CHAPTER 25

INTERVIEWING

Study Documents Referred to in this Chapter:

- Telephone Screening Interview
- Contact Information
- Demographics
- Disability Questionnaire
- MAT-sf
- Process Measures
- 3MSE
- Medication Inventory
- Medical, Hospital Admission History
- Cancer Follow- Up
- Quality Well Being
- Health Care Utilization
- CHAMPS Battery
- HRQL
- Updated Contact Information
- ATS-DLD Questionnaires
- Napping, Caffeine, and Energy Drink Inventory
- Epworth Sleepiness Scale Questionnaire
- Insomnia Severity Index
- Pittsburgh Sleep Quality
- Berlin Questionnaire
- Spirometry
- Borg Scale/Index
- Outcome Events

CHAPTER 25

INTERVIEWING

25.1. STANDARDIZED INTERVIEWING PROCEDURES

Consistency and standardization in procedures is critical for good data collection. All interviewers in the LIFE study should follow standard procedures in reading questions and recording participant information. 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 participants in the study. The data collection forms contain specific instructions and scripts that should be followed precisely.

It is essential that interviewer's present questions appropriately, record participants' replies precisely and accurately, and probe for additional information meaningfully. To maintain an objective information-gathering atmosphere, the interviewer must convey that he/she is an understanding, interested person capable of accepting information in a non-judgmental manner. When talking to a receptive, supportive interviewer, participants will feel more comfortable without fear of appearing inadequate.

Previous studies have identified several factors that increase the respondents' receptiveness:

- Be prepared and know your material. Participants need to feel that you are interested in the study and in their opinions. Be an active listener and establish comfortable eye contact with the participant.
- Offer convincing statements about the purpose of the study.
- Describe the beneficial uses of the research findings to both the respondent and to the community.

There are two main types of questions, closed-ended and open-ended. With closed-ended questions, the interviewer will check the appropriate box. With open-ended questions, the interviewer will record the participant's answer word-for-word by writing it in the space provided. Open-ended questions do not suggest possible answers; the participant's responses should be recorded in his/her own words.

Questions:

- Read slowly in a natural conversational rhythm and in a normal tone of voice.
- Always read the entire question before getting the participant's response.

- 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.
- Offer to reread a question if you believe the participant did not understand what was asked.
- Ask questionnaire items in order and exactly as worded.
- Unless the instructions indicate otherwise, 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 any questionnaire items.

Responses:

- LEARN THE PURPOSE OF EACH QUESTIONNAIRE ITEM. You need to understand the information we are trying to obtain through each question. Unless you understand its purpose, you will not be able to judge when a response is adequate.
- 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. 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.
- DON'T DEFINE TERMS USED IN QUESTIONS UNLESS THE STANDARD DEFINITION IS INCLUDED FOR THE QUESTION. Some participants may ask, "What is meant by a word used in a question?" Leave the matter of definition to the participant. For example, you might respond, "Whatever you think it means" or "However you use the term."
- DON'T LEAVE A QUESTIONNAIRE ITEM UNTIL YOU HAVE AN ADEQUATE RESPONSE OR HAVE DETERMINED THAT A PARTICIPANT CAN'T GIVE A CLEARER RESPONSE.
- PARTICIPANTS MAY REFUSE TO ANSWER ANY QUESTION. However, refusal to answer some questions, such as those determining study eligibility, can affect whether or not a person may participate in LIFE.

Probing:

- SILENCE. The value of silence cannot be overestimated. The interviewer who can wait quietly and patiently will soon find that 15 seconds of silence will often allow a participant to expand or clarify a previously inadequate response.
- REPEATING THE QUESTION OR RESPONSE CATEGORIES. Be sure to repeat the question as stated in the questionnaire. This is particularly useful when

the participant provides an inappropriate response. In some cases it is 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" RESPONSE OR A REFUSAL WITHOUT PROBING AT LEAST ONCE. If a response is "don't know," probe by asking, "Well, what do you think?" If the question deals with facts, an approximation is preferable to no answer at all. The interviewer might probe, "What's your best guess or approximation?" to convey the idea that 100% accuracy is not required. If the participant persists with "don't know," do not harass him/her; accept that as him/her answer. A made-up answer to please the interviewer is no better than a "don't know." If a participant refuses to answer a question, you might remind them that their answers are completely private and confidential, and will not be revealed to anyone without their consent.
- USE NEUTRAL PROBES THAT DO NOT SUGGEST ANSWERS. Probes are needed to obtain more complete, accurate answers. All probes must be nondirective, 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, whenever the participant seems to have trouble expressing himself/herself, whenever the participant seems too shy to speak at length, and whenever there is any reason to believe that the participant has not given a complete report of his/her thoughts. Finally, reassuring probes are needed when a participant seems to lack confidence.

- EXAMPLES OF OTHER NEUTRAL PROBES:
  - "Could you tell me in what way?"
  - "Can you give me an example?" or "For example?"
  - "Can you explain that in a little more detail?"
  - "I am wondering how you are using the term . . .?"
  - "If you had to choose, which would you say?"
  - "In general, overall . . .?"
- 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.
  - DON'T ASK, "Do you mean . . .?" People tend to say "yes" to any suggestion, either because it is easy or because they think it is the right answer.
- MAKE PROBES CONSISTENT WITH THE PURPOSE OF THE QUESTION. 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 VAGUE, INCOMPLETE ANSWERS. A probe such as, “Tell me more about . . .”, is effective.
    - Do not accept qualified answers or “depends”. When the participant gives a response of this nature, it is advisable to use probes such as repeating the question or prefacing the question with a phrase such as, “Well, in general . . .”

25.1.1. Appearance and Demeanor

Clean, neat, professional dressing and style are important. The interviewer’s dress and demeanor should convey that he or she is an appropriate representative of the medical community, that the research is important, and that the participant is a respected member of the study.

The demeanor of the interviewer should be casual, yet professional. This is a difficult balance to maintain and requires a thorough familiarity with the questionnaires and procedures prior to interviewing the first participant. Although it is essential that the structured interview be followed verbatim, the interviewer should not sound like a recording. The interviewer should know the questions so well that it never sounds as if he or she is reading them formally. The interviewer should use a natural, conversational style. At the same time, the interviewer needs to “stay on track” and politely, but firmly, lead the participant through the interview.

Finally, the interviewer should be pleasant and friendly. As noted by Backstrom and Hursh-Cesar (1981), “A major objective is to put the respondent at ease. If the participant isn’t relaxed, [the interviewer] can’t make the participant talk.” Similarly, “the burden of ignorance has to be lifted from the respondent’s shoulders—that is, he or she must not be made to feel ashamed of his/her lack of information. [The interviewer’s] attitude, therefore, must be sympathetic and understanding. Emphasize that there are no correct answers. Rather, [the participant] must realize that what he or she thinks really is what counts. An opinion can never be wrong.”

25.1.2. Privacy and Confidentiality

It is critical that each interview be conducted in a quiet, private area within the clinical center. Each clinic should have a designated area that is comfortable for the participant and free from intrusions.

