evenly distributed on both feet, and relaxes the abdominal wall muscle as much as possible during the procedure and breathes normally. The arms are hanging relaxed at the sides.

2. Select a site 3 cm lateral (toward the right side of the participant) to the midpoint of the center of the umbilicus and 1 cm inferior to it. Mark a cross at the site.

Marking the Thigh Skinfold Site (Figure 6):

1. The participant bends his/her leg by resting the right foot on a stool, with arms hanging relaxed at the sides.

2. To locate the midpoint of the thigh, the examiner places the zero point of the tape at the inguinal crease along the midline of the long axis of the thigh and then extends the tape to the proximal border of the patella along the side of the thigh. The midpoint of the distance between these two points is marked with a horizontal line.

3. To mark the location of the thigh skinfold site, determine the midline of the front of the thigh by visual inspection and place a vertical mark to cross the horizontal mark (+).

Skinfolds

Equipment: Lange calipers

Marking pen or Maybelline eyeliner pencil

Nonstretchable tape

Men only: Pectoral (Chest) Skinfold (Figure 7):

1. The participant stands erect, feet together, with arms hanging relaxed at the sides.

2. The pectoral skinfold thickness is measured using a diagonal fold that follows the natural cleavage lines of the body. The skinfold is picked up 1 cm above the the midpoint between the anterior axillary line and the nipple (estimated by visual inspection).

Triceps (Figure 8):

1. The participant stands erect, feet together, with arms hanging relaxed at the sides.

2. The examiner stands behind the participant. The examiner picks a vertical fold 1 cm above the cross mark, applies the tips of the calipers to the skinfold at the marked level, and takes a reading to the nearest millimeter (1.0 mm).

Subscapular (Figure 8):

1. The participant stands erect, feet together, with arms hanging relaxed at the sides.

2. To locate the site, the examiner palpates the scapula, running the fingers until the inferior angle is identified. A diagonal skinfold is lifted below the inferior angle of the right scapula, along the natural cleavage lines of the body.

If the scapula is difficult to locate, ask the participant to rotate his/her arm to move the scapula. Once the scapula is located, have the participant relax his/her arm again.

For some women, particularly those who are overweight, it may be necessary to ask them to unclasp their bra to avoid its interference with taking the measurement.

3. The caliper jaws are applied 1 cm below the thumb and forefinger raising the fold, and the thickness is recorded to the nearest millimeter (1.0 mm).

Abdominal (Figure 9):

1. The participant stands erect, feet together, with arms hanging relaxed at the sides.

2. Raise a vertical skinfold 1 cm above the marked site. The caliper jaws are applied at the marked site. Record to the nearest millimeter (1.0 mm).

Suprailiac (Figure 10):

1. The participant stands erect, feet together, with arms hanging relaxed at the sides.

2. The suprailiac skinfold is picked on a diagonal anterior to the iliac crest following the natural cleavage lines of the body. The iliac crest is the highest extension of the pelvic bone, and it must be palpated forward and backward to find the highest point.

3. The caliper jaws are applied 1 cm below the thumb and forefinger. Record the thickness to the nearest millimeter (1.0 mm).

Thigh (Figure 11):

1. The participant stands erect, legs relaxed, arms hanging relaxed at the sides. The body weight is shifted to the other foot while the leg on the side of the measurement is relaxed with the knee slightly flexed and the foot flat on the floor. If maintenance of balance is a problem, the participant can hold a counter top or high-backed chair.

2. A vertical fold is taken 1 cm above the mark and the caliper jaws are applied at the mark. The thickness of the fold is recorded to the nearest millimeter (1.0 mm).

General Equipment Calibration and Maintenance:

Scales: **[COORDINATING CENTER TO REVIEW STATEMENTS IN ITALICS]**

Scales should be certified at the start of the study by the local Bureau of Weights and Measures or an equivalent body. Recertification must be completed annually thereafter ***and posted in the appropriate column of the scale log sheet with any documents kept on file. This same log sheet is to be used to record monthly in-house checks*** of the scale accuracy using from 10 to 50 kg weights held by the technician and added to the technician's weight so as to ensure accuracy in the range of weights to be measured during the study. The weight should be accurate to within 0.2 kg and should be checked monthly.

Skinfold Calipers: Calibrate the calipers using the standard calibration blocks at 10 mm increments up to 40 mm. ***Record the measurement taken at each of the five steps of the metal block on the Equipment Calibration Log.*** Calipers with more than a 1.0 mm discrepancy from the calibration block should not be used and should be returned to the manufacturer for adjustment. Calipers should be calibrated once a month.

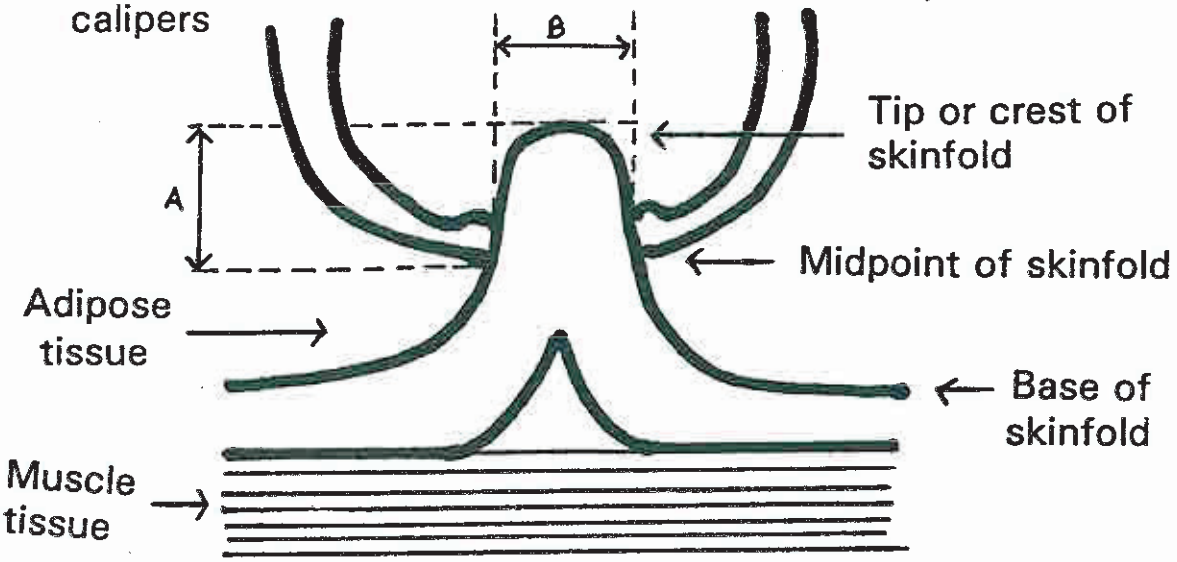
Cleaning: Wipe the surfaces of the skinfold caliper and tape measures with alcohol as necessary.

Training and Certification

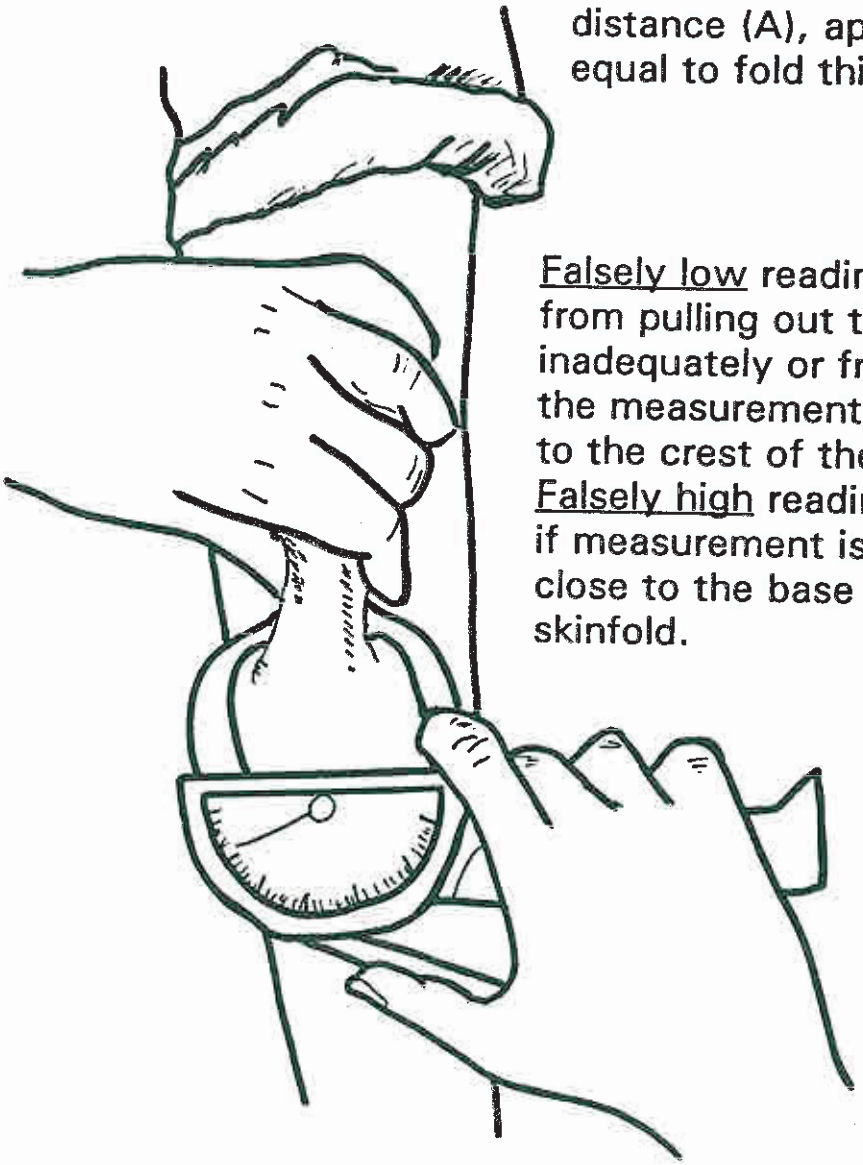
All examiners assessing height, weight, circumferences, and skinfolds are trained and certified in these procedures. Initial training of master local trainers is performed centrally by a central trainer. Master trainers train local staff who conduct the measurements. To be certified, the trainee must do a complete set of height, weight, circumferences, and skinfold measurements on three subjects twice and at least one set of measurements must be observed by the central trainer. The values must agree with the central trainer within tolerance limits and the replicate measures must agree within the limits set for reproducibility (see below).

Master trainers are recertified by a central trainer once a year. Local examiners are recertified by the master trainer twice a year. To be recertified, the local examiner must do a complete set of skinfolds on three subjects twice. The master trainer must observe the local examiner's technique on at least one subject. Observations of technique are noted on the Anthropometry Training and Certification Checklist.

Figure 1. General description of skinfold and placement of calipers



Place calipers in from the tip or crest of the skinfold at distance (A), approximately equal to fold thickness (B).

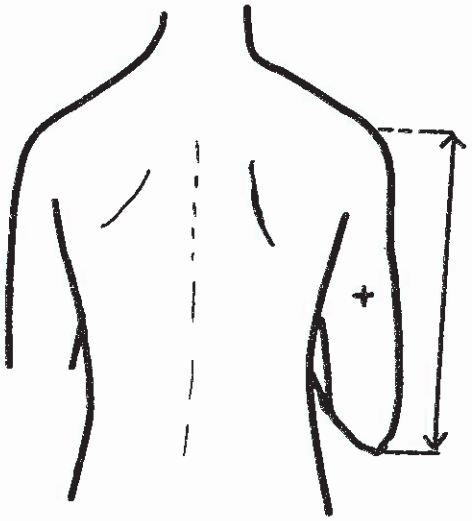


<u>Falsely low</u> readings result from pulling out the skinfold inadequately or from taking the measurement too close to the crest of the skinfold. <u>Falsely high</u> readings occur if measurement is taken too close to the base of the skinfold.

Figure 2. Waist circumference, above the suprailiac place, usually at the level of the ubilicus

Figure 3. Hip circumference, at the maximum protruberance of the buttocks

Figure 4. Marking the site for the triceps skinfold measurement, midway between the acromion and olecranon.



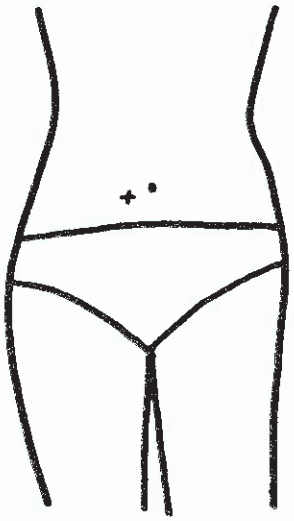


Figure 5. Marking the site for the abdominal skinfold measurement, 3 cm to the left and 1 cm inferior to the umbilicus

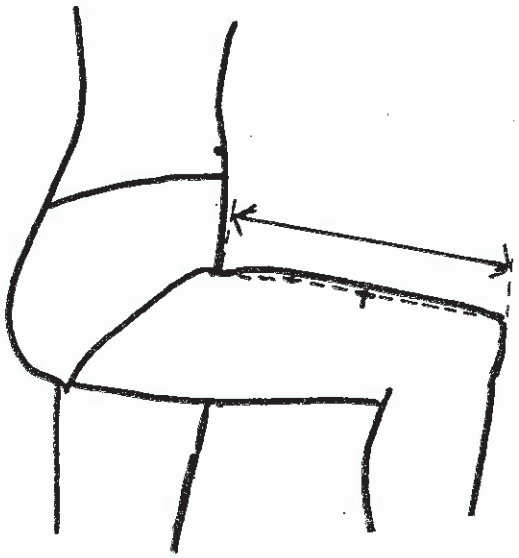


Figure 6. Marking the site for the thigh skinfold measurement, midway between the inguinal crease and the patella

Figure 7. Location of chest oblique skinfold measurement

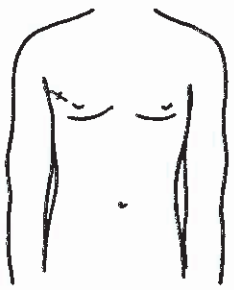


Figure 8. Locations of the triceps vertical and subscapular oblique skinfold measurements

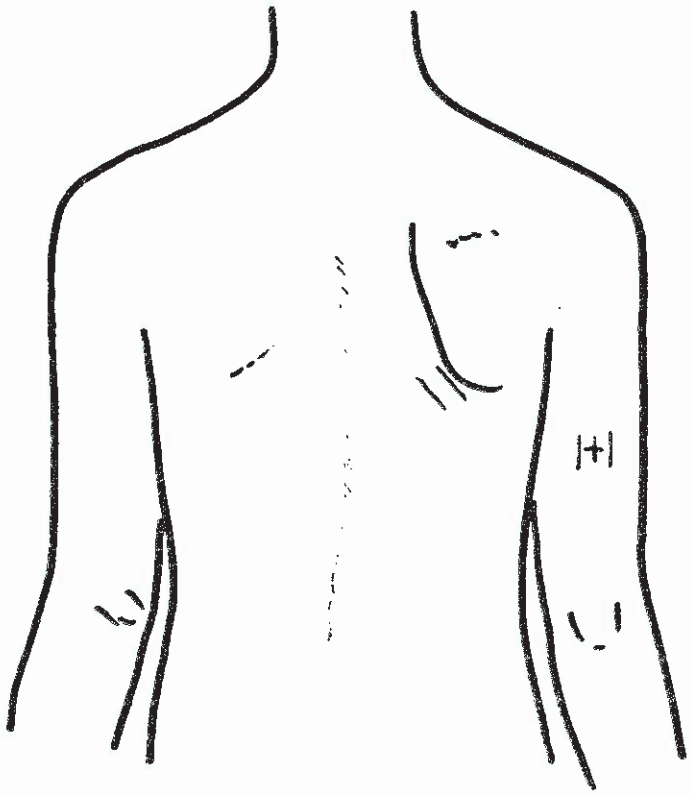


Figure 9. Location of the abdominal vertical skinfold measurement

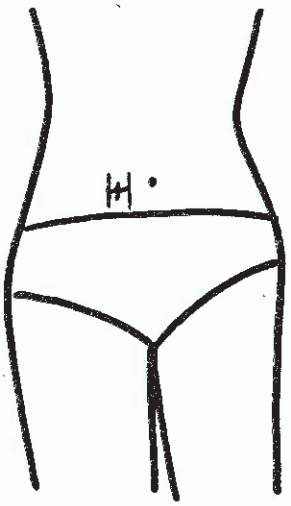


Figure 10. Location of the suprailiac oblique skinfold measurement

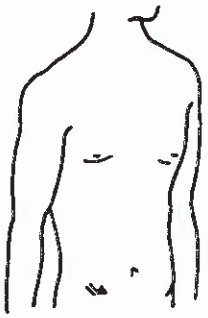
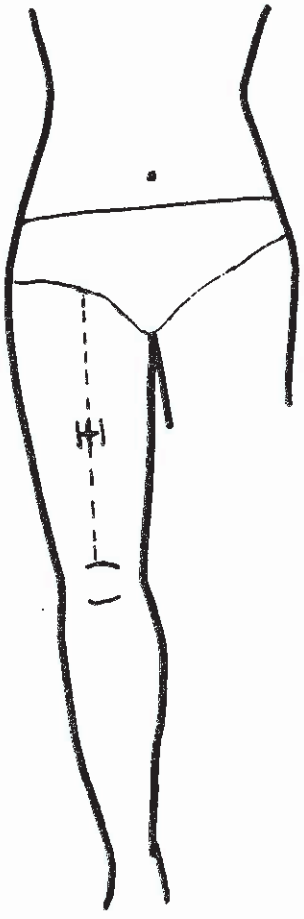


Figure 11. Location of the thigh vertical skinfold measurement



ACT Clinical Measures Form

ID ☐☐☐☐☐☐ Acrostic ☐☐☐☐☐☐

Date of Visit ☐☐/☐☐/☐☐ (Mon / Day / Year) Visit Code ☐☐☐

Resting Blood Pressures

Arm Circumference ☐☐.☐ cm

Time of Day ☐☐:☐☐ ☐ AM ☐ PM

Cuff Size

- ☐ Pediatric (16.0-22.5 cm)
- ☐ Adult (22.6-30.0 cm)
- ☐ Large Arm (30.1-37.5 cm)
- ☐ Thigh (37.6-43.7 cm)

Pulse Disappearance Pressure ☐☐☐ mmHg

\+ 3 0

Maximal Inflation Level ☐☐☐ mmHg

Blood Pressures (mmHg)

	Systolic	Diastolic
First BP	☐☐☐	☐☐☐
Second BP	☐☐☐	☐☐☐
Third BP	☐☐☐	☐☐☐

Average of 3 BPs: SBP ☐☐☐ / DBP ☐☐☐

Comments?

☐ Yes

☐ No

Measured by ☐☐ (staff code)

F18

Acrostic ☐☐☐☐☐☐

Anthropometry Measurements

Height ☐☐☐.☐ cm

Weight ☐☐☐.☐ kg

Waist/Hip Circumferences (cm)

	First	Second	Third*
Waist	☐☐☐.☐ cm	☐☐☐.☐ cm	☐☐☐.☐ cm
Hip	☐☐☐.☐ cm	☐☐☐.☐ cm	☐☐☐.☐ cm

**Make third measurement only if first two differ by >1.0 cm.*

Skinfold Thicknesses (mm)

	First	Second	Third**
Chest (men only)	☐☐ mm	☐☐ mm	☐☐ mm
Triceps	☐☐ mm	☐☐ mm	☐☐ mm
Subscapular	☐☐ mm	☐☐ mm	☐☐ mm
Abdominal	☐☐ mm	☐☐ mm	☐☐ mm
Suprailiac	☐☐ mm	☐☐ mm	☐☐ mm
Thigh	☐☐ mm	☐☐ mm	☐☐ mm

***Make third measurement only if first two differ by >3.0 mm.*

Comments?

☐ Yes

☐ No

☐ Skinfolds greater than 65 mm (specify): _____

☐ Could not be measured (specify): _____

☐ Participant refused (specify): _____

☐ Other (specify): _____

Measured by ☐☐ (staff code)

ACT Activity Counseling Trial
Manual of Procedures

Protocol for Testing and Certification of Anthropometric Personnel

Trainee: _____ **Site:** _____
Examiner: _____ **Date:** _____

By the end of the training session, the trainee should be competent in each of the individuals skills listed below. The trainee will be considered to be certified to perform ACT anthropometric measurements when the form has been signed and each of the following items have been checked, verifying that he/she has properly measured anthropometrics according the ACT protocol in the MOP.

Introduction

____ 1. Introduces self to participant and places participant at ease.
____ 2. Explains purpose/procedures of anthropometric measurement, verifies understanding of informed consent.

Height and Weight

____ 1. Stadiometer/scale meet MOP standards and are placed on firm surface.
____ 2. Participant shoes are removed and clothing is appropriate.
____ 3. Participant/examiner are positioned correctly for accurate measurements.
____ 4. Height measured to within 1.5 cm of MasterTrainer & 1.0 cm of Trainee.
____ 5. Weight measured to within 0.2 kg of MasterTrainer & 0.1 kg of Trainee.

Circumference Measures

____ 1. Using proper tape, iliac crest palpated, tape held horizontal, waist circumference is measured within 1.5 mm of MasterTrainer and within 1.0 cm of Trainee.
____ 2. Hip circumference at maximum protuberance of buttocks measured within 1.5 mm of MasterTrainer and within 1.0 cm of Trainee.

Skinfold Site Markings

____ 1. Sites are properly marked on right side of the body using measuring tape and marking pencil.
____ 2. Lange skinfold calipers are used and calibration is verified.
____ 1. **Chest**: marked 1 cm above midway between anterior axillary fold and the nipple (Males only).
____ 2. **Triceps**: marked at midpoint between acromion to olecranon processes in the midline.
____ 3. **Subscapular**: marked at site 1 cm below inferior angle of the scapula.
____ 4. **Suprailiac**: marked at site 1 cm above anterior angle of iliac crest.
____ 5. **Abdominal**: marked at site 3 cm lateral to the midpoint of umbilicus and 1 cm inferior to it.
____ 6. **Thigh**: marked at site midpoint between crease of thigh (knee bent, foot on stool with thigh horizontal) and proximal border of the patella.

Skinfold Measures

____ 1. **Chest** skinfold measured at site using an oblique fold.*
____ 2. **Triceps** skinfold measured at site using a vertical fold.*
____ 3. **Subscapular** skinfold measured at site using a diagonal (45 degree angle) fold.*
____ 4. **Suprailiac** skinfold measured at site using a diagonal fold following natural contour of body.*
____ 5. **Abdominal** skinfold measured at site using a vertical fold.*
____ 6. **Thigh** skinfold measured at site using a vertical fold.*

* Note: All skinfolds must be measured within 4.0 mm of MasterTrainer and within 3.0 mm of Trainee's last measurement. The Master Trainer measures the test subject at least twice using the acceptable tolerance limits in MOP. One complete set of measurements is performed before the second set is done.

_____ _____
Trainee (Signature) Date

_____ _____
Examiner (Signature) Date

Certification Checklist

Tolerance Limits for Accuracy Compared with Master Trainer		Tolerance Limits for Reproducibility of Trainee	
Height:	1.5 cm	Height:	1.0 cm
Weight:	0.2 kg	Weight:	0.1 kg
Waist:	1.5 cm	Waist:	1.0 cm
Hip:	1.5 cm	Hip:	1.0 cm
Skinfolds:	4.0 mm	Skinfolds:	3.0 cm

F.2 Measurement of Blood Pressure

Background and Rationale

Blood pressure (BP) levels are subject to biologic and observer variations. The purpose of a specific protocol in ACT for the measurement of BP and a certification procedure for technicians who measure BP is to minimize error and variability in its measurement.

Blood Pressure Alert Values

Average BP in Clinical Center	Category
< 130 and < 85	Normal
130-139 and 85-89	High Normal
140-159 or 90-99	Mild hypertension (HTN), Stage 1
160-179 or 100-109	Moderate HTN, Stage 2
180-209 or 110-119	Severe HTN, Stage 3
≥ 210 or ≥ 120	Very Severe, Stage 4

Category	Instructions		
	New DX	Known DX, not complaint to RX	Known DX, complaint to RX
Mild HTN	See MD within 2 months	Restart meds and/or contact MD	See MD as scheduled
Moderate HTN	See MD within 3-4 weeks	Same as mild	See MD within 3-4 weeks
Severe HTN	See MD within 1 week	Restart meds and see MD within 1 week	See MD within 1 week
Very Severe HTN	See MD/ER today	See MD/ER today	See MD/ER today

Overview

The design and operation of the standard mercury sphygmomanometer are based upon the combined principles of compression of the brachial artery under an elastic, inflatable cuff and direct registration of pressure levels by a mercury manometer. The observer inflates the cuff, listens for the first (systolic) and the last (diastolic) Korotkoff sounds, reads the mercury level in the column, deflates the cuff, and records the readings. The last Korotkoff sound is known as the 5th phase diastolic blood pressure.

A. Criteria for Measuring Systolic and Diastolic Blood Pressure

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

The systolic value is the pressure level where the first of two or more sounds are heard in appropriate rhythm.

The diastolic value can be identified as the pressure level where the last of these rhythmic sounds is heard (i.e., it is the last audible rhythmic sound).

The mercury should be made to drop at 2 mm Hg per second, from the maximum pressure until 10 mm Hg below that of the last regular sound heard. The control of the deflation rate is essential for accurate readings and depends on handling of the bulb and its control value.

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

All readings are made to the nearest even digit.

Any reading which appears to fall exactly between markings on the mercury column should be read to the next higher marking i.e., 2, 4, 6, 8, or 0.

All readings are made at the top of the meniscus, or rounded surface of the mercury column.

When the pressure is released quickly from a high level, a vacuum is formed above the mercury and the meniscus is distorted. Allow a few moments for it to reappear before reading the manometer.

B. Required Equipment

- One high quality standard stethoscope (suggest Litman) with bell. All resting blood pressures for ACT wil be recorded using the bell. It is recommended that a single stethoscope be used for all ACT blood pressure measurements.
- One standard mercury column sphygmomanometer (Baumanometer, floor model is preferred so that height can be properly adjusted to "eye level" of examiner).
- BP cuffs in four sizes:

  child or pediatric

  adult or regular

  large arm

  thigh
- Metric tape
- Black pen

- Chair and table (table must provide for a comfortable resting posture for the arm with mid-cuff at heart level)
- Blood Pressure Form

C. Cuff Size

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

CUFF SIZE INDICATED BY MEASURED ARM CIRCUMFERENCE	
Arm Circumference (cm)	Cuff's Bladder Size (cm)
16.0 to 22.5	9.0 (child or pediatric)
22.6 to 30.0	12.0 (adult or regular)
30.1 to 37.5	15.0 (large arm)
37.6 to 43.7	17.5 (thigh)

D. The Maximal Inflation Level

For each participant you will determine the maximal inflation level. This is the pressure to which you will inflate the cuff each time you measure the subject's blood pressure. The procedure described below assures that the cuff pressure at the start of the reading exceeds the systolic blood pressure and thus allows the first Korotkoff sound to be heard.

Specific Instructions

1. Procedure for Determining Cuff Size

- Have the ACT participant remove his/her upper garment if long sleeve.

- Have the participant stand, holding right forearm horizontal to the floor.
- Measure arm length from the acromion (bony extremity for the shoulder girdle) to the olecranon (tip of the elbow), using a metric tape.
- Mark the midpoint on the dorsal surface of the arm.
- Participant relaxes arm along side of the body.
- Draw the tape snugly around the arm at the midpoint mark.

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

- Use the criteria in the Table is Section 4.C for determining proper cuff size.
- Record the cuff size used on the form.

2. Wrapping the Blood Pressure Cuff Around the Arm

- The participant should then be seated, legs uncrossed, in a quiet room, with the right elbow and forearm resting comfortably on a table with the palm of the hand turned upward. The arm to which the cuff is to be applied must be bare.
- Locate the brachial artery by palpation and mark the skin with a little dot. (The brachial artery is usually found at the crease of the arm, under the muscle and slightly towards the body).
- Place the appropriate cuff around the upper right arm so that:
- The midpoint of the length of the bladder lies over the brachial artery, and
- The mid-height of the cuff is at heart level.

NOTE: Confirm for yourself where the midpoint of the length of the bladder is by folding the bladder in two. Do not trust the marking on the cuff.

- Place the lower edge of the cuff, with its tubing connections, about 2 inches above the natural crease across the inner aspect of the elbow.

- Wrap the cuff snugly about the arm, with the palm of the participant's hand turned upward. Make sure that the long edges of the cuff lie on top of each other as you wrap the cuff around.
- Secure the wrapped cuff firmly by applying pressure to the locking fabric fastener over the area where it is applied to the cuff.
- Do not wrap the cuff too tightly around the arm.

3. Procedure for Determining the Maximal Inflation Level

- Attach the cuff tubing to the standard mercury sphygmomanometer.
- Palpate the radial pulse.
- Inflate the cuff until the radial pulse in no longer felt (palpated systolic) by inflating rapidly to 70 mm Hg, then inflating by 10 mm Hg increments.
- Deflate the cuff quickly and completely.
- On the form record the pressure at which the pulse is no longer felt This is the Pulse

Disappearance Pressure

- To this pressure, add 30 mm Hg. This sum is the Maximal Inflation Level. On all blood pressure readings for this visit you will be inflating the cuff to this maximum inflation level to guarantee you do not miss the systolic blood pressure.

4. Taking the First Blood Pressure Measurement

- The participant should sit quietly for a period of 5 minutes before the first blood pressure is taken. Ideally room lighting should be low and participant is left alone.
- Wait at least 60 seconds after complete deflation of the cuff following any preceding inflation.
- Place the earpieces of the stethoscope, with the ear pieces turned forward, in to the ears.
- With arm remaining relaxed on the table, palpate the brachial artery again.
- Apply the bell of the stethoscope over the brachial artery, just below but not touching the cuff or tubing.