Similarly, it is important that the participant be the only respondent during the interview. The spouse/partner, friends, or relatives should not be present during the interview, because their presence will influence the participant’s responses to questions. If someone is with the participant and is reluctant to leave, explain the

necessity of privacy for study purposes and be prepared to suggest places where this individual can wait comfortably. You might say, “This will take about 15 minutes; the coffee shop is located down the hall”, etc.

Participants must be assured of confidentiality and it is critical that confidentiality be maintained throughout the study. As noted by Westat (1987): “An interviewer must often ask questions that one would not think of asking even a close friend. Most people, however, are willing to answer such questions when they are asked in an interview. They are willing to give information because they trust that it will be used only for serious purposes.” Your protection of all information about participants gained during the conduct of research is therefore essential. This means to protect not only the information you get in direct response to the questions you ask in an interview, but also the information you gather through incidental observations of the participant.

It is also important that care be taken in maintaining confidentiality of completed questionnaires while they are in your possession. Always make sure that questionnaires are not left where non-research staff can view them. You must safeguard the completed questionnaires by not leaving them unattended, such as in your car where they might be stolen, or in a school room, clinic room or office where anyone could walk in and read them.

It is your duty to keep the promise of confidentiality. Never divulge names or tell facts about or reveal the opinions of anyone you interview.

Information collected or seen during an interview can be shared only with the research team, whose members are under the same ethical or moral obligation as you are to the participants interviewed. As you may know, persons who participate in research studies have rights to privacy that are protected by federal law. Maintaining confidentiality of data is not just a philosophical issue for an interviewer. It means that an interviewer must be aware of the importance of protecting the confidences of the study participants on a day-to-day basis. For example, an interviewer’s comment to a friend outside of the research team about a particular participant or about a participant’s response is a breach of confidentiality and is considered unprofessional conduct.

25.1.3. Preparation for Interview

The interviewer should:

1. Review the Manual of Procedures and training materials.
2. Go through the structured interview carefully.

3. Organize all the necessary materials, including pencils, extra paper, a clipboard, etc.
4. Be certain the interview room is neat and organized.
5. Review the information available on the participant and information needed for the interview (e.g., time of appointment, name of participant, etc.)
6. Be certain his/her appearance is appropriate for the interview.
7. Obtain the necessary response cards, which are numbered sequentially.

25.1.4. Response Cards

For some questions/instruments, the interviewer is instructed to show the participant a response card, which will include the possible response categories for the relevant question(s). These cards are numbered sequentially and should facilitate ascertainment of accurate responses and minimize the need to repeat the response categories.

25.1.5. Respondent Questions

The interviewer should be familiar with all questions and their meaning. In response to requests for clarification, reread the question exactly as it appears, stressing by your voice intonation references to time, place, and question intent – for facts or feelings. Stem questions should be repeated periodically as needed. Do not ad-lib an explanation of the question. It is critically important to stay with the literal expression of the questions since this is the best way to ensure that data collected at the many clinical sites are comparable.

25.1.6. Respondent Complaints

Always empathize with the participant who has a complaint about the questionnaires (or other clinic activities). Give them the courtesy of listening to their complaint. For instance, if the participant complains of particular wording or redundancy or length of the questionnaire, say, you don't know why it was done as it was, but it is important for the participant to answer as best they can. Indicate that some of our forms are standardized forms and because of that they may seem redundant. In any case, it is important for them to do the best they can.

25.1.7 Administration of Instruments to Hispanic/Latino Participants

Bilingual staffs are requested to ask potential participants what their language of preference is (English or Spanish) and administer questionnaires in the language

they specify. Existing participants will be prompted to continue with the questionnaires in Spanish if they so desire.

1. Familiarize yourself with the script so that you read it accurately and clearly.
2. Weight and length/distance measures are provided in decimal units (meters, kilograms) in the questionnaires for participants who are more familiar with the decimal system.
3. Bear in mind that some Hispanic/Latino participants may have seasonal or temporary jobs and receive weekly wages. Thus, they may find it difficult to ascertain their annual income. If that is the case, multiply their weekly wages times 52 to obtain the annual amount earned.

For example:
In the Demographics questionnaire, question 14, on salary information.

14. Aproximadamente, ¿qué ingreso se recibió en su casa de toda fuente el año pasado sin los descuentos por impuestos (incluyendo sueldos, jubilaciones, inversiones, etc.)? *(Show response card demg 1)*

A. Menos de $5.000	☐	F. $35.000 a $49.000	☐
B. $5.000 a $9.999	☐	G. $50.000 a $74.999	☐
C. $10.000 a $14.999	☐	H. $75.000 o más	☐
D. $15.000 a $24.999	☐	I No sé/Se negó a contestar	☐
E. $25.000 a $34.999	☐		

4. Due to low literacy level among many Hispanic individuals, it may be necessary to read Informed Consents to them.
5. Medication Inventory: You may want to encourage participants to inform of any home remedy they may have been using or taking.

25.2. SELF- ADMINISTERED QUESTIONNAIRES

This method of administering questionnaires for data collection is used sparingly in the LIFE study, i.e. only for the cost-effectiveness, process, NEWS-A and HRQL measures. As with the interviewer-administered questionnaires, it is critical that the self-administered questionnaires be handled in a standardized manner.

Responses to questions in self-administered interviews will often be incomplete, missing or inappropriate. The questionnaires should be reviewed carefully before participants leave the clinic so that discrepancies can be resolved immediately. Specific items to check are covered in the sections under each questionnaire, but in general check for:

- Unanswered questions or blank spaces.
- More than one answer marked if directions indicate “check only one.”
- Incorrect skip pattern responses.
- Participant attempting to change the wording of the question and answering it according to the “new wording.” For example, if the question asks, “How often do you drink regular soda pop?” and the participant crosses out the word “regular” and writes in “diet.”

Changes on questionnaires made by study staff should be made in a different color pen than that used by the participant; these changes should be initialed and dated. Do not erase any marks made by participants. Rather, draw a line through any marks to be ignored by data entry.

All questionnaires, interviewer-administered and self-administered, should be rechecked an additional time by a second data collector/interviewer before submitting the questionnaire to data entry. Initials of the two staff persons checking the questionnaire should be used to verify that it is ready for data entry.

25.2.1. Mailed Questionnaires

Participants are asked to complete the Quality of Well-Being and Health Care Utilization questionnaires at home and bring them to the second pre-randomization screening visit and subsequent semi-annual clinic visits. The questionnaires are provided to participants after the first pre-randomization screening visit and are mailed to participants prior to the follow-up clinic visits. As noted above, these questionnaires should be carefully reviewed during the clinic visit to ensure completeness and accuracy.