- By closing the thumb valve and squeezing the bulb, inflate the cuff at a rapid but smooth, continuous rate to the Maximal Inflation Level. The eyes of the examiner should be level with the mid-range of the manometer scale and focused at the level to which the pressure will be raised.

- By opening the thumb valve slightly, and maintaining a constant rate of deflation at approximately 2 mm per second allow the cuff to deflate, listening throughout the entire range of deflation, from the maximum pressure past the systolic reading (the pressure where the first regular sound is heard), until 10 mm Hg below the level of the diastolic reading (that is, 10 mm Hg below the level where the last regular sound is heard).

- Deflate the cuff fully by opening the thumb valve. The stethoscope earpieces are removed from the ears and the systolic and diastolic readings are entered in the spaces provided on the blood pressure form.

5. Taking the Second Blood Pressure Measurement

   - Hold the participants arm vertical above head for full 5 seconds.

   - Wait at least 60 seconds before proceeding with the second readings.

   - Repeat the steps in Section 4 to obtain the second blood pressure readings.

6. Taking the Third (Last) Blood Pressure Measurement

   - Hold the participants arm vertical for full 5 seconds.

   - Wait at least 60 seconds before proceeding with the third readings.

   - Repeat the steps in Section D to obtain the third blood pressure readings.

   - Remove the cuff and store the equipment safely after the last reading.

7. Informing Participant of Blood Pressure

   Prior to making the first blood pressure measurement tell the participant that you will inform them of their blood pressure after all three measurements have been recorded, and that you will not inform them after each measurement. After the third measurement is recorded, tell participant his/her blood pressure values (emphasize lowest values). If blood pressure is elevated, follow instructions on page 1 regarding physician referral. If blood pressure is stage 4

(>210/120), participant's physician should be contacted by telephone prior to the participant leaving the ACT clinic.

E. **Summary of Korotkoff Phases and Auscultatory Gaps**

The arterial sounds heard in the auscultation of blood pressure are called Korotkoff's sounds and can be distinguished in the following 5 phases:

Phase 1: Clear tapping sounds

Phase 2: Tapping sounds, continuing as a murmur

Phase 3: Higher pitched and louder tapping sounds without a murmur

Phase 4: Muffled sounds

Phase 5: Last sounds heard

For ACT, systolic pressure is recorded at the onset of Phase 1 and diastolic pressure at the onset of Phase 5 (i.e., at the last sounds heard).

The tapping sounds during Phase 1 of the Korotkoff sounds may be interrupted by a variable period of silence. In these cases, a sequence of tapping sounds is heard, commencing with the onset of systolic blood pressure. Then there is a period of silence, called the auscultatory gap, as the pressure in the cuff diminishes and the mercury column continues to fall. This period may last for 5 to 10 seconds. Then the tapping sounds of Phase 2 resume and are followed sequentially by the sounds of Phases 3-5. Sometimes the whole Phase 2 may be absent.

To avoid measurement error due to the presence of the auscultatory gap, use the following rule: record systolic pressure at the point of hearing the first of two consecutive tapping sounds of Phase 1. Ignore an isolated, single tapping or muffled sound at the beginning of Phase 1.

F. **Blood Pressure Certification**

Certification of staff for the recording of resting blood pressure in ACT requires the following:

1. Staff member has been trained in the use of ACT blood pressure protocol at central ACT training session or by ACT "clinical specialist" who was trained at central ACT training session.

2. Staff member has measured resting blood pressure on at least 10 different people using ACT protocol. ACT blood pressure forms should be completely filled out on each subject and retained in staff member's ACT certification folder.

3. Staff member being certified and certified trainer will measure blood pressure on five subjects using the ACT blood pressure protocol and teaching stethoscope. All of these recordings should remain blinded between the two examiners until the blood pressure of all five subjects have been recorded. For each subject, an ACT blood pressure form should be completed by each examiner. Once the blood pressure measurements has been completed, the certified examiner should compare the mean value of the three blood pressure measurements for each subject recorded by the two examiners. The difference between the mean blood pressure recorded by each examiner should not be greater than 4 mmHg for either systolic or diastolic pressure. If the average values exceed 4 mmHg for one or more subjects, the staff member should perform additional practice blood pressure recordings and then repeat the certification procedure. These recording forms should be kept in the staff member's ACT certification folder.

References:

1. 1988 Joint National Committee, The 1988 Report of the Joint National Committee on Detection, Evaluation, and Treatment of High Blood Pressure. Arch Intern Med, 148, 1988, pp. 1023-1037.

2. Working Group on Hypertension in the Elderly, Statement on Hypertension in the Elderly. JAMA, 1986, 256, No. 1, pp. 70-74.

3. Labarthe DR, Palmer M. Measurement of Blood Pressure: A Manual for Training and Certification. Adapted for the Systolic Hypertension in the Elderly Program SHEP. June 5, 1985.

4. Borhani N., LanBaw F, Bunkle S. Blood pressure measurement in an ambulatory setting In: Ambulatory blood pressure monitoring. New York: Springer-Verlog 1984: 75-81.

5. Frohlich EC, Grim C, Labarthe DR, et al. Recommendations for human blood pressure determination by sphygmomanometers. Hypertension 1988, 11: pp. 209A-222A.

6. Atherosclerosis Risk in Communities Study (ARIC) Protocol, Manual 2: Cohort Component Procedures, Version 2.0 1/88. ARIC Coordinating Center, Suite 203 NCNC Plaza, 137 E. Franklin St, Chapel Hill, NC 27514.

ACT Activity Counseling Trial
Manual of Procedures

Protocol for Testing and Certification of Blood Pressure Personnel

Trainee: _____ **Site:** _____
Examiner: _____ **Date:** _____

By the end of the training session, the trainee should be competent in each of the individuals skills listed below. The trainee will be considered to be certified to perform ACT blood pressure measurements when the form has been signed and each of the following items have been checked, verifying that he/she has properly measured blood pressures according the ACT protocol in the MOP.

Introduction

____ 1. Introduces self to participant and places participant at ease.
____ 2. Explains purpose/procedures of blood pressure measurement, verifies understanding of informed consent.

Preliminary Measures

____ 1. Obtains preliminary information on participant: name, ID, etc.
____ 2. Has necessary equipment at station: chair, measuring tape, variable cuff sizes, mercury sphygmomanometer on stand, and double-head stethoscope for examiner.

Initial Measures

____ 1. Measures arm circumference, determines cuff size, marks brachial artery.
____ 2. Prepares setting: table /chair to allow arm with midcuff at heart level.
____ 3. Places cuff on securely - hand palms up - midline over brachial artery.
____ 4. Places stethoscope bell on mark, determines maximal inflation level.
____ 5. Participant rests for 5 min prior to first BP measurement.

Measurement of First, Second, and Third Systolic/Diastolic Pressures

____ 1. Pumps pressure to maximal inflation level and deflates @ 2 mm/sec.
____ 2. Obtains systolic BP (1st Korotkoff sound).
____ 3. Obtains diastolic BP (4th and/or 5th Phase)
____ 4. Maintains midrange of manometer at eye level of examiner.
____ 5. Follows protocol of raising arm vertical for 5 sec and waiting 55 sec before repeating second and third readings.
____ 6. Completes form and dismisses subject.

_____ _____
Trainee (Signature) Date

_____ _____
Examiner (Signature) Date

ACT SV1 Blood Pressure Form

ID ☐☐☐☐☐☐ Acrostic ☐☐☐☐☐☐

Date of Visit ☐☐/☐☐/☐☐ (Mon / Day / Year) Measured by ☐☐ (staff code)

Resting Blood Pressures

Arm Circumference ☐☐.☐ cm

Time of Day ☐☐:☐☐ ☐ AM ☐ PM

Cuff Size

- ☐ Pediatric (16.0-22.5 cm)
- ☐ Adult (22.6-30.0 cm)
- ☐ Large Arm (30.1-37.5 cm)
- ☐ Thigh (37.6-43.7 cm)

Pulse Disappearance Pressure ☐☐☐ mmHg

\+ 3 0

Maximal Inflation Level ☐☐☐ mmHg

Blood Pressures (mmHg)

	Systolic	Diastolic
First BP	☐☐☐	/ ☐☐☐
Second BP	☐☐☐	/ ☐☐☐
Third BP	☐☐☐	/ ☐☐☐

Average of 3 BPs

SBP ☐☐☐ / DBP ☐☐☐

Comments?

☐ Yes

☐ No

_____

_____

APPENDIX G

ACTIVITY COUNSELING TRIAL (ACT) LABORATORY MANUAL

Procedures for the collection, processing and shipping of blood samples

G.1 GENERAL ISSUES REGARDING COLLECTION OF SPECIMENS ..... G- 3
G.1.1 General Precautions for the Handling of Blood ..... G- 4
G.1.2 General Policies for Collection of Blood Samples ..... G- 4
G.1.2.1 Facilities for Blood Draws ..... G- 4
G.1.2.2 Personnel ..... G- 5
G.1.2.3 Venipuncture Technique ..... G- 5
G.1.2.3.1 Site of Venipuncture ..... G- 6
G.1.2.3.2 Routine Blood Drawing ..... G- 6
G.1.2.3.3 Time of Blood Draw (Circadian Fluctuations) ... G- 8
G.1.2.3.4 Fainting Episodes ..... G- 8
G.1.2.3.5 Posture During Blood Draws. G-10
G.1.2.3.6 Difficult Venipuncture G-10
G.1.3 General Information on Processing of Blood Samples G-11
G.1.3.1 Clinical Facilities G-11
G.1.3.2 Personnel G-12

G.2 SPECIFIC INSTRUCTIONS FOR COLLECTION AND PROCESSING OF BLOOD SPECIMENS G-12
G.2.1 Instructions for Participants Prior to ACT Blood Draws G-12
G.2.2 Directions for Staff When Participants Do Not Follow Instructions .. G-13
G.2.3 Collection of Blood Specimens G-15
G.2.3.1 Blood Collection and Processing Log G-15
G.2.3.2 Specimens to be Collected G-15
G.2.3.3 Labeling Samples G-16
G.2.3.4 Sample Collection G-17
G.2.4 Processing of Plasma G-19
G.2.5 Instructions for Sealing and Freezing Samples G-20
G.2.6 Collection and Processing Flow Chart G-20

G.3 STORAGE AND SHIPPING OF SPECIMENS G-20
G.3.1 Storage of Specimens G-20
G.3.2 Shipping of Specimens to Penn Medical Laboratory G-22
G.3.2.1 General Policies for Shipping G-23
G.3.2.2 Preparation of Specimen Shipping Log Forms G-24
G.3.2.3 Supplies Required for Shipping G-24

G.3.2.4 Packing Shipping Containers G-25
G.3.2.5 Shipping Schedule G-27
G.3.3 Packing and Shipping Flow Chart G-28

G.4 ACT CENTRAL LABORATORY INFORMATION G-28

G.5 CLINIC EQUIPMENT AND SUPPLIES G-28

G.6 TRAINING IN BLOOD COLLECTION AND PROCESSING G-30

G.7 LABORATORY RESULTS G-31

Exhibit G1. Checklist "Questions to be Asked Prior to ACT Blood Draw". G-32

Exhibit G2. ACT Collection and Processing Flow Chart G-33

Exhibit G3. Sample ACT Shipping Log G-34

Exhibit G4. ACT Packing & Shipping Flow Chart G-35

Collection, Processing, Storage

and

Shipping of Penn Medical Laboratory Blood Samples

G.1 GENERAL ISSUES REGARDING COLLECTION OF SPECIMENS

G.1.1 General Precautions for the Handling of Blood

All clinic and laboratory personnel need to take the proper precautions in the handling of blood. It is well known that the improper handling of blood from participants with infectious diseases can lead to infection. The most easily transmitted blood borne disease is hepatitis, which is a far greater concern than HIV. Many of these diseases can be transmitted by ingestion, contact with mucous membranes or eyes, or inhalation. To avoid these risks:

> All specimens should be regarded as potentially hazardous.

- Never pipette samples by mouth.
- Avoid direct contact with blood, sera or plasma. Cover any scratches or cuts on fingers and hands very carefully. Always use proper gloves in the handling of specimens.
- All tubes, containers and other materials exposed to blood must be disposed of in appropriately labeled waste receptacles for biohazardous materials.
- Wear protective eye wear (goggles) while processing samples to protect against airborne agents which are released when rubber caps are removed from collection tubes. When removing stoppers from Vacutainer™s, use a splash shield. Wipe counters with disinfectant at the end of each day of processing.
- All samples should be stored in sealed containers or tubes.
- All clinic and laboratory personnel should be informed of and guided by current OSCHA and CDC guidelines particularly those concerning "Universal Blood and Body Fluid Precautions" published by the CDC.

- Immunization against Hepatitis B is highly recommended for persons drawing blood and handling biological specimens.

G.1.2 General Policies for Collection of Blood Samples

One of the most common clinical procedures that will occur during the ACT Study is the drawing of blood samples. Since venipuncture involves a small amount of pain for the participant, it is very important that the techniques be seriously considered and reviewed by clinic staff involved in this process. The following general policies will be observed in the collection of blood specimens.

G.1.2.1 Facilities for Blood Draws

1. The room in which phlebotomy will occur should be clean and tidy with no obvious evidence of previous blood draws such as used needles, blood stains, etc. Room temperature should not be too cool. A phlebotomy chair should be available for 15-20 minute periods to allow subjects to be seated for 10 minutes prior to a blood draw. If not available within the room, there should be quick access to a bed or examining table and ammonia capsules in case a subject feels faint and to emergency equipment in case of cardiac arrest. Ideally, only the participant and phlebotomist (and assistant when needed) are in the room during the procedure.

2. The room should be set up in advance with basic supplies for blood collection:

- Vacutainer tubes *pre-labeled* with the participant's ACT identification number, visit type and date of collection
- Multi-sample Vacutainer needle - 21G x 1 1/2"
- Needle Holder (Vacutainer™ hub)
- Tourniquet
- Chux
- Disposable gloves

- Alcohol preps and sterile cotton gauze sponges
- Waterproof marking pen such as Baxter S¦P Brand Water-resistant Lab Marker

3. Have an ice bucket ready to cool the tubes immediately after collection.

G.1.2.2 Personnel

Phlebotomists should be highly experienced with Vacutainer™ blood collections, prepared to handle common problems, such as fainting, and familiar with precautions to avoid exposing themselves to blood (see G.1.1).

- Ideally they will have cardiopulmonary resuscitation (CPR) certification.
- It is suggested that they read "Collection and Handling of Laboratory Specimens: A Practical Guide"[1] or a similar phlebotomy manual.
- They should wear clean white lab coats (with no blood stains) and maintain a neat appearance.
- They should wear name tags and introduce themselves (if necessary) prior to blood draw.
- Long hair and bangs should be pulled back.
- Phlebotomists and assistants should not chew gum or have any food in their mouths during blood draws. Food must never be brought into areas used for blood drawing or processing.
- No one staff member will attempt more than three venipunctures on the same subject. After three failures, another person will be asked to make any further attempts.

G.1.2.3 Venipuncture Technique

Blood samples will be collected from ACT participants using the conventional

---

[1] Slockbower, J.M., and Blumenfeld, T.A., (Eds.). Collection and Handling of Laboratory Specimens: A Practical Guide. Philadelphia: J.B. Lippincott Company, 1983.

vascular access with a multi-sample Vacutainer™ needle and collection of the blood sample into Vacutainer™ tubes.

G.1.2.3.1 **Site of Venipuncture**

The Antecubital site of either arm will be used as the first choice for venipuncture. The median cubital vein is the one used most frequently. If the venipuncture of this vein is unsuccessful, the cephalic and basilic may be the next appropriate choices, followed by veins on the back of the hand. For known mastectomy participants, avoid use of an arm where there has been axillary lymph node dissection.

G.1.2.3.2 **Routine Blood Drawing**

The following guidelines should be followed by ACT clinic personnel in the collection of routine samples.

1. Confirm that participant has observed the pre-visit requirements with respect to fasting, exercise and alcohol consumption (See section G.2.1).

2. Be sure all necessary supplies and equipment are available and set up in advance. Note number and type of Vacutainer™ tubes required. Label tubes with Visit type , Date and Study ID# (see G.2.3.3 for information about labeling specimens). Prepare equipment, if not already prepared.

3. Wash hands and put on protective gloves.

4. Explain the procedure to the participant e.g., "I will be drawing a blood sample from an arm vein. You will probably feel a small prick when I insert the needle."

5. Position participant's arm on a Chux on the drawing table. Extend the arm towards you, palm up.

6. Apply tourniquet 3 inches above venipuncture site. Tourniquet must not be in place more than one minute. If it is necessary to apply a tourniquet for preliminary vein selection, release it for one minute and reapply immediately prior to entering the vein.

> If no radial pulse can be felt, the tourniquet is too tight. *Tourniquet must not be in place more than one minute.*

7. Request participant to make a loose fist or to open and close his/her fist gently a few times.

8. Palpate vein. If no vein is felt, try other arm or another site (see section G.1.2.3.6 on "Difficult Venipuncture").

9. Clean site with alcohol swab or prep. Be sure skin is dry before inserting the needle.

10. Insert a 21-gauge multi-draw needle bevel up, parallel to vein. Use straight stab; do not poke around. The needle is sterile; do not touch it while performing venipuncture. If vein rolls, withdraw needle slightly without coming back through the skin and try a second thrust. Never reinsert a needle that has been pulled out after an unsuccessful thrust. If the vein collapses, remove Vacutainer™ tube, call over another staff person to reapply tourniquet, have participant open and close the fist, then reinsert tube. If there is still no blood, stop the procedure and use techniques in section on "Difficult Venipuncture" (G.1.2.3.6).

11. Release tourniquet. *If tourniquet is on longer than one minute, release it and either try other arm or wait one minute* before trying again on the same arm.

12. Draw required blood tubes (always fill the tube) and prepare for processing.

13. Apply slight pressure to gauze and withdraw needle, then immediately apply pressure to site.

Fibrinogen levels may be affected by leaving a tourniquet on too long or placing it too tightly around the arm!!

14. Request participant to apply pressure at site for 2-3-minutes while leaving the arm fairly straight at the elbow. This is much less likely to result in a bruise than elevating the arm or bending the elbow, which some participants might do automatically.

15. Dispose of the entire needle set up into proper (Sharps) disposal container. *Never try to re-cap a needle since this puts you at risk for a needle puncture.*

16. Check site. If blood oozes from the site, have the participant apply pressure to the site 1-2 minutes longer or as long as is necessary with arm horizontal and straight. Apply band-aid.

G.1.2.3.3 **Time of Blood Draw (Circadian Fluctuations)**

Because outcome variables can vary in concentration over the course of the day, all fasting blood draws should be completed by 12 noon. If this is not possible, try to reschedule the blood draw(within the next few days). If the participant refuses to reschedule, document this information in the clinic log book and on the visit form. This will be considered missing data.

G.1.2.3.4 **Fainting Episodes**

If participant shows signs of becoming faint (loss of color in the face, unusual sweating on the forehead) or reports feeling dizzy:

- Finish drawing blood if possible but do not proceed if participant is clearly in trouble.
- Have participant lay head on table

- Continue talking to participant to assess level of consciousness.
- Prevent injuries from possible fall or seizure.
- Have participant lie down for 5-10 minutes after removing the needle; apply pressure on vein.
- Apply cool compress to forehead.
- Have participant prop feet up on pillow or cushion or elevate legs above head.

  Note: It is ideal to have phlebotomy "lounge" chairs which allow you to easily elevate the legs and recline the person quickly avoiding the "challenges" associated with moving the person to the floor or to a bed.

If participant faints:

- Withdraw needle immediately and apply pressure at site.
- Call for help.
- Move participant into a fully reclined position, if possible.
- Elevate participant's legs above her head.
- Apply cool compress to forehead.
- Keep participant in a reclined position until she feels better.
- It may be worthwhile to take blood pressure readings to assess recovery.
- Offer water, juice and food after participant has recovered.

Realize that the participant might be disoriented, embarrassed, or irritable and needs reassurance and attention.
Recognize also that this incident will have an impact on future blood drawing, and possibly to study adherence and must be handled well. Make a note in the participant's file so that clinic staff will be aware of the situation prior to future blood draws.

Note: If sample is not collected, try to reschedule the visit especially if the technician and participant agree that this is an unusual situation that is not likely to occur again. If participant does not wish to reschedule, indicate "refusal" in the comments column of the clinic blood processing log. See G.2.3.1

G.1.2.3.5 **Posture During Blood Draws**

A participant should be seated during blood draws. However, if the participant is clearly uncomfortable with the blood drawing situation, because of a previous fainting episode or a fear of fainting, have the participant sit for 10 minutes then quickly move them to a bed or a reclined position and proceed immediately with the blood draw attempting to collect all samples within ten minutes. This is to ensure that blood is collected as close to the standardized posture as possible before body fluid shifts occur, which could alter plasma concentrations of outcome variables. It is desirable that less than **10 minutes** elapse between the participant's lying down and completion of the blood draw.

G.1.2.3.6 **Difficult Venipuncture**

There will be several common situations in which vascular access may be difficult. These will include but are not limited to the following.

- Palpated vein feels small or rolls
- Excess subcutaneous tissue and fat lies over veins.
- Participant complains of being stuck more than once on a previous visit (no single staff person will attempt more than three venipunctures on a single participant at a single clinic visit) or has had a bad experience elsewhere.
- Participant has been stuck once already and none of the usual veins are palpable.

All reasonable efforts should be made to collect a blood sample. However, clinic personnel should keep in mind that blood samples are collected to measure secondary end points and that future participation in the study may be compromised by repeated attempts at difficult venipuncture situations.

If the participant experiences any of the above problems, and is agreeable to a repeat attempt, check back of hand and forearm for venipuncture sites with larger veins and attempt to draw from one of these.

Attempt to finish venipuncture following procedures outlined above. If multiple attempts at venipuncture are unsuccessful, do not reschedule the participant unless both

the technician and the participant agree that this is an unusual situation and that there is a high probability of obtaining a sample on the first try at another visit. Encourage the participant to drink plenty of fluids prior to the next visit.

Although the following vein dilation methods may distort values of many blood constituents, they can be tried as a last resort:

- Have participant dangle arm at side with tourniquet in place for one minute.
- Use blood pressure cuff as a tourniquet by pumping pressure to 60-80 mm Hg.
- Hot pack venipuncture site with warm, wet towel or apply heating pad for 3-5 minutes.
- Have participant hold hand in warm water for 3-5 minutes.

If it becomes obvious that less than the desired volume of blood will be obtained at this visit, try to reschedule the participant. If this is not possible, proceed to collect a blue top tube followed by a lavender or purple top. Prepare as many of the required aliquots as is possible and record any missing aliquots in the blood collection and processing log that will be maintained at each clinic.

G.1.3 General Information on Processing of Blood Samples

G.1.3.1 Clinical Facilities

1. Clinical facilities should include a refrigerated centrifuge with appropriate buckets for 4.5 ml and 10 ml tubes. The centrifuge temperature should be held at 4°G.
2. Basic supplies for blood processing include:

- Refrigerated Centrifuge
- Disposable pipettes
- Shipping vials and caps
- Labels for shipping vials
- Compartmentalized storage boxes

3. All clinics should have crushed ice and refrigerator space for blood processing, adequate -80°C freezer space for short-term storage (until samples can be shipped), and dry ice available for packing samples for shipment.

4. All clinics should have a tube rotator to allow adequate mixing of plasma samples with specific anticoagulants.

G.1.3.2 **Personnel**

Technicians should be skilled at pipetting and generally well-organized and careful. They should

- wear gloves while handling specimens
- wear goggles when removing caps to protect against aerosol components
- be very familiar with precautions against exposure to blood

G.2 SPECIFIC INSTRUCTIONS FOR COLLECTION AND PROCESSING OF ACT BLOOD SPECIMENS

Note: Blood pressure measurements should always precede venipuncture at ACT clinic visits. If this is not possible, wait at least 30 minutes after a blood draw before taking blood pressure measurements.

G.2.1 Instructions for Participants Prior to ACT Blood Draws

Prior to the visit, each participant should be informed (by whatever means individual clinics choose) of the need to prepare for the collection of blood specimens by observing the following.

1. Fast (i.e., nothing by mouth except water) for 12-16 hours before all ACT blood collections. There are some exceptions allowed as noted in Section G.2.2. *To reduce the likelihood of fainting, the subject should be encouraged not to initiate the fast much more than 16 hours before the blood draw and to drink plenty of water throughout the fast.*

2. Fasting participants should take all prescribed medications (except for oral medications used to control diabetes) at the usual time with a small amount of water on the morning of the blood draw.

couple bites of other food items. If participant failed to initiate the fast 10 hours prior to blood draw, attempts should be made to conduct other visit procedures first, to delay blood draw until 10 hours have elapsed; otherwise, reschedule the visit. Be sure to note any deviation from the fasting policy in the laboratory log book and on the ACT Shipping Log.

2. Alcohol can have an effect on triglycerides for up to 72 hours but this effect is most obvious during the first 12-24 hours; therefore a 12 hour grace period should be applied for alcohol rather than 10 hours, meaning that if alcohol was consumed within the past 12 hours, reschedule the visit. If alcohol is consumed during 12-24 hours prior to blood draw, proceed with blood draw but make a note of this in the log book and on the shipping log.

3. If a participant has smoked during the hour prior to blood draw, attempts should be made to conduct other visit procedures first until an hour has elapsed since the last cigarette.

4. Vigorous exercise can affect hemoconcentration and triglyceride levels. If a participant has done vigorous activity within 8 hours of blood draw, attempts should be made to conduct other visit procedures until 8 hours have passed since the exercise session. If the activity was quite recent, indicate this in the log book and in the comment section of the shipping log.

NOTE: The ACT Shipping Log will be the only central record of participant deviations from pre-visit fasting, exercise and alcohol requirements.

G.2.3 **Collection of Blood Specimens**

G.2.3.1 **Blood Collection and Processing Log**

Each clinic should set up a blood collection and blood processing notebook or laboratory log book (in advance) to be located in the blood collection/processing area. If these are at two different sites, two notebooks should be set up. This should be a hard-bound notebook from which pages can not be easily removed. Pages should be identified by visit type (Screen, Baseline, 6-Month, etc.) and should have columns headed for date, visit number, participant name and ID, as well as room to write "comments" about any problems with blood draws or processing, including hemolysis of samples, etc. The Table should look like this:

3. **Drink water ad libitum** during the fasting period, to reduce the likelihood of fainting.

4. **Refrain from consuming alcohol for at least 24 hours prior to blood draw.**

5. **Do not smoke for at least one hour prior to blood draws.**

6. **Perform no vigorous physical activity** (such as jogging, bicycling) **for** at least **12 hours** prior to blood draw.

7. **Wear clothing which allows the sleeve to be easily raised above the elbow without constricting blood flow to forearm and hands.**

Exhibit G-1 (Exhibits are located on pages 32-35) " Questions to be asked prior to blood draw." is a form that can be used as a checklist to determine the status of the participant with respect to fasting, smoking, alcohol and exercise. If a participant has deviated from the pre-visit blood collection requirements, and the sample is still collected, this will need to be indicated in the remarks section of the ACT Shipping Log.

G.2.2 **Directions for Staff When Participants Do Not Follow Instructions**

In general, if a participant does not meet fasting criteria for venipuncture, continue to complete the other visit requirements but reschedule the blood draw (within the next few days). If the participant refuses to reschedule, do not draw the blood sample and document this information in the clinic log book and on the visit form. This will be considered missing data.

Use the following information and guidelines in decisions on venipuncture.

1. The visit should be rescheduled if participant has "accidentally" ingested *more than* a couple sips of juice, coffee (decaffeinated or regular), black tea, or alcohol (see next item for further details on alcohol) or *more than* a

Accurate measurement of insulin and lipids requires a fast of 12-16 hours to precede the blood draw

Date	Visit Type	Participant Name	Pt. Id #	Comments

G.2.3.2 **Specimens to be Collected**

The same set of fasting blood samples will be collected at Screening Visit 2 and the 24-month Follow-up Visits for a lipid panel, insulin, fibrinogen analyses as well as two long term storage samples. (Rev. 10/96) ***The 6-month visit will be a non-fasting visit and will include samples for lipids and fibrinogen only.*** A brief description of each of these tests follows.

1. **Lipid Panel (Indirect Beta Quantification, IBQ)** - This panel includes an analysis of total cholesterol, triglycerides, HDL-Cholesterol, and estimated LDL-Cholesterol. Blood is collected in *a 10 ml lavender or purple (K_3EDTA) Vacutainer™ tube.*

Penn Medical Laboratory measures *true* triglyceride concentrations. Sometimes, this results in TG values that are ~5% lower than methods which do not take into account free glycerol.

Fasting insulin measurements are a good reflection of insulin resistance. Inactivity, obesity and some genetic influences tend to raise insulin values.

2. **Fasting Insulin** -The plasma for this sample will be obtained from the lavender or purple EDTA tube collected for the Lipid panel.

3. **Storage Samples (2)** -The plasma for these samples will be obtained from a second *10 ml lavender or purple (K3 EDTA) Vacutainer™ tube.*

Fibrinogen levels are directly related to the risk of heart disease. Exercise tends to lower fibrinogen levels.

4. **Fibrinogen** - This sample will be

collected in a *4.5 ml blue top Vacutainer™ tube (3.8% sodium citrate)*

G.2.3.3 Labeling Samples

Before proceeding to label the vacutainer tubes, check the expiration date on the tube/box. It is very important that the date shown on the tube/box has not passed, to ensure a good vacuum and to be sure any chemical reagents within them have not deteriorated. Be sure to check these dates on a regular basis.

Each vacutainer tube used for the collection of blood and each cryogenic vial used for the plasma aliquots should be labeled with the participant ID number, date, visit type and sample type. The central laboratory will provide labels for the SV2 samples. Staff members will need to enter the ACT ID number, acrostic and the date the sample is collected in the appropriate spot on each label. Sets of preprinted labels for the 6-month and 24-month Visits will be prepared and distributed by the Penn Medical Laboratory. Clinic Staff will only need to enter the date of collection on these labels.