25.2.2. Literacy or Vision Difficulties

While the self-administered questionnaires are designed for ease of administration, for a variety of reasons you can anticipate that some participants will have difficulty completing the questionnaires by themselves. Approximately 6% of the American population (with a range from 2-14% across individual states) is formally considered functionally illiterate, having completed fewer than four years of schooling. This rate is probably a gross underestimate of the number of individuals who are likely to have difficulty completing a self-administered questionnaire because of problems in concentration, reading fluency, or comprehension. In addition, some participants will have vision problems or difficulty in writing responses. Individuals with low literacy skills come from a variety of educational backgrounds and age levels. One of the stereotypical myths about illiteracy is that you can recognize an individual who is illiterate by their appearance. One must remember that an individual’s

comprehension skills are silent and invisible. Many individuals will have high intellectual skills in areas of visual memory and good verbal skills. To identify individuals who may have problems filling out forms, look at answers to questions on forms that may be inconsistent with what you know about the participant. Be aware that participants will try to conceal the fact that they cannot read well or understand; participants may use excuses such as, “I don’t have my glasses;” “my eyes are tired, would you read this for me?” Another clue is when a participant says, “I want a family member/friend to look at these first.”

While we cannot accurately estimate the number of participants in LIFE who will have literacy or vision difficulties, some participants are likely to have problems in these areas. It is important to provide these participants with the opportunity to have the questionnaires administered by the interviewer. When handing the questionnaire to the participant, the interviewer should say to the participant, “We have found that some people prefer to have the questions read to them. Would you like me to read these questions to you?” If the participant says no, the interviewer should indicate availability to answer any particular question, which may arise during completion of the questionnaire.

25.2.3. Confidentiality and Comfort

As with other interviews, it is important to indicate to the participant that his/her responses to self-administered questionnaires are confidential.

When required, assist the participant in finding a comfortable, quiet place to complete the questionnaire. If this place is not in the immediate clinic area, it is important that you take responsibility in making sure that the participant is returned to familiar surroundings once the questionnaire is completed. Be sure that the room is tidy and ready and that any needed supplies, such as pens and forms, are available.

We ask that the participant complete the questionnaire without the help of a spouse or friend, and you should discourage others from staying with the participant while he/she is completing the questionnaire. Although this may not always be possible, you should reinforce the value of the participant’s own responses.

Emphasize again that you are available to answer any questions that may arise.

25.3. SCHEDULE OF ADMINISTRATION

The schedule of administration of the interview forms is shown in Table 25.1 on the following page.

Table 25.1. LIFE Interview Forms Schedule

Visit type	Scr	Scr	Rnd	Fu	Fu	Fu	Fu	Fu	Fu	Fu	Fu
Visit Code		SV1	SV2	F06	F12	F18	F24	F30	F36	F42	Cls
Clinic or Home Visit number		1	2	3	4	5	6	7	8	9	10
Telephone call	1										
Activity/assessment Month		-0.5	0	6	12	18	24	30	36	42	
Form name											
Telephone screener	x										
CHAMPS[x]		x		x	x		x		x		x
Contact Information / update		x		x	x	x	x	x	x	x	x
Demographic, social, economic		x									
Medication inventory		x			x						
Medical, hospital admission history		x									
Cancer Follow up ^^^		x									
Disability Questionnaire		x		x	x		x		x		x
Process measures		x^	^		x			x			
Mobility Assessment Tool, short form MATsf			x			x		x			
3-MS Exam and cognitive battery		x^^	x^^				x				
Complete cognitive assessment[&]			x				x				
Quality of well being (CEA)			x	x	x	x	x	x	x	x	
Health care utilization (CEA)			x	x	x	x	x	x	x	x	
Claudication questionnaire			x					x			
Sleep-wake disturbances			x	x		x		x			
Pulmonary questionnaires, ventilatory capacity			x	x		x		x			
Health Related Quality of Life (HRQL)			x		x		x				
Proxy ADL Questionnaire[%]				x	x	x	x	x	x	x	x
Assistive Device Questionnaire[$]				x	x	x	x	x	x	x	x
Outcome Events				x	x	x	x	x	x	x	x
Other Health Events Questionnaire				x	x	x	x	x	x	x	x

Scr=Screening visit; V=Visit; Rnd=Randomization; F=follow-up visit; Cls=Close out visit; CEA=Cost Effectiveness Analysis; [x]CHAMPS-18 can be completed during group information/screening sessions prior to SV1; ^^3MSE, HVLT, and DSST at SV1 and computer-based battery at SV2; Efficacy for Walking; the others should be completed at SV2; The proxy ADL questionnaire is administered when a participant is not available to complete a follow-up assessment. [$]The Assistive Device Questionnaire is administered by phone when a participant cannot come to the clinic or when a home visit cannot be done. ** Measures to be obtained at closeout only if the measures were missed at the scheduled follow-up or if the scheduled follow-up visit occurred more than one year to the closeout visit.^^^ Only administer if participant reports a history of cancer on Question 10 of the Medical and Hospital Admission History form.

25.4. TRAINING AND CERTIFICATION FOR LIFE CENTERS

After carrying out the questionnaire training, program coordinators (PCs) should conduct at least two sessions with each data collector/interviewer prior to having them collect data on real participants. The following format is suggested:

Volunteers: Use colleagues, clinic staff, or other nonparticipant volunteers.

Central Training at Clinics: Interview prospective age-eligible participants/volunteers. (See Certification form description Chapter 24.)

From Pre-randomization Screening Visits 1 and 2

1) Contact information
2) Demographic, social, economic
3) Medical and hospital admission history
4) Cancer Follow up
5) 3MSE

From the Follow-up Clinic Visits

1) Outcome events
2) Health related quality of life measures
3) Cognition
4) Process measures, physical activity
5) Medications, Quality of well being, health care utilization

Corrective Actions: Should any problems related to bias, standardization, interviewing skills, or forms editing be apparent, the PC should work with the data collector/interviewer on these areas. Retaping with additional volunteers should then occur within a seven to ten day period.

The second set of tapes should be reviewed as soon as possible. If problems are still apparent, the PC should assess the appropriateness of using this staff member for data collection on LIFE.

Tip: Every data collector/interviewer must meet LIFE standards in order to be a part of the study.

Certification: Certification of each data collector/interviewer is complete when the training and audiotape practice has been completed to the satisfaction of the Program Coordinator.

Re-certification: Re-certification on standardized methods of administering the questionnaires should take place annually by the Program Coordinator or another certified assessor. The process should be the audiotape procedure described under certification. Periodic checks might also be conducted by "sitting in on a random interview" (after asking permission from the participant) and/or by "double checking questionnaires for correct completion" before they are sent to data entry.

25.5. SPECIFIC QUESTIONNAIRE INSTRUCTIONS

25.5.1. Telephone Screening Interview

This questionnaire is administered to prospective participants either by phone or in person. It is used as the first screen to establish eligibility. The questions included are designed to 1) obtain basic demographic information about prospective participants, and 2) screen out prospective participants who are clearly ineligible. This interview should not be administered until the verbal consent script has been read and the prospective participant has agreed. LIFE Study ID's are not assigned until verbal consent has been obtained.
If a participant breaks off the interview, mark all remaining unasked questions "refused".

The answer boxes are color coded. Answers that lead to exclusions are shaded. Eligible participants will only have unshaded boxed marked.

Instructions

Page 1

Ask all participants all questions on this page, unless it is established that the participant either geographically or age ineligible.