A total of five 4 ml cryogenic vials will be used for the plasma samples from each participant at SV2 and 24 months. *Four 4ml cryogenic vials wil be used for the 6-month non-fasting visit since Insulin aliquots will not be prepared.* Color cap inserts have been provided for these tubes in order to quickly distinguish them from each other. Prepare a set of cryogenic vials for each participant using the color scheme described in Table G-1. Always be sure that type of sample as indicated on the vial label corresponds to the color insert in the vial cap as designated in Table G-1. i.e. that the white top vial has a label for "lipids", the red top a label for "insulin", the blue a label for "fibrinogen" and the two yellow top vials a label for "storage".

Table G-1

SPECIMEN VIAL COLOR SCHEME

Specimen	Cap Top Insert	(number) and type of Vial(s)
Lipids	**white**	(1) 4-ml cryovial

Specimen	Cap Top Insert	(number) and type of Vial(s)
Insulin	**red**	(1) 4-ml cryovial
Fibrinogen	**blue**	(1) 4-ml cryovial
Storage	**yellow**	(2) 4-ml cryovial

G.2.3.4 **Sample Collection**

The phlebotomist proceeds to collect the blood sample into previously labeled vacutainer tubes, following the venipuncture guidelines discussed in section G.1.2.3. Always allow the vacutainer tubes to fill to capacity to ensure a standardized ratio of anti-coagulant to sample in the tube. Blood samples for the ACT study should be collected in the following order.

(See Exhibit G-2 for a diagram of the Sample Collection and Processing Procedure.)

1. **COLLECT and DISCARD one blue top vacutainer tube (Blue #1) . Then proceed to collect the required series of participant vacutainer tubes in the following order.**

2. **Blue Vacutainer™ tubes (sodium citrate)**: *Always collect the blue top tube first. Collect one 4.5 ml blue top tube* containing 3.8% sodium citrate for the fibrinogen sample. Tubes need to be filled to ensure a proper concentration of sodium citrate in the blood collected. After processing, a **one ml** aliquot will be pipetted into a blue cap cryogenic vial [If the initial venipuncture has complications that suggest trauma to the vein, subsequent samples will be inappropriate for fibrinogen and may be hemolyzed, which is not appropriate for lipids. Therefore, it is better to start over on the other arm unless the participant is unwilling. See section G.1.2.3.6 on Difficult Venipuncture.]

VERY IMPORTANT
All tubes need to be gently inverted 7-8 TIMES to properly mix the preservative with the blood.

3. **Lavender/Purple Vacutainer™ tubes (K3 EDTA)**:

Collect two 10 ml lavender/purple top tubes containing 15% K_3 EDTA Fill tubes to ensure proper concentration of EDTA. These tubes will be used for Lipid, Insulin and Storage aliquots. After processing for plasma, transfer

- 2ml of plasma to a red top vial (do not prepare a red top for the 6-month visit)
- 2ml of plasma to a white top vial
- 2ml of plasma to **each of two** yellow top vials.

It is very important that each EDTA tube be *filled completely* to ensure a proper concentration of EDTA in the blood collected, even if this means collection of excess blood.

All tubes for plasma samples should be gently inverted, 7-8 times, immediately and then placed on a tube rotator or tilter for 30 seconds to ensure proper mixing of the blood with the preservative. The tubes should then be placed on ice after mixing of blood with the anticoagulant until they can be centrifuged, which should occur as soon as possible and not longer than 20 minutes from collection.

G.2.4 Processing of Plasma

Centrifuge tubes in a refrigerated centrifuge at about 4°C for 20 minutes at 1500 X G (usually 2500-3000 rpm on most centrifuges), taking care that the centrifuge is properly balanced.

All plasma samples should be processed immediately following centrifugation. If this cannot be done immediately, samples should be placed in a refrigerator or on ice until processing can occur, which should be no longer than 30 minutes from centrifugation.

Do not use the same pipette for transferring aliquots of plasma from the lavender/purple top and from the blue top vacutainer tubes. Use a separate disposable pipette for each type of vacutainer tube.

During pipetting of the sample, special care should be taken to avoid contact with the buffy coat between the plasma and cells. If the cells or buffy coat are disturbed, do not continue pipetting. Re-centrifuge the sample at 4°C for 20 minutes at 1500 X g or 2500-3000 rpm. Make a note of this in the blood processing log book. If blood is hemolyzed, redraw the sample if possible; otherwise, send the plasma but note this in the blood processing log book.

Prepare the following aliquots from the processed plasma:

1. **Blue top vacutainer**-transfer one ml of plasma to a blue top cryogenic vial which should be placed on dry ice (ideally in a powdered form) to quickly freeze the sample.

2. **Lavender/Purple top vacutainer**-transfer

   2ml plasma to a red top cryogenic vial (except 6-month visit)

   2ml plasma to a white top cryogenic vial

   2ml plasma to each of **two** yellow cap cryogenic vials

Excess plasma will be discarded.

G.2.5 Instructions for Sealing and Freezing Samples

After plasma has been aliquotted into appropriate vials, it is ideal to transfer vials onto ice as soon as possible. **Do not leave them at room temperature.** For screwcap vials, be sure cap is screwed in completely. Generally, follow the volume instructions for each sample. *It is important that vials do not contain excess plasma because expansion or freezing may crack the vial or force the cap off.* It is also undesirable to fill the vial *much less* than its capacity because this provides increased opportunity for sublimation of the sample onto the sides during frozen storage. Be sure that all vials are properly sealed, and transferred as quickly as possible to a -80G. freezer. These specimens will be stored in small compartmentalized freezer boxes and shipped in batches to the Penn Medical Laboratory on a monthly basis. See Section G.3.2 for Storage and Shipping Instructions.

There should be:

a) 2 ml of EDTA plasma in a cryogenic vial for lipids (white cap)
b) 2 ml of EDTA plasma in a cryogenic vial for insulin (red cap) - except 6-mo vis.
c) 2 ml of EDTA plasma in each of **two** cryogenic vials for storage (yellow)
d) 2 ml sodium citrate plasma in a cryogenic vial (blue cap) for fibrinogen.

G.2.6 Collection and Processing Flow Chart

The Penn Medical Laboratory will provide each clinic with a flow chart, Exhibit G-2 (revised 10/96) outlining the procedures for collection and processing of laboratory samples. Clinic staff may find it helpful to post a copy of this flow chart in the area where samples will be collected and processed.

G.3 STORAGE AND SHIPPING OF SPECIMENS

G.3.1 Storage of Specimens

Specimens that are collected at each Clinical Center will be stored locally in small compartmentalized freezer boxes and sent in batches, monthly, (See schedule G.3.2.5) to the Penn Medical Laboratory. Prior to shipment to the Central Facilities the specimens should be stored locally using the following guidelines.

1. All vials will be frozen and stored upright at -80°C (or colder) until shipment to Penn Medical Laboratory. Freeze samples immediately. Do not allow vials to sit out unless they are on dry ice. Freezer temperature should be stabilized at -80oG. ± 2°C (or colder). This should be monitored routinely by logging the temperature on a record kept on the freezer door. CO_2 back-up systems are recommended. Samples must be frozen for at least one hour before they are packaged to be shipped.

2. Observe all precautions for biohazardous materials in the sorting, handling and packaging of stored samples.

Table G-3 **Description of Storage Boxes and Dividers for ACT Specimens**

Specimens	Vial Size	number vials	box size	maximum # specimens/box
Lipid Panel	4 ml	1	5x5x3	49
Insulin - fasting	4 ml	1	5x5x3	49
Fibrinogen	4 ml	1	5x5x3	49
Storage Samples	4 ml	1	5x5x3	49

4. Prepare a separate ACT Shipping Log (See G.3.2.3 for instructions) for each type of aliquot i.e., one for lipid, insulin fibrinogen and storage samples. Exhibit G-3 in the back of this appendix is a sample ACT Shipping Log. Enter specimen information as you collect and box the specimens.

   NOTE: Information on participant non-compliance to the pre-visit requirements for venipuncture with respect to fasting, exercise, alcohol etc., should be entered in the "Remarks" column of the log (e.g., non-fasting sample, alcohol in last 12-24 hours, exercise < 8 hours). This will be the only central record of non-compliance to these requirements.

   Update the Shipping Logs daily as you store the samples, and this will minimize the time required for rechecking and packing prior to shipment to the Penn Medical Laboratory.

G.3.2 **Shipping of Specimens to Penn Medical Laboratory**

The packaging and shipping of frozen specimens to the Penn Medical Laboratory is the responsibility of each Clinical Center. The procedures

10 lbs of dry ice gives some insurance against thawing if the package is delayed a few hours.

described in this section should be followed very carefully in order to minimize the chances that specimens will be lost, damaged or spoiled in transit.

G.3.2.1 General Policies for Shipping

The following policies should be observed in the preparation of samples for shipment to the Penn Medical Laboratory:

1. Samples will be mailed by Federal Express overnight *PRIORITY* mail service at scheduled monthly intervals to the Penn Medical Laboratory, in supplied styrofoam containers with at least 10 lbs of dry ice!!!.

2. An ACT Specimen Shipping Log Form detailing the contents of the package (originating Center, destination, time packed, date shipped, ID numbers, color of vial and remarks) will be included.

3. Mailings may be made only on designated days of the week to insure arrival at the Penn Medical Laboratory on a working day (See G.3.2.5 for Shipping Schedule). All specimens must be shipped on a Monday, Tuesday or Wednesday. This reduces the chance that a lost or delayed shipment

Penn Medical Laboratory is closed on the following holidays:

Labor Day	September 4, 1995
	September 2, 1996
	September 1, 1997
Veteran's Day	**November 11, 1995**
	November 11, 1996
	November 11, 1997
Thanksgiving	November 23, 1995
	November 28, 1996
	November 27, 1997
Christmas Day	**December 25, 1995**
	December 25, 1996
	December 25, 1997
New Year's Day	January 1, 1996
	January 1, 1997
ML King Day	**January 15, 1996**
	January 20, 1997
President's Day	February 19, 1996
	February 17, 1997
Memorial Day	**May 27, 1996**
	May 26, 1997
July 4th Holiday	July 4, 1996
	July 4, 1997

will arrive at a Penn Medical Laboratory on the weekend when there will be no personnel available to receive it. Adjustments have been made in the schedule for weeks where a holiday occurs.

5. Samples will be shipped to the Penn Medical Laboratory prepaid. The shipping fee will be paid by the ACT Penn Medical Laboratory. Instructions for contacting Federal Express are included in Section G.3.2.4

G.3.2.2 Preparation of Specimen Shipping Log Forms

Ideally, the preparation of the shipping log has been an ongoing process. Information about the samples, ID number and remarks (non-fasting, alcohol <12 hours, exercise <8 hours, etc.) has been entered as the samples were collected/processed and placed in the compartmentalized box for local storage. On the day that the samples are to be shipped to Penn Medical Laboratory, complete the information in the top section of the log. This includes the name of the clinic, type of sample (lipid, insulin, fibrinogen, storage), type visit, time packed, date shipped and total number of specimens enclosed.

A copy of the shipping log must accompany each shipment. It is printed on a two-part carbonless copy form. Keep one copy for your records and place the other on top of the Styrofoam container but inside the protective, outer cardboard container. When your shipment is received, Penn Medical Lab technicians will perform an inventory to be certain that all samples in the box correspond to those indicated on the shipping log. If the lab finds any discrepancies, they will call you to ask for your assistance in identifying extra samples or finding "lost" samples.

G.3.2.3 Supplies Required for Shipping

The following supplies are required for shipping:

Provided by Penn Medical Laboratory:

- Shipping Log Form
- Polyfoam shipping containers with cardboard cartons
- Pre-printed Federal Express Shipping Labels

Provided by Coordinating Center:

- Revco freezer storage boxes with dividers
- Biohazard plastic bags for freezer storage boxes

Provided Locally:

- Dry Ice
- Paper Towels for wrapping Storage Boxes
- Self-addressed (Clinic Address) envelope
- Small zip-log plastic bags (sandwich size)
- Newspaper or Styrofoam chips - for filling empty container space to prevent rattling
- 3/4" Scotch Brand Filament Tape

G.3.2.4 **Packing Shipping Containers**

The safe packaging and shipping of all frozen samples is the responsibility of each Clinical Center. Prepare specimens for shipment using the guidelines that follow.

(1) **Order dry ice prior to expected shipping dates. At least 10 pounds of dry ice is necessary to keep the specimens frozen for 48 hours.**

(2) Identify the freezer box(es) of specimens that are being sent to a particular Penn Medical Laboratory. Check all of the specimens in the box against the Shipping Log Form to be sure there are no transcription errors or missing specimens.

(3) The frozen samples are shipped in the small freezer boxes in which they have already been stored at the Clinical Center. Wrap each freezer box in several layers of paper towels and seal each box in a plastic biohazard bag. The paper towels serve as absorbent material in the event that vials are broken or cracked. Place upright in the supplied polyfoam shipping container. The boxes may be stacked or placed side by side depending on which size Styrofoam container is used. Stuff any empty space around the boxes tightly with crushed newspaper, paper towels. Place the 10 pounds of dry ice on top of the sealed biohazard bags.

(4) The Shipping Log Forms along with a self-addressed envelope should be enclosed in a Zip-Lok bag and taped to the top of the lid of the polyfoam container. A description of the log and instructions for completing it are found in Section

G.3.2.2.

(5) Place the lid on the polyfoam container and seal with 3/4" filament tape (scotch brand or equivalent).

(6) Place the sealed polyfoam container into a cardboard carton and seal the carton with 3/4" filament tape. Place the following preprinted labels on the outside of the cardboard carton.

(a) Clinic return address label.

(b) "KEEP FROZEN", label.

(c) "Class 9" (dry ice) label.

(d) A preprinted Federal Express air bill that has been supplied by the central laboratory. Attach it to the top of the shipping box using one strip of tape on the left hand side of the Air Bill. Federal Express will add the weight and cost to the bill.

(7) Samples will be shipped by air courier so that they arrive at the laboratory WITHIN 24 HOURS. A special account has been established with FEDERAL EXPRESS for mailing ACT specimens. Once the shipment has been packed and labeled, the clinic:

Be sure to check the form on the FedEx label that indicates overnight *PRIORITY* shipment to insure arrival at the lab by 10:30 am the next morning.

(a) **Calls Federal Express at 1-800-238-5355** and requests a pick-up for an overnight package. Some Clinical Centers may have already established a policy with respect to local pick-ups by Federal Express. Each Clinical Center should inquire as to the policies for daily Federal Express Pick up at their Center.

(b) Retains the carbon copy of the air bill as a receipt for later auditing by the ACT Coordinating Center. Shipping fees will be billed to an account that will be maintained by the ACT Central Laboratory

(c) ***You must call or fax Penn Medical Laboratory and inform them that a package***

is being sent. Please give the following information:

- the name of the person responsible for shipping the package
- your location
- the federal Express Airbill number

This information will allow the lab to track the package quickly if it does not arrive as planned

(8) Shipments should be made according to the Shipping Schedule described in section G.3.2.5

Penn Medical Laboratory
Medlantic Research Institute
108 Irving St. NW
Washington, DC 20010

tel 202-877-3302
fax 202-877-3209

G.3.2.5 **Shipping Schedule**

In general, all frozen specimens will be shipped to the Penn Medical Laboratory not less than monthly.

Table G-4, Shipping Schedule for ACT Specimens, indicates assigned shipping times for each ACT Clinic. All specimens are shipped on a Monday, Tuesday or Wednesday to insure arrival at the Penn Medical Laboratory on a weekday when personnel will be available to process them.

On a rare occasion when a Clinical Center is not able to send samples to a Penn Medical Laboratory on the designated day, the Clinic should contact the Penn Medical Laboratory and ask if they are prepared to receive that shipment on a different day.

Table G-4

Site	Shipping Schedule
Stanford	First week of the Month
Texas	Second week of the Month
Tennessee	Third week of the Month

G.3.3 Packing and Shipping Flow Chart

The Penn Medical Laboratory will provide each clinic with a one page flow chart, Exhibit G-3 outlining the procedures for packing and shipping of laboratory samples. Clinic staff may find it helpful to post a copy of this flow chart in the area where samples will be be stored and prepared for shipping.

G.4 ACT Central Laboratory Information

If you have any questions regarding sample collection, shipping procedures or alert level reports, please feel free to call the following individuals at Penn Medical Laboratory:

Contact Person	Title	Phone number
Marilyn Cadorette	Laboratory Manager	202-877-3596
Sample Department	Shipping and Receiving	202-877-3302
David Robbins, MD	Medical Director	202-877-5481 or hhbf07a@prodigy.com

G.5 CLINIC EQUIPMENT AND SUPPLIES

The list that follows indicates the items that will be supplied centrally, as well as those that each Clinical Center will need to purchase locally.

CLINIC SUPPLIES:

SUPPLIED CENTRALLY (by the ACT Coordinating Center)

- 10 ml purple Vacutainer™ tubes - 15% K3 EDTA
- 4.5 ml blue Vacutainer™ tubes - 3.8% sodium citrate
- 4 ml CORNING cryogenic vials and blue, white and red color cap inserts
- Biohazard bags
- Vacutainer™ holders
- Multisample Vacutainer™ needles - 21G x 1 1/2"

- Disposable graduated transfer pipettes
- Freezer storage boxes 5"x 5"x 3"
- Box dividers 49 slot

Arrangements will be made by the ACT Coordinating Center for a shipment of *centrally supplied* items to be delivered to each Clinical Center every six months. If a Clinical Center anticipates running short of a specific item, they should contact the ACT Coordinating Center by E-Mail, or telephone (910) 716-2837 or (910) 716-9486 and indicate their need for additional items. The ordering and delivery of any item may require a few weeks notice, therefore each Clinic will need to regularly check their supplies in order to avoid the delays caused by shortages.

SUPPLIED LOCALLY

All Clinical Centers should arrange to purchase or have access to the following items or equipment.

Specimen Collection

- alcohol wipes or swabs
- sterile cotton or sterile gauze pads
- band aids
- Chux pads
- disposable gloves
- paper cups
- emesis basin
- tourniquets
- biohazard labels
- biohazard needle disposal box
- waterproof marking pen

Specimen Processing

- Tube Racks or supports
- Waterproof marking pen
- Refrigerator

- Test tube rotator
- Centrifuge (refrigerated)
- 3/4" Filament Tape (Scotch or equivalent) for sealing shipping carton
- -80°C Freezer
- Dry Ice
- Crushed Ice

These are the basic supplies that each clinic should have on hand. Local preferences, procedures and regulations may require that each clinic have access to items that have not been included on this list. It will be the responsibility of each clinic to arrange for these.

G.6 TRAINING IN BLOOD COLLECTION AND PROCESSING

Clinic personnel will be instructed in the protocol for blood collection and processing procedures as part of a training session held prior to the beginning of recruitment. Each clinic should have at least one staff member who will be actively involved in this process attend the session. This person, in turn will be responsible for training additional personnel at his/her clinical center. The training session will cover all procedures related to supplies, equipment, preparation of log sheets, labeling, collection, processing, storage, packing and shipping of specimens.

The Clinic Coordinator or another qualified observer should regularly monitor and evaluate the work of those involved in the collection and processing of blood samples. Specific plans should be made to train new staff members at a clinic. These should include a detailed review of the ACT Laboratory Manual as well as supervised practice in the application of the techniques required by the protocol.

G.7 **LABORATORY RESULTS**

It is important to remember that plasma samples are shipped on a monthly basis and that there will be a long lag time between the collection of samples and the report of results. The results of the Lipid Profile for each participant will be reported monthly to each clinic by the Penn Medical Laboratory. The format will be a one page report for each participant with the Act Study ID number and the values for total cholesterol, HDL-c, estimated LDL-c and triglycerides. The clinic staff will need to identify the participant by name and forward this information to the participant's physician. See next page/section..."Reporting participant blood pressure results."

Each clinic will need to identify a staff person responsible for receiving these reports from the Penn Medical Laboratory and forwarding them to the appropriate physician.

In cases where an extreme laboratory result may require more immediate intervention, the Penn Medical Laboratory will report this result by telephone to the designated staff member at the ACT Clinic. **The designated ACT staff member will be responsible for communicating this information to the participant's physician.** Specific intervention for these "extreme" results will be left to the individual clinician's discretion.

APPENDIX H

FORMS AND INSTRUCTIONS

H.1 Introduction 2

H.2 General Description of ACT Forms 2

H.3 Forms Completion 2

H.4 Forms Review and Editing 4

H.5 Processing Form Correction 6

H.6 Submission of Forms to the CCC 6

APPENDIX H

FORMS AND INSTRUCTIONS

H.1 Introduction

Accuracy in the completion of forms helps to ensure the collection of high-quality data. Once a paper form is incorrectly completed, logic and range checks, built into the data entry system, may not always be able to detect the error(s). Because some ACT forms are self-administered by the participant, they are more likely to contain improperly completed or inconsistent responses. Listed below are procedures to be implemented regarding forms completion for interviewer and self-administered forms, instructions for reviewing forms, and instructions for processing form corrections. Refer to each form type for specific form completion instructions.

H.2 General Description of ACT Forms

Some of the ACT forms used in screening and follow-up will be 2-part forms. Caution should be taken in completing these forms, in terms of inserting the cardboard cover sheet in between each page, in order to prevent written imprints from being transferred to the wrong pages. Once data have been collected, reviewed with the participant, checked by ACT staff for completeness and continuity in preparation for data entry, and data entered, CC staff will tear off the CCC copy and send this to the CCC. The "CC copy" will be retained at the site.

H.3 Forms Completion

When completing a form, use an ink pen, not a pencil, to record the information. Encourage all participants to use a pen to complete the take-home self-administered forms. Legibility of handwriting is extremely important; illegibility of handwriting is confusing to CC staff and data entry personnel, and CCC staff, both for numeric and character values and comment fields. Encourage participants to write legibily on the self-administered forms.

H.3.1 Participant identification number (sid) and acrostic

It is extremely important to record the correct study identification number in the boxes on the form. Clearly record the six digit identification number that is computer-generated prior to

entering Telephone Screening Form. This identification will remain the same during follow-up. Staff should record the participant's identification number on the self-administered forms prior to the participant completing the rest of the form.

Likewise, record the computer-generated acrostic; the acrostic consists of the first three letters of a participant's last name, the first two letters of the participant's first name, and the first letter of the participant's middle name.

Example of an acrostic:

Name: John Steven Doe

Acrostic: DOEJOS

Do not record an apostrophe in the acrostic boxes; instead, use the next following letter of the person's name. When the computer generates the acrostic, if an apostrophe is included in the leading letters of a name, the computer will automatically use the next following letter.

Example of a name with an apostrophe for acrostic:

Name: Emily Jane D'Agostino

Acrostic: DAGEMJ

If a participant does not have a middle name, record a hyphen in the last box of the acrostic. Again, when the computer generates the acrostic, the computer will automatically enter a hyphen if the participant does not have a middle name.

Example of a two-name acrostic:

Name: Rod Stewart

Acrostic: STERO-

H.3.2 Date of visit/exam/form

Record the date of the visit/exam/form using leading zeros, followed by the month, day, and year.

Example of date:

Date: August 1, 1995

Form date recording: 080195

Be especially careful to avoid transposing numbers when recording a date.

Example: Date - August 1, 1995

Incorrectly recorded date: 080159

Correct date: 080195

H.3.3 Personnel codes

Each ACT staff person will have an assigned two-digit personnel code. When completing forms, record the correct staff personnel code at the appropriate location on the forms, for example, reviewer code, data entry code.

H.4 Forms Review and Editing

Before sending forms to data entry personnel, an appointed staff person should review the completed forms for missing items, blank or inappropriate responses, and out-of-range values.

Periodically throughout the study, it is a good idea to perform a check for continuity of data across forms for individual participants. Data such as weight, age, certain disease conditions, etc. should not vary much from visit to visit, and the forms should reflect this.

H.4.1 Missing items

Special attention should be given to missing items, or items that were left blank, such as date of visit, birth, or date that various measurements were performed; the person reviewing the form should make an extra attempt to resolve a missing date on the form. If a date cannot be determined, the reviewer should enter a "PM" on the form to indicate that the date is permanently missing. The data entry person and CCC will know that an attempt was made to retrieve the missing date.

H.4.2 Blank or inappropriate responses

Inappropriate responses may be mistakenly written on the form by either the staff or participants. For example, a participant may indicate on the form that his/her birth date year is different from the birth date year that the staff person perceives the participant to be. If this problem is noted on a self-administered form while the participant is on-site, the reviewer should investigate the problem as soon as possible while the participant is on-site.

A possible clarification for a blank or inappropriate response is easier to correct or obtain while having face-to-face contact with the participant rather than a telephone call later. Some form questions may be sensitive and intimidating to a participant; therefore, the participant will intentionally leave the form questions unanswered. Use discretion in trying to obtain further information from the participant. It is important that we respect the participant's right to refuse to answer any questions he/she chooses.

If a question that requires a non-numeric response is left unanswered, the reviewer should write "PM" in non-numeric question response area on the form as a visual clue to the data entry person and CCC that the information is permanently missing.

If a question that requies a numeric response is left blank, enter a "-5" in the question response area on the form as a visual clue to the data entry person and the CCC that the information is permanently missing. The computer will record this information automatically as a -5 as the data

entry person will have this -5 option as a response when keying.

H.4.3 Skip patterns

When reviewing forms, make certain that appropriate skip patterns have been followed when the form was completed. These skip pattern questions are usually multiple-part questions where one condition may imply answering additional qualifying/quantifying information or either skipping down to the next question. Staff should briefly indicate skip pattern question examples to participants.

H.5 Processing form corrections

In the course of correcting an error on a form, staff should cross-out the incorrect response and record the correct response above the crossed-out response. The staff person should write his/her name and date that the item was changed next to the corrected entry. Do not erase or white-out an incorrect item.

If appropiate, enter on the form a brief justification for the change. Forward the corrected form copy to the data entry person to correct the database. After rekeying the item, the data entry person should write "Rekeyed..." followed by his/her name and date on the form. Photo-copy the corrected form, along with page one of the form that contains the standard identifying information such as identification number, acrostic, date of form/visit,etc., mark "update/correction" on the corrected page, and send to the CCC for processing. Return the corrected page to the participant's chart.

H.6 Submission of Forms to the CCC

Mail forms and corrections weekly to the CCC. The address is:

Susan Anthony
ACT Coordinating Center
Bowman Gray School of Medicine
Medical Center Boulevard
Winston-Salem, NC 27157-1063

APPENDIX I

Cost Analysis Data Collection Procedures

(currently being developed)

APPENDIX J

MEASUREMENT OF PULSE WAVE VELOCITY

Introduction 2

Methods 2

Overview of Measurements 3

Positioning of the Participant 3

Placement of the Continuous Wave Doppler Probes 4

Data Management 6

Monitoring and Quality Control 7

Index for Figures 8

Figure 1 Method for the Measurement of Pulse Wave Velocity . . . . .

Figure 2 Schematic of the Ascending and Descending Aorta . . . . .

Figure 3 Typical Wave Forms Obtained by Doppler Recording of the Right Carotid . . . . .

Figure 4 Bony Thorax, Anterior View Demonstrating the Sternal Notch . . . . .

Figure 5 Diagram of the Breast Bone . . . . .

DRAFT

APPENDIX J

MEASUREMENT OF PULSE WAVE VELOCITY

INTRODUCTION

The aorta and other major arteries are normally very compliant conduits. These flexible tubes facilitate the movement of oxygenated blood and nutrients from the left ventricle of the heart to all areas of the body. In healthy subjects these arteries provide a very low resistance path for the distribution of blood. With each contraction of the heart, a flow wave is generated which travels the length of the arterial system. The physical properties of the arteries can dramatically influence the ways in which these flow waves travel. Pulse wave velocity (PWV) is the detailed measurement of the speed at which a flow or pressure wave travels the length of an artery.

Certain diseases, like diabetes, atherosclerosis, and hypertension can dramatically alter the physical and elastic qualities of the arterial tree. These alterations have many adverse effects on the heart and predispose to premature heart disease. Pulse wave velocity is a non-invasive means to measure the speed of a flow wave in centimeters per second (cm/sec). The speed of the flow wave is proportional to the stiffness of the arterial tree. Older subjects who have very stiff arteries may have a PWV of approximately 1000-1300 cm/sec. Younger subjects may have a PWV around 500-600 cm/sec. The non-invasive measure of PWV provides some of the information that is obtained during cardiac catheterization and it does so in a very safe and simple fashion. Throughout this trial we will use this technique to assess the stiffness of the arterial tree and measure the possible effects of medications on the degree of arterial stiffness.

METHODS (TO BE CLARIFIED)

Pulse wave velocity (PWV) measurements are to be conducted in all ACT participants during SV2 and at the 24-month exit examination. It may be easiest to conduct these examinations while ???

The technique of pulse wave velocity measurement is straight forward and painless for the participant. As with many measurements, it must be done in a consistent fashion, making every effort to obtained the most exacting and detailed signals. You will record a Doppler flow signal

repeated measuring flow in the aortic arch and the right common femoral artery.

A) Overview of Measurements

A Doppler Probe is positioned proximally, on the carotid artery. A second probe is placed simultaneously on the right common femoral artery. Ultrasound beams emitted by the probes will reflect off the moving column of blood. The reflected sound waves return to the probe with a different frequency. The shift in frequency or "Doppler shift" is used to generate a visual flow wave signal (**Figure One**).

If you then measure the distance in centimeters and divide this value by the time in milliseconds, you obtain the velocity in cm per second. Again, the stiffer the arterial tree the faster the PWV.

The primary hypothesis of this substudy is that assignment to interventions designed to increase physical activity will result in more compliant arteries and a slower pulse wave velocity.

During the testing procedure you will measure the following:

1) Doppler flow waves from the right common carotid and femoral artery, gated to the R wave of a good quality ECG.

2) Doppler flow waves from the root of the femoral artery, gated to the R wave of a good quality ECG.

3) The distance from the mid-portion of the manubrium to the sampling site on the right common carotid.

4) The distance from the mid-portion of the manubrium to the umbilicus.

5) The distance from the umbilicus to the femoral artery sampling site.

6) The systolic and diastolic blood pressure from the right arms, using standard techniques following ten minutes of rest and before measuring the flow velocity.