Question 1 asks about where the participant heard about the study. This information is useful for tailoring recruitment strategies.

Question 2 Determine if the zip-code of the prospective participant is in the target area for your clinical site. Participants will have to travel frequently to intervention sites, and if they live a long way from the site they are unlikely to be able to participate fully. The interview can be terminated once it is established that participant does meet the zip code criteria.

Question 3a Participants who say "no," they "don't know" or refuse to answer are ineligible.

Question 3b Participants who plan to be out of the area for more than 6 consecutive weeks in the next year are ineligible.

Question 4a Ask the participant his/her age. Record the given age on the form. If the age is outside of the target age-range of 70-89 the participant is ineligible and the interview can be terminated. Indicate if the participant's age is in the target age-range in the boxes. Participants who say they "don't know" or refuse to answer are ineligible.

Questions 4b-6 are self-explanatory.

Question 7 The NIH requires that all studies involving humans report the gender and ethnic make-up annually. The NIH distinguishes between "ethnicity" and "race." Question 7 asks about Latino/Hispanic ethnicity. Participants may refuse to provide this information and still be eligible for the study.

Question 8 This question asks about race. Participants may refuse to provide this information and still be eligible for the study.

Questions 9-10 These questions ask about participation in the LIFE Pilot Study. Participants who participated in the pilot study are not eligible.

Page 2

Question 11 refers specifically to using a walker. The use of a cane does not count, and persons using canes may be eligible.

Question 12 . Participants who refuse to answer are ineligible. Participants who say they "don't know" can be brought in for a screening visit to determine their ability to walk this distance.

Question 12a does not impact eligibility criteria.

Question 13 The time reference is the past month. A participant saying they used to exercise until they got sick two months ago would be eligible. The additional questions are for the purpose of probing the participant to ascertain the type, frequency, and total amount of exercise.

Question 14e Interviewer note to calculate the total number of minutes per week spent exercising.

Question 15 If the participant is hard of hearing or cannot talk clearly or does not seem to understand the questions the interviewer should mark "YES," and the participant is ineligible.

Question 16 The Interviewer should check to see that only unshaded boxes have been checked on Questions 2-4a, 10-12, 13-13a, and 15; and that the total number of minutes of exercise per week is less than 20 minutes for Question 14. If this is true, the interviewer should check "Yes" and go on to page 3. If any shaded boxes have been checked, the interviewer should check "No" and go on to the bottom of page 4.

Page 3

Questions 17-26 Any answer of "Yes" on this page results in exclusion. Because some older people can be poor medical historians, answers of "Don't Know" are acceptable answers and do not lead to exclusion. These responses can be followed-up by the study medical officer during the first screening visit. If a participant refuses to answer any question on this page, they are also ineligible.

Question 19 & 22 The interviewer may not recognize certain medical problems. If you are unsure, write the participant's verbatim response in the space provided. Do not mark an answer for this question and continue with the interview. Check with the study physician and your site PI to see if the condition warrants exclusion. Complete the questionnaire and follow-up with the participants appropriately.

Question 27 After completing Question 26 confirm the participant is still eligible (only unshaded boxes are checked) and proceed to Page 4.

Page 4

Question 28a – 28b.These questions ask about cancers or malignant tumors participants may have had. We are only interested in cancers diagnosed or treated in the three years before the interview. Participants with tumors diagnosed more than 3 years ago are eligible for the study.

Some people may have had more than one cancer diagnosed or treated in the past 3 years. Mark each box as appropriate. If a person has had two cancers, one of which would have made the person ineligible (for example, leukemia for which they are currently receiving treatment) and one that would not (for example, squamous cell skin cancer), they are ineligible.

Participants with non-melanoma skin cancer are eligible for the study. This includes basal cell carcinoma and squamous cell carcinoma. If the person does not know what kind of cancer they might have had they should be considered eligible. The study physician will follow-up during the screening visit.

There are 8 common cancers that can have varying prognosis: breast, cervical, colon, prostate, rectal, uterine, thyroid, and oral cancer. Participants are eligible if they have completed a course of treatment for these cancers. If they are currently receiving either radiation therapy or chemotherapy, they are not eligible. Chemotherapy does not include certain drugs that are used to suppress cancer

recurrence such tamoxifen. If you are unclear about the drug, mark the person as eligible, and have the study physician follow-up.

If a person is ineligible read the script at the bottom of the page and terminate the interview.

Question 29 Confirm the participant's eligibility based on pages 2-3 of the form. If the participant is eligible, go on to page 5. If the participant is ineligible terminate the interview by reading the script at the bottom of page 4.

Page 5

Questions 30-39 This page lists temporary exclusions. These are exclusions that may only apply for a short-while. It is up to the interviewer to determine whether participants are likely to become eligible during the recruitment period. If the participant might become eligible make plans to recontact the participant at the appropriate times. If not, terminate the interview.

Questions 30-36 Refer to health events in the previous 6 months. If a participant answers 'Yes', determine how long ago the event occurred. If six months will have elapsed between the event and the end of the recruitment period, schedule a follow-up call for that time.

Questions 37-38 - Refer to physical and cardiopulmonary therapy. Participants are eligible once physical or cardiopulmonary therapy has ended.

Question 39 - Refers to the participation in other trials. Participants should not be in two trials at the same time. Many studies, especially drug studies, can be of a relatively short duration. Participants are eligible for LIFE once they have completed other studies they may be in.

Question 40 – After completing Questions 31-39, if the participant is only temporarily ineligible, get permission to recontact him/her in 1-6 months.

Question 41 If a participant is eligible based on answers to the previous questions, schedule him/her for a clinic screening visit. The participant may want additional information about the study at this point, and you should be prepared to provide it. If a participant refuses participation at this point mark the reason for refusal on the form and terminate the interview.

Page 6

Questions 42-45 If the participant is eligible for Screening Visit 1, collect contact information. This information is crucial because instructions for the preparation for the first screening visit are sent to this address, and the phone number is used to remind participants of appointments. Check the accuracy of the address and phone number carefully.

Derive the Acrostic

Once the full name is collected, the interviewer is able to derive the acrostic for the participant. The Acrostic is a secondary identifier for the participant that is used as a cross-check. It is a 5-letter code made up of the first three letters of the participant's last name and the first two letters of the participant's first name. Instructions for deriving the acrostic are provided in Chapter 4.

25.5.2. Contact Information

Contact information should be obtained during the first pre-randomization screening visit.

Complete and accurate collection of contact information is essential for minimizing missing data and losses to follow-up. Contact information should be collected on the participant, a potential proxy, two other persons who know the participant well, and the participant's primary health care provider. Please ask for cell phone numbers and email addresses, when available.

Whenever possible, ask to see the participant's social security and Medicare cards. Some persons may be hesitant to provide this information. Emphasize that all information collected for the study is strictly confidential and that identifying information is omitted from all study forms.

It is essential that complete information be obtained for at least one potential contact. The goal should be to collect information for a potential proxy respondent (Q6-6a) and two different contacts (Q7-7b, 7d, 7e). If the participant cannot recall the complete addresses and/or phone numbers, ask them to bring this information to the second pre-randomization screening visit.

The ideal proxy respondent lives with the participant. If the participant lives alone, identify the person who knows the participant best. Ideally, this person sees or talks to the participant at least three days a week.

If the participant cannot recall the complete contact information for their primary health care provider, ask them to bring this information to the second pre-randomization screening visit.

25.5.3. Update of Current Contact Information

The initial contact information form should be updated as indicated during the course of the study. During each clinic visit, the participant should be asked whether the currently identified proxy is still suitable. The ideal proxy respondent lives with the participant.

If the participant lives alone, the person who knows the participant best should be identified. Ideally, this person should see the participant at least three days or 10 hours a week. If the participant identifies an alternative proxy, this information should be indicated on the Update of Current Contact Information form and the Contact Information form should be updated accordingly.

25.5.4. Demographics

Demographics information should be obtained during the first pre-randomization screening visit. This information will allow us to accurately describe our study population and to determine whether certain subgroups of individuals are more or less likely to benefit from the study interventions.

For the Other response category for Q5 (education), write in the last school year/grade (beyond 16) completed in the space provided.

For Q13 (Occupation), do not read the response categories. Use the participant's response to identify the correct category.

For Q14 (Income), some participants may be reluctant to provide this information therefore response cards should be used for this question. Emphasize again that all information collected for the study is strictly confidential and that identifying information is omitted from all study forms.

25.5.5. Disability Questionnaire

The Disability Questionnaire should be completed prior to the 400 Meter Walk during the first (or second) pre-randomization screening visit and subsequently at 6, 12, 24, 36 month follow-up clinic visits and close-out, if not completed in the past 3 months.

The Disability Questionnaire assesses the participant's ability to complete an array of important day-to-day activities without difficulty and, for a subset of activities, without personal assistance. This information will allow us to determine whether the study interventions improve the ability to manage day-to-day activities.

For Q3, 11, 14, 17, 18, 20 participants who have difficulty with the task, even they don't do for other reasons, should be asked whether they usually receive help from another person for the task.

For Q2-Q23, the interviewer should periodically repeat the stem. If the questionnaire is administered over the phone (i.e. when participant cannot come to the clinic), repeat the response options periodically as well. For participants who respond that they were unable to do a task, verify that this was for health reasons. If the task was not done for health-related reasons, mark an X in the

box labeled, “Unable to do the activity”. If the task was not done for reasons not related to health, mark an X in the box labeled “Did not do for other reasons”.

For Q24, show participant response card “DQ2.”

25.5.6 The Mobility Assessment Tool (short form): MAT-sf

The MAT-sf is a 10-item computer based assessment of mobility using animated video clips. The use of animation in the videos: a) removes potential biases in judgments that may arise from characteristics such as the sex, race, age or experience of the actor, and b) standardizes item interpretation since respondents view the actual demands of the task and are no longer required to make implicit judgments regarding item content, e.g., for climbing a flight of stairs, we can present the task standardizing the speed, number of steps, light conditions and the presence or absence of handrails.

The 10 items in the MAT-sf cover a broad range of functioning. The items include walking on level ground, a slow jog, walking outdoors on uneven terrain, walking up a ramp with and without using a handrail, stepping over hurdles, ascending and descending stairs with and without the use of a handrail, and climbing stairs while carrying bags. The items were selected based on individual response and information curves derived from Item Response Theory. Each item is accompanied by an animated video clip together with the responses for that question (number of minutes, number of times, yes/no). The test can be done on any assessment laptop and scores are saved to an exportable file. The time required to do the test with instructions from the examiner is <5 min.

The MAT-sf should be completed prior to the 400 Meter Walk during the first (or second) pre-randomization screening visit and subsequently at 18 and 30 month follow-up clinic visits.

To begin the MAT-sf testing the assessor should:

1. Double click on the MAT-SF icon on the desktop
2. Accept the License Agreement panel that appears
3. Click “Take Test” button
4. Read the instructions on the screen to the participant
5. Enter the Respondent ID (7-digit Participant ID), Visit Code (3 digit visit code SV1, etc.) and acrostic (5 letters) and Click Start

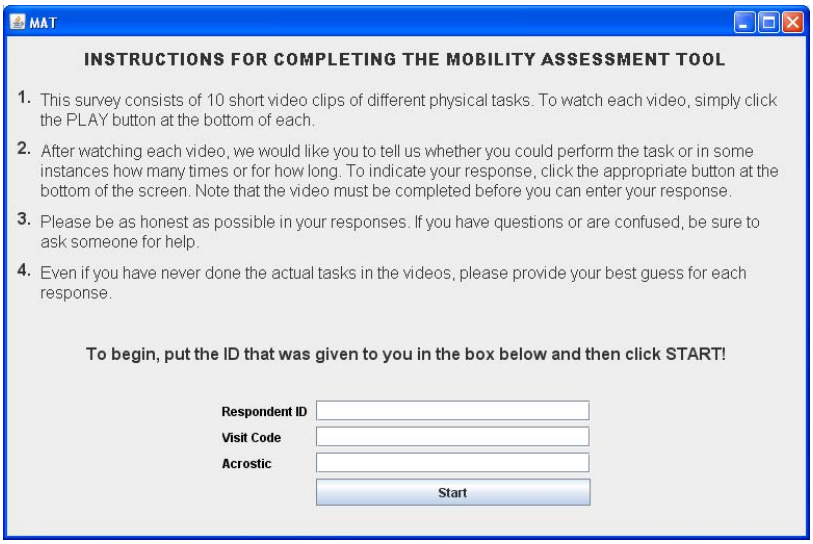

Figure 1. Instruction Screen

6. Once the first test is up, the subject clicks “Play” and watches the video, then responds to the question below. Until the video completes after Play has been pushed, the buttons across the bottom are grey out (un-selectable). Once the video completes, the buttons are active and the subject can answer the question and move to the next question
7. Then proceed through the remaining questions
8. After all the items are answered by the participant the program will automatically save the data to a scores.xml file.

DATA UPLOAD

Upon completion of the MAT-sf the data files will be stored in C:\LIFE MATsfData.

Within 24 hours of completing the MAT-sf assessment the data should be uploaded to the LIFE website by double-clicking on the LIFE Data Upload icon, located on the computer’s desktop (see icon below). The upload will be completed automatically.

Figure 2. Data Upload Icon

25.5.7. Process Measures

This instrument is self-administered and is used to evaluate the psychological and behavioral processes hypothesized to be affected by the LIFE intervention consists of a) Efficacy for Walking; b) Barriers to Active Living; c) Body Satisfaction; and d) Desire for Physical Competence. The Process measures

should be self-administered during the first screening visit (SV1; baseline) and subsequently at 12 and 30 months.

Please note the following regarding the administration of this questionnaire:

- The Efficacy for Walking measure should be completed immediately following the 400 M Walk. At baseline, the Process Measures, including the Efficacy for Walking measure, should not be collected if the participant did not complete the 400M Walk within 15 minutes.
- At the follow up assessment clinic visits, the Process Measures should be collected if the 400 M walk is either completed or attempted but not completed and/or terminated.
- At either the baseline or follow up assessment clinic visits, the Process Measures should not be collected if the 400 M walk is not attempted. This will be missing data.