B) Positioning of the Participant

These measurements are done while the participant is supine and has rested for 10 minutes. Since you will need to place ECG leads on the participant's chest, it is best to have them in a hospital gown. Use standard techniques to obtain the ECG signal and the systolic and diastolic blood pressures. The computer will need a good QRS complex from a standard ECG for analysis of the flow wave.

C) Placement of the Continuous Wave Doppler Probes:

1) Carotid Artery: The right common carotid artery originates directly from the arch of the aorta, by way of the innominate artery. Doppler flow wave forms are obtained from the point of the maximal palpable impulse along its course though the neck (**Site I on Figure Two**).

Place the participant in the supine position with the chin elevated and the head moderately rotated to the left. To help assure the subject's comfort, a small pillow or towel is rolled and placed under the nap of neck to facilitate the comfortable extension of the head.

Before palpating the artery, place the bell of a stethoscope over the artery close to the angle of the jaw. If a bruit is noted (the rushing sound produced by turbulent blood flow) there is a distinct likelihood that there is a significant carotid plaque impairing flow. Please note this finding on the clinical evaluation form. Carefully palpate the artery to find the maximal point of its pulse. This will be the place to sample the artery to achieve the highest fidelity recording. Mark this site with a tissue pen. You will need to know this site later to measure the distances.

Your primary goal is to obtain the most defined waveform to facilitate data analysis. Apply a liberal amount of ultrasonic gel to the skin. Carefully apply the probe with a comfortable amount of pressure on the artery to achieve the maximal intensity of the flow wave signal. The wave should have minimal background noise, a stable baseline, and a sharp foot at the onset of the upstroke of the flow wave (**Figure Three**). The audible single from the Doppler probe will be loudest when the waveform is most desirable. Remember to keep the angle between the probe and the course of the artery to less than 60°. This will ensure a good quality recording.

Note the relationship of the flow wave signal and the respiratory cycle of the patient. If the signal increases in noise or intensity with inspiration you are likely getting some measurement of the jugular vein's blood flow. This is easily corrected by re-positioning the probe to achieve a true arterial flow wave form. Be patient and remember that small changes in the angle or position of the

probe can result in significant changes in flow wave contour.

Do not stop measuring the proximal site in the carotid until your assistant has obtained a reliable femoral blood flow tracing. Once both probes are recording good quality signals, record several samples for the permanent record.

2) Recording the Aortic Arch

This is a little harder than recording the carotid or femoral vessels **(Site II on Figure Two)**. The aortic arch is sampled by placing the probe above the sternal notch at the base of the neck **(Figure Four)**. Apply a generous amount of ultrasound gel in the supra-sternal notch. Carefully angle the probe under the manubrium, aiming it toward the right hip. Move the probe to the left and right and deeper if needed to obtain the maximal single. Even though you cannot directly palpate the aortic arch, if you obtain the maximal signal you are most likely sampling the aorta.

3) Recording the Femoral Artery

The right common femoral artery is easily measured **(Site III on Figure Two)**. This site comprises the end of the aorta and the signal is recorded simultaneously with the proximal sites in the carotid and aortic arch.

Identify the inguinal ligament and palpate the femoral artery below the level of this ligament. Mark the skin with a marker in a manner similar to the carotid artery. With the second Doppler flow probe and a generous amount of ultrasonic gel find the maximal flow signal of the artery simultaneous with either the carotid or aortic arch recordings. Remember to keep the angle between the probe and the skin to less than 60 degrees. You may also have problems with the femoral vein signal. It will fluctuate with respiration, similar to the jugular vein. The artery typically is found lateral to the vein or outside to the femoral vein. Therefore, if the signal is noisy try carefully moving the probe to the lateral aspect of the leg. Remember to always stay over the maximal point of the arterial impulse.

4) Measure the Distances

Three specific distances need to be measured: 1) the distance from the mid-portion of the manubrium to the sampling site on the right common carotid artery; 2) the distance from the

mid-portion of the manubrium to the umbilicus; and 3) the distance from the umbilicus to the sampling site on the right common femoral artery.

The breast bone in the center of the anterior chest wall is composed of three bones (**Figure Five**). The upper most is the manubrium, the middle and longest bone is the sternum, and the smallest and most inferior is the xiphoid. You must first find the mid-portion of the manubrium. First, make a mark on the skin at the sternal notch. Then carefully feel along the manubrium to the level of the joint between it and the body. This is called the sternal angle or Angle of Louis and typically is raised. Make a mark on the inferior margin of the manubrium, where it meets the sternum. Measure this distance between these two points and make a mark at the midpoint. The midpoint of the manubrium is the key location for the other measurements.

a) Aorta to Carotid Distance (ACD)

The ACD is measured from the previously marked sampling site on the right common carotid to the midpoint of the manubrium. Record this distance in centimeters.

b) Aortic to Umbilicus Distance (AUD)

The AUD is measured from the midpoint of the manubrium to the inferior portion of the umbilicus.

c) Umbilicus to Femoral Distance (UFD)

The UFD is measured from the inferior portion of the umbilicus to the sampling site on the right common femoral artery.

D) Data Management

Data management tasks for the pulse wave velocity substudy consists of completing a PWV Clinical Evaluation Form after each PWV examination, mailing copies of this form to the ACT Coordinating Center and the PWV Reading Center, and mailing copies of the PWV diskette to the PWV Reading Center.

1) The PWV Clinical Evaluation Form: A copy of the PWV Clinical Evaluation Form appears at the end of this appendix. The purpose of this form is 1) to track the occurrence of PWV examinations, 2) to record detection of bruits or other complications that may prevent ACt from

obtaining readable PWV images, and 3) to allow for the monitoring of diskette mailings and processing. The PWV form should be filled out for each PWV examination that is attempted. Please be careful to fill each field on the form clearly so that data entry will be accurate and complete. One copy of the form should be mailed to the ACT Coordinating Center:

Susan Anthony
ACT Coordinating Center
Public Health Sciences
Bowman Gray School of Medicine
Winston-Salem, North Carolina 27157-1063

These forms can be batched and mailed every two weeks. It is important, however, not to allow more than two weeks to pass by without a mailing sot that the Coordinating Center can monitor the PWV examinations. A second copy of the PWV form should accompany the diskette mailed to the PWV Reading Center, as described below.

2) Diskettes: Diskettes containing PWV data and a copy of the PWV form should be mailed to the PWV Reading Center within 24 hours of when the examination has been conducted. For these mailings, use the Federal Express mailers provided by the PWV Reading Center. The address for the mailings is:

Dr. Peter Vaitkevisius
Johns Hopkins Geriatrics Center
5505 Hopkins Bayview Circle
Baltimore, Maryland 21224

E) Monitoring and Quality Control

It will be very important to maintain a high standard of quality control for the collection of PWV data so that the best scientific use can be made of these important data. Careful training of all PWV technicians will be conducted by staff from the PWV Reading Center. Only staff who have been certified by the Reading Center will be allowed to conduct PWV examinations. The staff ID entered in the PWV clinical Evaluation Form will be monitored to ensure that only certified staff are conducting these examinations.

As diskettes arrive at the PWV Reading Center, a quick scan will be made to assess whether they are judged to be readable. The PWV staff will assemble a database that will allow us to describe the prevalence of readable records across time and by clinic. The PWV Reading Center will also conduct internally a systematic quality control program that will examine intra-reader and inter-reader repeatability.

Regular reports on the number of exams being conducted, processing time, readability, and repeatability will be prepared by the PWV Reading Center and the ACT Coordinating Center for use by the ACT Steering committee, the ACT Data and Safety Monitoring Board, and the National Institute on Aging Program Office. A comparison will be made between the PWV clinical Evaluation Forms received at the ACT Coordinating Center and the diskettes received by the PWV Reading Center will be made to ensure that all examinations are accounted for.

INDEX FOR FIGURES

Figure One: Method For The Measurement Of Pulse Wave Velocity. Pressure waves are recorded simultaneously along the path of wave travel from the heart. The delay from the foot of the proximally to the distally recorded waves is measured and wave velocity is calculated as the distance between sites divided by the delay. (Adapted form, O'Rourke M, Kelly R, Avolio A. The Arterial Pulse. Philadelphia & London: Lea & Febiger, 1992:)

Figure Two: Schematic Of The Ascending And Descending Aorta. Ao = Aortic Valve, Aa = Ascending Aorta, Da = Descending Aorta, Aba = Abdominal Aorta, Fem = Femoral Artery, I = Sampling site on the right common carotid, II =Sampling site in the aortic arch obtained from the supra-sternal notch, III = Sampling site in the inguinal area on the femoral artery.

Figure Three: Typical Waveforms Obtained By Doppler Recording Of The Right Carotid. There is significant variability with minor changes in the position of the sampling probe. The optimal wave should be upright with a well defined foot, as depicted in the upper left panel.

Figure Four: Bony Thorax, Anterior View Demonstrating The Sternal Notch

Figure Five: Diagram Of The Breast Bone. This figure depicts the sternal notch, manubrium, sternal angle, body, and xiphoid process.