Before the end of the clinic visit, each of the instruments should be reviewed for completeness. During this review, some caution is warranted to avoid unmasking as participants could inadvertently reveal their group assignment.

The process measures were created based on social cognitive theory and assess participants' perceptions of their capabilities to perform various physical tasks and their satisfaction with and desire for physical functioning. Responses for each scale are averaged and are analyzed individually.

Assessors should note that participants may find some items in this questionnaire battery to be quite strange. Additionally, they possess a high potential for unmasking. Therefore, the following script is read prior to administering the questionnaire battery:

"Some of the items on these questionnaires may sound strange, but please answer as openly and honestly as possible. Also, I would like to remind you again, that for scientific reasons, please don't tell me to which of the two LIFE groups you were assigned."

Self-Efficacy for Walking

This scale assesses participants' confidence in their ability to walk incremental distances one week from now: 5 laps, 10 laps, 15 laps, 20 laps, and 25 laps. These distances were chosen because of their relationship with the assessment of the main study outcome: the 400 meter walk. Therefore, the instructions for this measure were written so as to give participants a frame of reference (in relation to the number of laps walked during the 400 meter walk) so that they may more precisely evaluate their capabilities. In other words, after performing the 400 meter walk, participants are asked to rate their confidence in their ability to walk, "…5 laps."

It is also important that participants evaluate their capabilities in the future, one week from now. In essence, participants are being asked to predict their confidence in what their capabilities would be one week in the future. Participants will most likely be quite fatigued from performing the 400 meter walk. It is important that they understand that they should evaluate their capabilities to walk the specific distances one week from now, not right now (post-400 meter walk).

Most participants will not be familiar with "laps" as a unit of measure. The administrator should expect participants to have some difficulty creating an accurate "perception" of the distance to be rated in each item. Administrators should make every effort to relate the item to the 400 meter walk (e.g., "…half the number of laps you just walked.

Responses are rated on a scale from 0 (no confidence) to 10 (complete confidence). Participants mark the box that corresponds to their responses. They should mark only one box.

Instructions

"You have just completed a walk that was [X]* laps. Please answer the following questions that concern your confidence (or certainty) in being able to walk at a similar pace for different distances *one week from now*."**.** Please mark with an "X" a number between 0 (no confidence) and 10 (complete confidence)

Items:

1. How much confidence do you have in your ability to walk 5 laps, at the same pace, one week from now?
2. How much confidence do you have in your ability to walk the 10 laps (the same distance that you did today), at the same pace, one week from now?
3. How much confidence do you have in your ability to walk 15 laps, at the same pace, one week from now?
4. How much confidence do you have in your ability to walk 20 laps (about ½ mile), at the same pace, one week from now?
5. How much confidence do you have in your ability to walk 25 laps, at the same pace, one week from now?

Self-efficacy for Barriers to Active Living

The purpose of this scale is to assess participants' confidence in their capability to maintain their physical activity program when faced with a number of barriers or challenges. Each item represents a different barrier and the responses range from 0 (no confidence) to 10 (complete confidence). Participants should place a check in the box that corresponds with their level of confidence and should check only 1 box per item.

Instructions

As noted above, these questions may possess high potential for unmasking. Thus, administers should read the below script prior to the instructions for the measure.

"Some of the questions I am going to ask may sound strange, but I would like to remind you again, that for scientific reasons, please don't tell me to which of the two LIFE groups you were assigned."

"If you decided to be physically active on a regular basis, how confident are you that you could maintain your physical activity under the following conditions?"

It should be noted that not all participants are involved in a formal or regular physical activity program. The scale should be completed AS IF THE PARTICIPANT DECIDED TO PARTICIPATE IN A REGULAR PHYSICAL ACTIVITY PROGRAM. Thus, the participant may have to imagine or pretend that they are involved in a program.

Not all items are relevant for all participants. For example, one barrier is "bad weather." A participant may complete all of his/her physical activity indoors and, thus, s/he may feel that weather may not be relevant. If a participant indicates that an item is not relevant, the administrator should encourage the participant to answer as honestly and accurately as possible as it applies to him/her.

Body Satisfaction

The purpose of this scale is to assess participants' satisfaction with their physical functioning OVER THE LAST 4 WEEKS. Each item reflects a different aspect of physical functioning, such as "level of fitness" (item #1); "overall level of energy" (item #5).

Instructions

The following questionnaire asks you to rate how satisfied you are with different aspects of your physical function over the past 4 weeks. Please respond to each question by placing the appropriate number from the following rating scale in front of each item.

"In the past 4 weeks, how satisfied have you been with…"

Response scale:

- Very satisfied
- Somewhat satisfied
- A little satisfied
- Neither satisfied or dissatisfied
- A little dissatisfied
- Somewhat dissatisfied
- Very dissatisfied

It is important to note that this response scale is different than that used in the previous two scales; be sure to make this clear to the participant. It is also important to ensure that participants' evaluate their satisfaction OVER THE LAST 4 WEEKS. Thus, this scale aims to assess satisfaction with physical functioning for a relatively recent time frame.

Desire for Physical Competence

The purpose of this scale is to assess an individual's incentive to be able to perform various physical tasks. Sample items include, "the ability to walk at a quick pace for a mile" (item #4), "the ability to do light work in the home or yard" (item #7).

As it states in the instructions, it is important to note that the scale is not concerned with "objective ability," or whether the participant is actually able to complete the tasks. Rather, the scale aims to assess the participant's level of desire to be able to do each task.

Responses for this scale can range from "no desire whatsoever" to "very strong desire". Participants place an X in the box that corresponds to their response and should mark only one box.

Instructions

"Listed below are statements that describe different physical tasks. Please read each statement carefully and indicate which response best describes your current desire to be able to perform each task. It is very important to remember that we are not interested in whether you can do the tasks or not; rather, we are interested in your level of desire to be able to do each task.

Response scale:

- No desire whatsoever
- Low desire
- Moderate desire
- Strong desire
- Very strong desire

25.5.8. Modified Mini-Mental State Examination (3MSE)

Description

The 3MSE and other cognitive tests are described in MOP Chapter 15 – Cognition.

25.5.9. Medication Inventory

The Medication Inventory should be completed during the first pre-randomization screening visit and subsequently at the 12-month clinic visit.

Many older adults use both prescription and non-prescription pharmaceutical products. The use of these products is of interest for several reasons. Their use is an important indicator of overall health, and the nature of the drugs taken is a strong indicator of clinically manifest disease. The response to the interventions may be enhanced or diminished by some drugs. Finally, individuals who use nutritional supplements, herbs or other complementary products may have stronger sense of health self-efficacy, and thus the use of these products could be related to study adherence.

All participants are asked to bring all prescription and non-prescription medications taken in the past two weeks to their first pre-randomization screening visit in their original containers with medication label. Medications include: pills, tablets, drops, salves, injections, creams/ointments, inhalers, suppositories and dermal patches. Non-prescription medications include: vitamins, aspirin, laxatives, dietary supplements, and herbal preparations.

Ask whether the participant has taken any prescription or non-prescription medications in the past 2 weeks. If not, check NO and move on to the next assessment form.

Otherwise, transcribe the complete name, strength and units, of each product, exactly as it appears on the medication label, to the Medication Inventory. Transcribe the name, strength and units, and code the formulation from what is written on the medication label. If the participant indicates that s/he was instructed by his/her physician to take more or less of the prescribed dosage (as written on the medication label), record the strength and units that are reported by the participant. For tablets and capsules, which are the most common formulations, units are usually provided in mg (milligrams).

Write the name of each medication on a separate line. Do not record medications that have not been taken during the past two weeks. Record the names of all medications.
After the prescription medications have been transcribed, continue to the non-prescription (i.e. over-the-counter) medications and supplements. Record the manufacturer's name of all vitamins and herbal preparations. The strength of herbal preparations and multi-vitamins should coded as Permanently Missing (PM)

If the participant did not bring in their medications, ask to see their medication list. If a list is not available, ask the participant to recall all the prescription and nonprescription medications that they have taken during the past two weeks.

25.5.10. Medical and Hospital Admission History

Medical and hospital admission history should be obtained during the Screening Visit 1. This information will allow us to accurately describe the health history of our study population and to determine whether persons with specific health problems or conditions are more or less likely to benefit from the study interventions.

Overnight hospitalizations include acute care admissions for medical, surgical or psychiatric problems and/or procedures. Staying in an emergency room overnight is not considered a hospital admission. An admission to a rehabilitation facility is not considered a hospital admission.

For the chronic conditions, a Yes or No response is preferable. The Suspect or Possible response category should be used only if the doctor had told the participant that he/she might have the condition. If the participant is unsure, Don't Know should be marked.

Q15 under Chronic Conditions refers to non-hip fractures.

Q21 under Chronic Conditions includes amputation of a leg above or below the knee, but does not include amputation of toes or foot.

Responses that should trigger physician review are indicated with asterisks.

25.5.11 Cancer Follow- Up Form

The Cancer Follow- Up Form should only be administered if the participant answered YES to Q10 on the Medical and Hospital Admission Form at SV1.

25.5.12. Quality of Well-Being Scale – Self-Administered (QWB-SA)

Instructions for Reviewing the QWB-SA for completeness and accuracy.
Patients will self-administer the questionnaire. To be completed at home before Screening Visit 2 and before each subsequent follow-up assessment visit.

General Instructions

1. Make sure the participant ID label matches the ID assigned to the participant who completed the form.

2. Verify the "date completed" with the participant, and make sure it is a feasible date (in the previous 2 weeks). The participant should have received the form at either a screening visit or in the mail 2 weeks prior to their assessment visit.

3. For Part I, Sections A and B, review each page to make sure that a Yes or No box is clearly checked for each question. If neither of the boxes or both boxes are checked, please ask the participant to answer the question at that time. These are chronic symptoms and should not change since the "date completed".

4. For Part I, Section C, Part II and Part III, review each page to make sure that each question was answered with "No Days" or any combination of "Yesterday", "2 days ago", or "3 days ago". However, if "No Days" is checked, no other boxes should be checked for that individual question.

5. For Part IV and Part V, the same rules apply as above for the response choices "No Days", "Yesterday", "2 days ago", or "3 days ago". **However, Part IV, Question 9 should be blank, unless the participant reported that they spent all or most of the day in a wheelchair in the previous question (Part IV, #8). If #8 is "No Days" then #9 should be blank.**

6. For Part V, Question 3, make sure a description of the problem is provided if "Yesterday", "2 days ago", or "3 days ago" are endorsed.

7. Provide initials and date to show that form was reviewed.

25.5.13. Health Care Utilization Questionnaire

This questionnaire is self-administered by the participant and is completed at home before Screening Visit 2 and before each subsequent follow-up assessments.

Instructions

1. The forms are printed in both English and Spanish versions. Use the appropriate form for the participant.

2. Place the participant ID label on the front page of the questionnaire.

3. **Note: Participants will complete the QWB-SA at the same time as the Health Care Utilization Questionnaire. Always send them out and collect them together.**

4. Give participants both questionnaires along with the cover letter at the end of Screening Visit 1. They will bring the forms back at Screening Visit 2 or at an ancillary study. ****Participants should avoid completing the questionnaires in the 2 or 3 days following an ancillary study.**

5. Two weeks prior to each follow-up assessment, **mail** both forms with a cover letter to each participant.

6. Leave the date blank. This is completed when participant brings form to their next visit.
7. Research staff should be assigned to collect and briefly review the forms at the beginning of Screening Visit 2 and at each follow-up assessment. Review the forms for completeness. Clarify all missing and unclear responses. Forward the form to Data Entry.

8. Data Entry: Key-enter the form.

File the form in the participant's file.

25.5.14. Community Healthy Activities Model Program for Seniors

Volume of moderate physical activity will be measured as min/week and assessed using the Community Healthy Activities Model Program for Seniors (CHAMPS) physical activity questionnaire (PAQ). The reference for this instrument is:

> Stewart et. al. "CHAMPS Physical Activity Questionnaire for Older Adults: outcomes for interventions." *Med. Sci. Sports Exerc.*, Vol. 33, Nol. 7, 2001, pp. 1126-1141.

This document describes the operational protocol for administering the CHAMPS PAQ in The LIFE Study. The rationale underlying a formalized protocol for administering the CHAMPS PAQ is based on the fact that, in the present study, the CHAMPS is administered by interview rather than being self-report. This protocol contains guidelines and specific instructions that are intended to reduce measurement variability due to the manner in which the instrument is administered.

Data Collection Intervals

The CHAMPS PAQ is administered during either recruitment events or the first clinic visit (SV1) and at 6, 12, 24, and 36 month follow-up visit, and at the close-out visit, if applicable. All participants should complete the instrument during these time points.

Personnel responsible for administering the CHAMPS PAQ

The CHAMPS is used to screen participants to insure that they meet the inclusion criteria for level of physical activity and to measure volume of physical activity at baseline and follow-up assessments. The instrument may only be administered by research associates who have received training on this protocol, and are certified/approved to administer the instrument (see Chapter 24-Quality Control for certification requirements/form). Administration of the baseline CHAMPS by personnel who have not received training on this administration

protocol will invalidate the data collection and result in the data collected in such a manner as being coded as “Missing” in the study data base.

However, at follow-up, the CHAMPS can be administered by either certified masked or unmasked staff (e.g. randomizer) as long as they are not interventionists. The CHAMPS questionnaire should not be administered by the masked staff person who is completing the rest of the follow up assessment visit. In addition, the staff person administering the CHAMPS questionnaire at the follow-up assessment visit should not complete the rest of the assessment at any of the subsequent follow up clinic visits.