Figure One

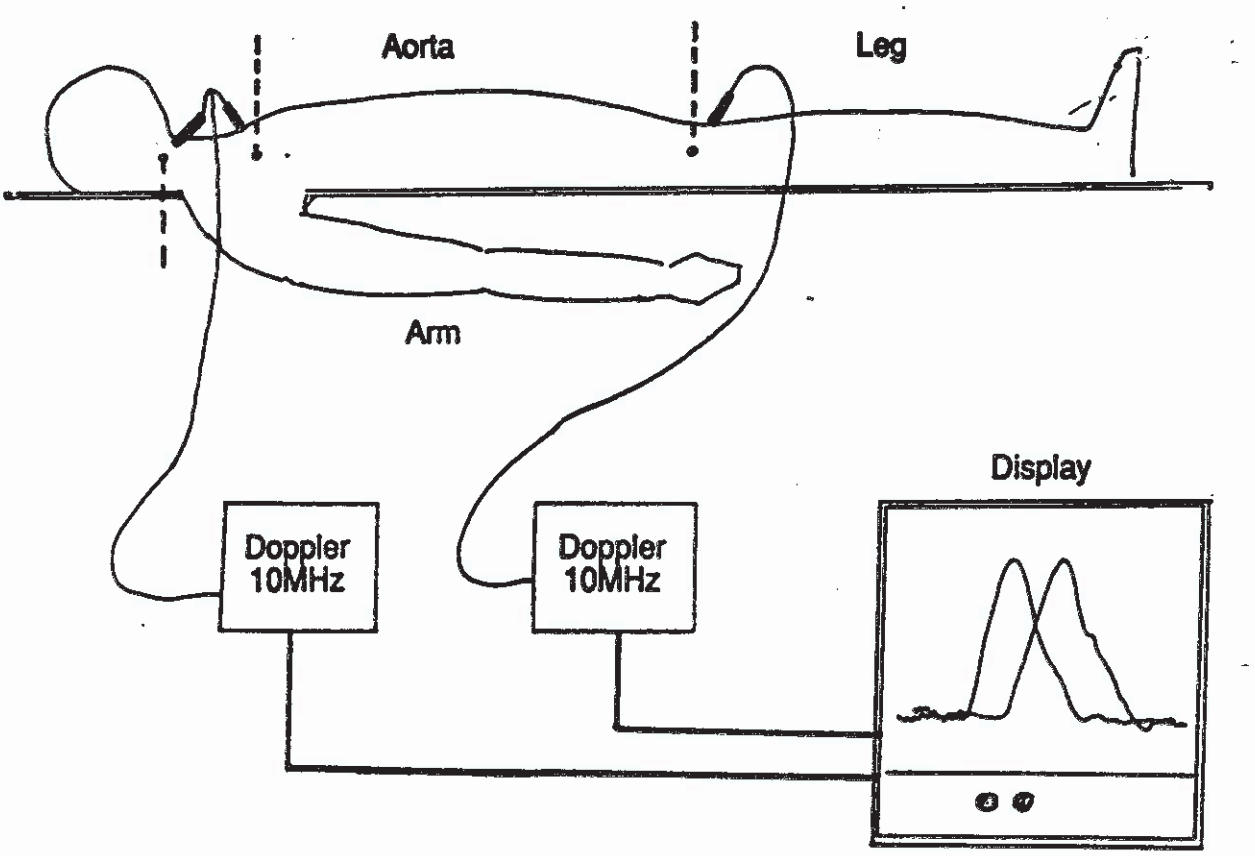


Figure Two

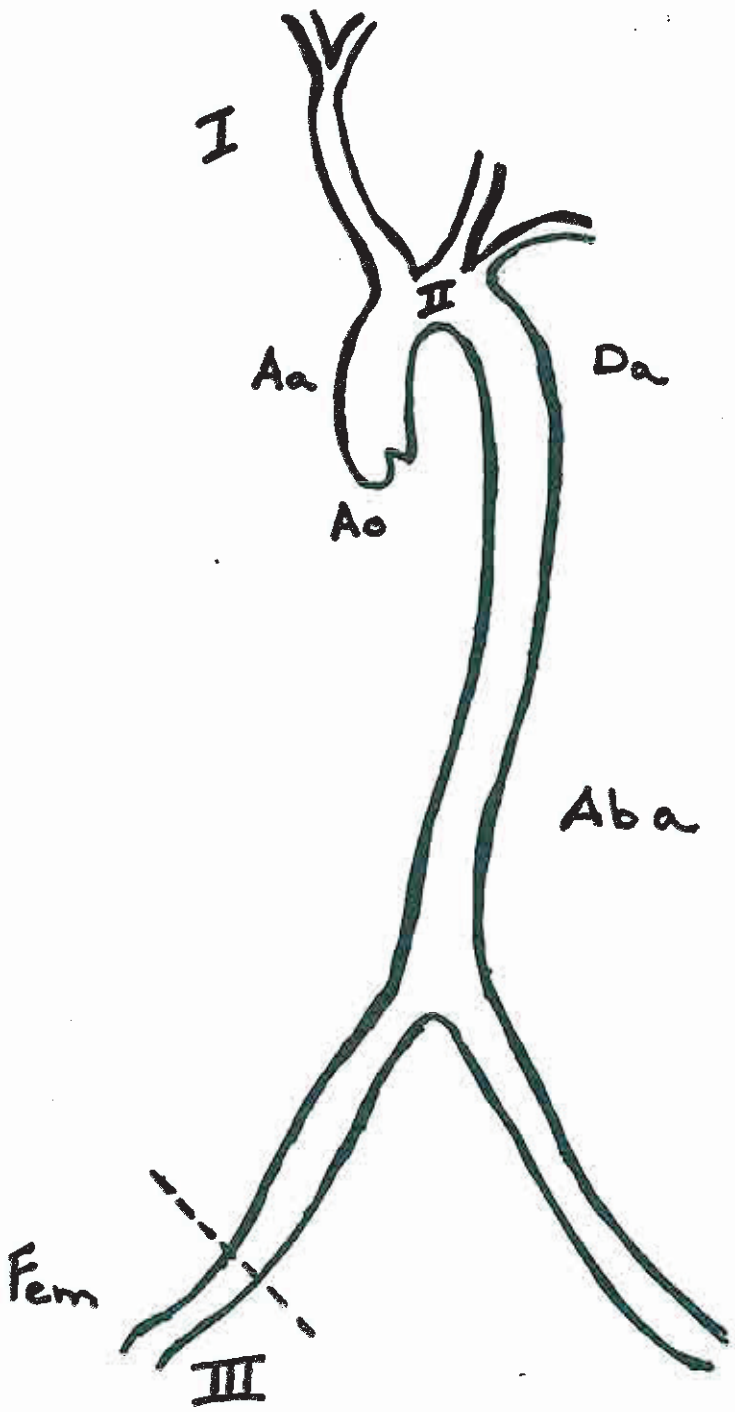


Figure Three

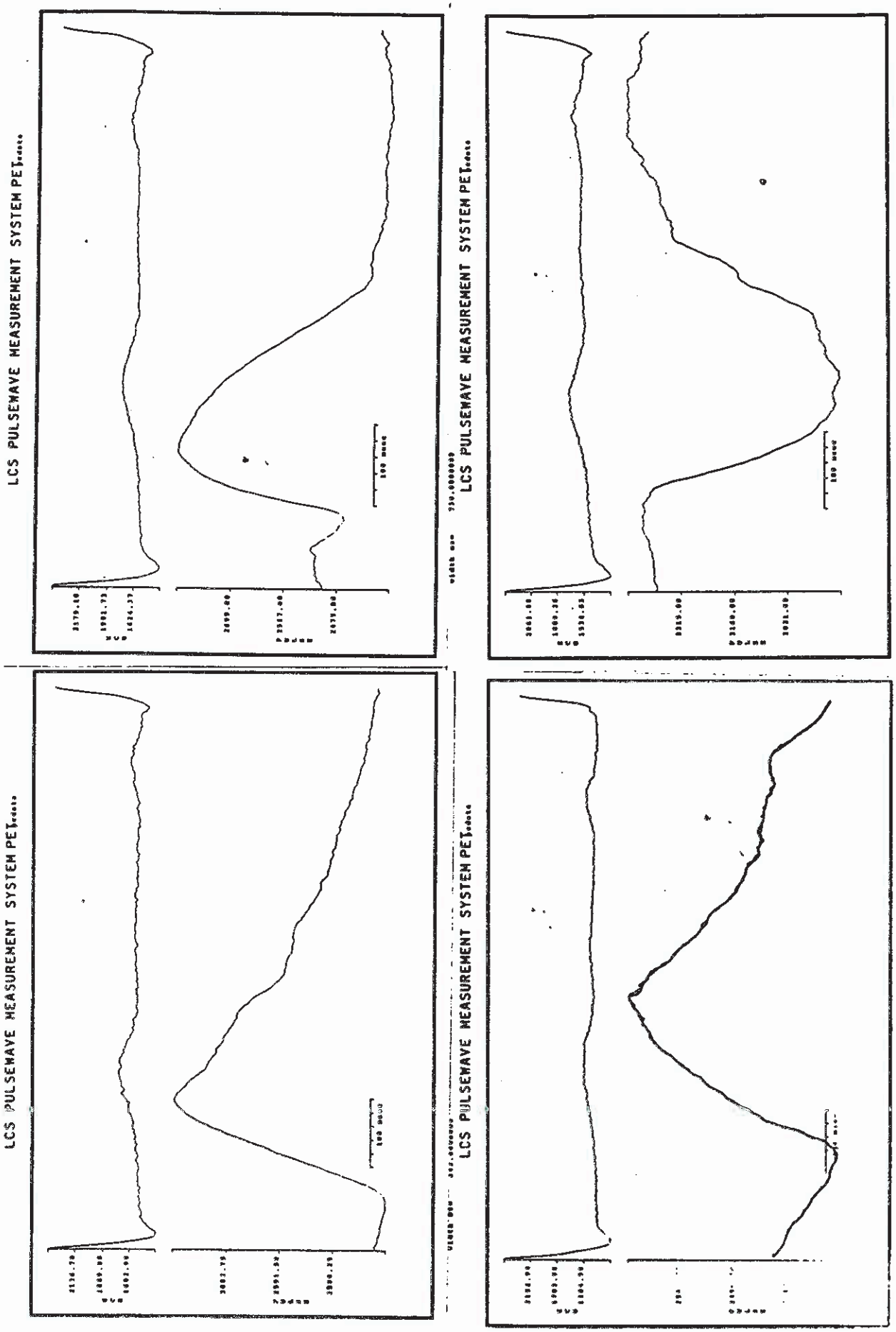
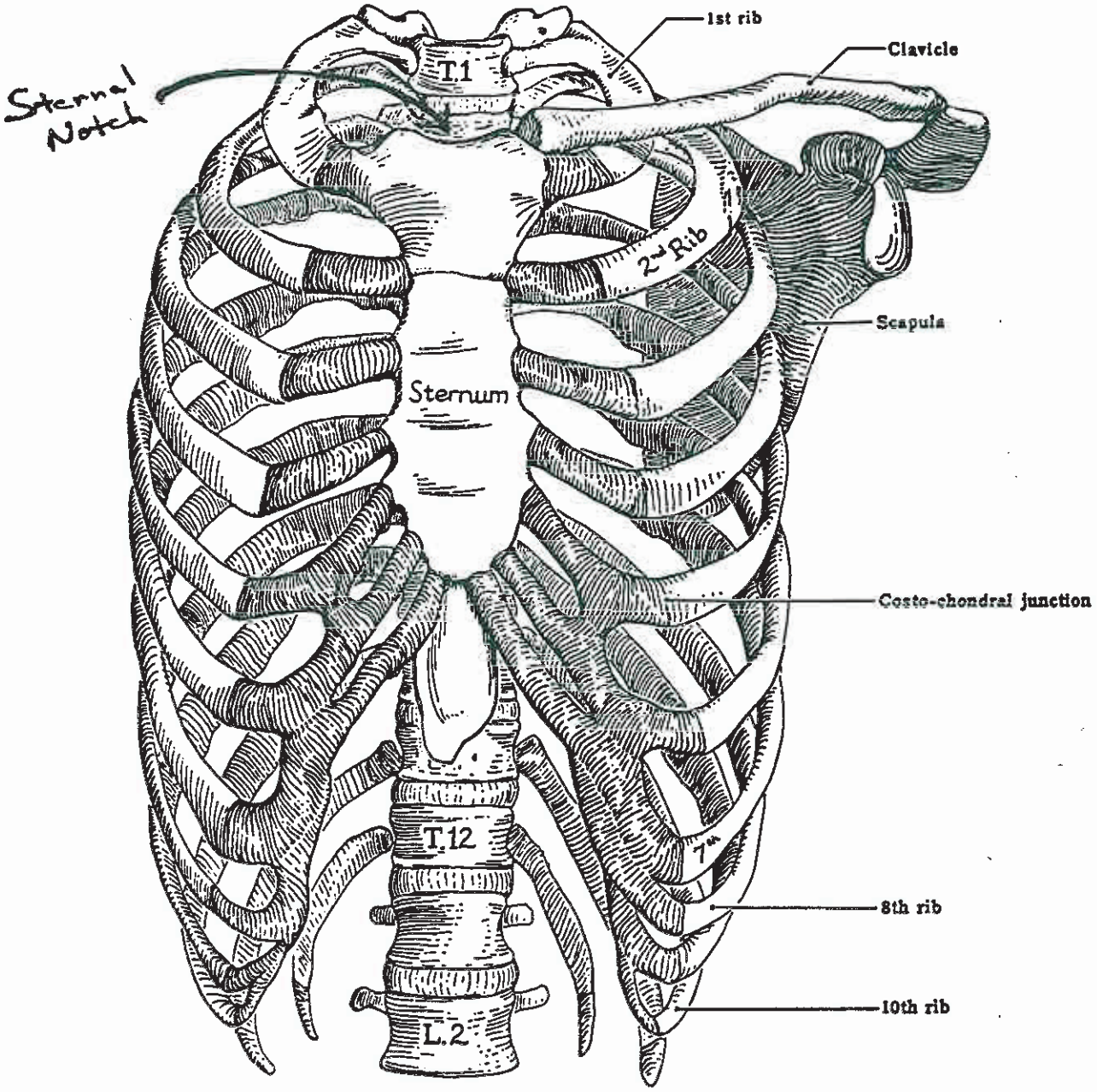
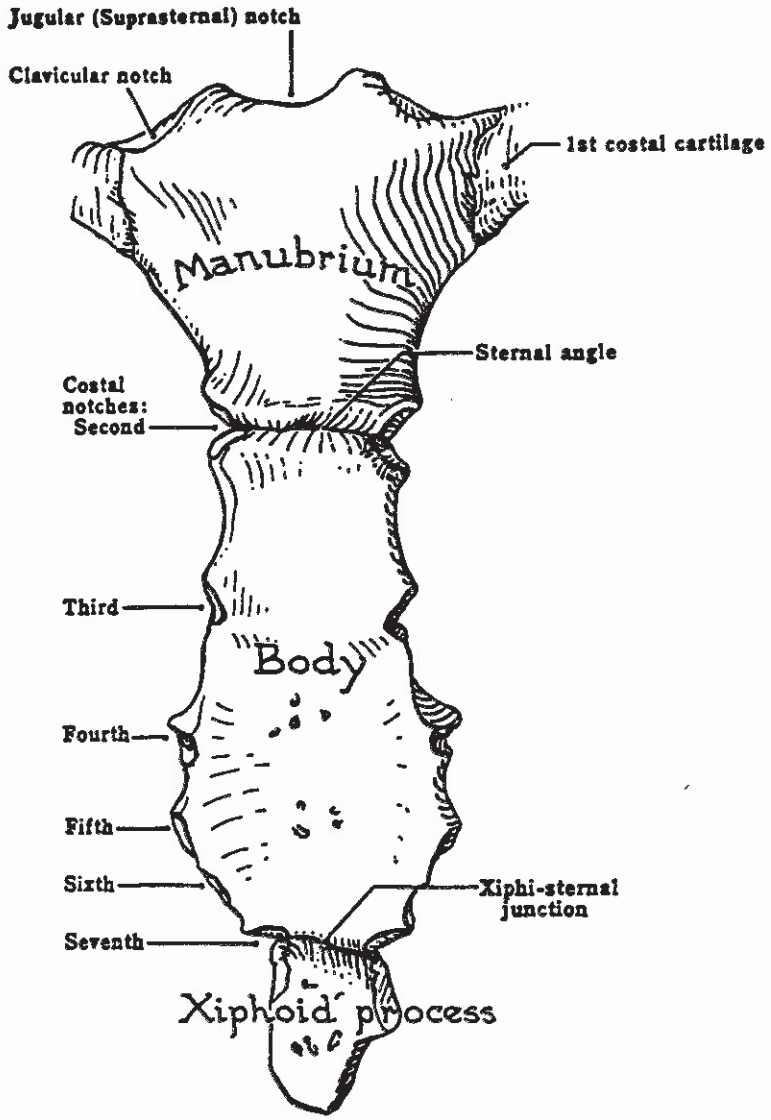


Figure Four



1-1 BONY THORAX, ANTERIOR VIEW

Figure Five


Jugular (Suprasternal) notch
Clavicular notch
1st costal cartilage
Manubrium
Sternal angle
Costal notches: Second
Third
Body
Fourth
Fifth
Sixth
Xiphi-sternal junction
Seventh
Xiphoid process

APPENDIX K

ACT Personnel and Affiliates

NAME	LOCATION
Albright, Cheryl	Stanford
Allender, Scott	NHLBI
Amoroso, Bobby	BGSM
Anderson, Roger	BGSM
Anthony, Susan	BGSM
Applegate, Bill	Memphis
Bagby, Andrew	Stanford
Barlow, Beth	Cooper
Barnes, Marion	NHLBI
Becker, Laura	Cooper
Blair, Steven	Cooper
Bradham, Doug	BGSM
Brown, Colleen	NHLBI
Byington, Robert	BGSM
Carpenter, Ruth	Cooper
Coday, Mace	Memphis
Cohen, Stuart	BGSM
Craven, Tim	BGSM
Cutler, Jeff	NHLBI
Dailey, Margaret	BGSM
Darroch, Shelia	Cooper
Dotson, Kathy	BGSM
Driscoll, Vivan	Memphis
Dunn, Andrea	Cooper
Edwards, Michelle	Cooper
Elam, Jan	Memphis
Espeland, Mark	BGSM
Ettinger, Walt	BGSM

APPENDIX K

ACT Personnel and Affiliates (cont)

NAME	LOCATION
Finch, Marolynn	Memphis
Furberg, Curt	BGSM
Garcia, Melissa	Cooper
Gibbons, Larry	Cooper
Griffin, Beate	Memphis
Harris, Darrin	BGSM
Haskell, William	Stanford
Havlik, Dick	NIA
Hogan, Patricia	BGSM
Horton, Veronica	Memphis
Howell, Lucy	Memphis
Johnson, Karen	Memphis
Kampert, James	Cooper
Khan, Jalil	Cooper/UTSW
King, Abby	Stanford
King, Jacqueline	BGSM/WFU
Klesges, Robert	Memphis
Kohl, Harold	Cooper
Kunze, Jeanne	Cooper
Lambeth, Joyce	Memphis
Lane, Lynda	Cooper
Laws, Amy	Stanford
Levine, Benjamin	Cooper/UTSW
Lewis, Nicole	NHLBI
Marcus, Bess	Cooper/Miriam Hospital
Margitic´, Susan	BGSM

APPENDIX K

ACT Personnel and Affiliates (cont)

NAME	LOCATION
Mayer, Elizabeth	BGSM
Miller, Mike	BGSM
Miller, Stephen	Memphis/Methodist Hospital
Moore, Willie	Cooper/UTSW
Morgan, Tim	BGSM
Morrow, Melba	Cooper
Obarzanek, Eva	NHLBI
Oka, Roberta	Stanford
O'Toole, Mary	Memphis
Palmer, Lisa	Stanford
Parker, Stephanie	Cooper
Pelts, Julie	Stanford
Peters, Debra	BGSM
Phillip, Wayne	Stanford
Pierce, Nancy	Cooper
Powell, Patricia	Cooper/UTSW
Pruitt, Leslie	Stanford
Ray, Debra	Memphis/Methodist Hospital
Reboussin, David	BGSM
Reece, Stephanie	BGSM
Rejeski, Jack	BGSM/WFU
Ribisl, Paul	BGSM/WFU
Sallis, James	Cooper/SDSU
Scheuring, Rachel	Stanford
Shih, Joanna	NHLBI
Shumaker, Sally	BGSM
Simons-Morton, Denise	NHLBI

ACT Personnel and Affiliates (cont)

NAME	LOCATION
Snell, Peter	Cooper/UTSW
Soberman, Judith	Memphis
Stefanick, Marcia	Stanford
Strasner, Amy	Cooper/UTSW
Taylor, J.L.	Memphis
Taylor, John	NHLBI
Vaitkevicius, Peter	Johns Hopkins
Vanderweg, Mark	Memphis
Via, Carol	Memphis
Vitolins, Mara	BGSM
Wasilauskas, Carol	BGSM
Western, Stephanie	Memphis

APPENDIX L
REFERENCES

(to be added later)