At the time of data collection, the research associate who administers the CHAMPS PAQ will record his/her staff ID on the data collection form. Masked assessors who did not administer the CHAMPS should not data enter the results. One possibility would be to have the staff person who administered the CHAMPS also enter the data. Another option would be to have a dedicated data entry person enter the CHAMPS and other assessment data.

Administration site

The CHAMPS PAQ should be administered in an environment that is appropriate for conducting a confidential, person-to-person interview. Extraneous factors that could potentially influence a participant’s reporting of physical activity should be minimized; these factors include disruptive noise, uncomfortable ambient environmental conditions, etc. It is recommended, although not required, that the CHAMPS PAQ be administered to all participants, at all data collection time points, in the same location to minimize any potential effect differences in the site of the interview might have on reported physical activity. If possible, the CHAMPS PAQ should be administered in a small, private room or office that is reserved exclusively, at the time of the interview, for administering the instrument.

The instrument may be administered via telephone or at a participant’s residence if the participant is unwilling or unable to visit the study clinic for data collection.

Operational guidelines

Introduction

In administering the CHAMPS questionnaire, a major effort should be made by the person conducting the interview not to be judgmental of patients’ responses. There are no right or wrong answers to questions being asked. 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 not to let the participant side track you. It may be difficult for some study participants to recall their activity over the past month. 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 realize that most of the participants you see will spend a vast majority of their waking hours in doing light activity. Many tiring and unpleasant household or occupational tasks do not have a very high energy cost. Also, for activities that are moderate or strenuous (MET values of ≥3), it is very important to accurately determine the actual time spent doing the activity. For example, many older adults will go walking for exercise but stop to talk to a neighbor or to let their dog check out some nearby post! People play golf for 5 hours may be walking as little as 1 hour! Thus, when participants say that they do a moderate or strenuous activity for a specified period of time each week, it is very important to probe and to be certain that then are active for the entire time.

Overview of the Interview

1. The interviewer should precede data collection with a brief explanation of the instrument and its rationale. For follow-up visits only, the interviewers should inform participants that it is important to report all physical activity when responding to CHAMPS questions; that is, activity performed in conjunction with the LIFE Study or any activity that they may be doing on their own, independent of the LIFE Study. Interviewers should indicate to participants that the amount of physical activity they may be doing will not unblind them as long as they do not tell them where the activity is being performed:

   I will ask you about various activities that you may have done in the past four weeks; for those activities that you have done, I will also ask you how many times you have done the activity and how many total hours you spent doing the activity. I also may ask you some questions about the activities you report doing to get a better understanding of those activities and to make sure we gather the most accurate information. There are no "right" or "wrong" responses, so please answer each questions as honestly and accurately as you can. When conducting follow-up visits also say the following: Although for scientific reasons, I ask that you not tell me to which of the two LIFE groups you were assigned, when responding to questions in this interview, please report all of your activity, whether the activity is or is not part of the LIFE intervention. As long as you do not tell me what group you are in, this information will not un-blind me. Do you have any questions?"

2. Not all items on the CHAMPS PAQ are included in the scoring algorithm for the moderate+ physical activity scale of the CHAMPS which is the focus for The LIFE Study; participant responses to the items not included (items 1-7, 10-13, 17-18, 20, 22, 27, 28, 34, 35, 39, 41) should be recorded on the interview form but do not require probing, clarification or verification as the other items might. Items that ARE included in the instrument scoring algorithms, and which require clarification or verification on "Yes" responses, are ***bolded,*** on the data collection form and have MET values associated with them.
3. For the initial question and each bolded item on the questionnaire, the interviewer will ask:
   "In a typical or "normal" week during the past four weeks, did you [INSERT ACTIVITY]."
4. If a participant has responded YES to an activity, then special care should be taken to ensure that a participant's reported activity corresponds to the CHAMPS definition of the activity. For example, participants who report performing "Heavy gardening" should have done heavy manual gardening tasks such as spading or raking. Using a tractor to till a small garden plot or spot-weeding a flower bed would not be interpreted as a "heavy gardening" task. Essential to this determination is an interpretation of the participant's activity intensity level; participants who report activities requiring MET levels ≥ 3 METS (items 8, 9, 14-16, 19, 21, 23-26, 29-33, 36-38, 40) should be asked to clarify the intensity level at which they perform the activity to determine if the activity conforms with the CHAMPS definition. The reason for this step is that positive responses to these questions influence a participant's final score.
5. It is extremely important not to count activities twice. One particular item that creates problems is item 25. Participants will give an estimate of how much time they walk up hills and then count this time again when asked how much time they spent in brisk walking. This item is meant to capture the activity of participants who hike uphill or walk up hills for extended periods of time. In general, this is a rare activity for most older adults.
6. If a participant's reported activity is not consistent with the CHAMPS definition for the activity, the interviewer will mark the appropriate response box on the interview form and move to the next item. The performance of any physical activity must last 10 consecutive minutes or longer to be counted as a bout of activity. If a participant's reported activity (moderate or vigorous) does conform with the CHAMPS definition for the activity, the interviewer will mark the appropriate response box on the interview form and ask:
   "How many times a week?"
7. For any bolded items (moderate or vigorous physical activity) that a participant responds "3", or more, times a week, the interviewer will follow-up with probes or clarifying questions to verify the accuracy of

the reported frequency. Special care should be taken to ensure that a participant does not report intermittent bouts of activity occurring during an "activity session" as several discrete activities. For example, if a participant walks his/her dog every week for twenty minutes, but stops to talk with neighbors every five minutes, the participant should report a frequency of "1" rather than "3" or "4". Note that the interview needs to be able to discriminate between continuous versus multiple bouts of activity. **An activity is only counted as a discrete bout if it is performed ≥ 1 hour following a previous bout of activity.**

8. The interviewer will then ask:
   "How many total hours a week did you usually do "it" [or "this activity"]? It is very important to follow-up with probes or clarifying questions to verify the accuracy of the time spent in different activities. For example:
   Question 8: When people dance they often take breaks. Of the total time that you reported, how much of the time were you actually active?
   Question 9: Although people play golf for 5 hours, roughly half of the time is spent on the greens, some time is spent waiting for others to hit, and then there is time on the tee box. With this in mind, how much time would you estimate that you actually were walking between tees or from tee to green?
   Question 19: When doing heavy work, it is common to stop and rest. If you think about the time that you have given me, what amount of it was actually spent digging or …?
   Question 25: This question is reserved for people who consistently walk or hike up hills. If you walk up and down small rolling hills as part of your walking time, this will be counted later in the interview under walking (items 26-28).

   Once you have checked the box for the number of hours the person did the activity, ask them to be more specific in minutes. For example, if they said they did an activity between 1 and 2.5 hours say "can you be more specific in minutes"? That is, was it closer to 60 min (I hr), 90 min (1.5 hrs), 120 min (2 hours), or 2.5 hrs?

9. At the conclusion of the interview, the interviewer shall review the data collection form for completeness and accuracy. Any notes regarding problems with or questions about, the administration of the instrument should be recorded on the form. In addition, the interviewer, before leaving the clinic for the day, should identify to the Project Manager and Principal Investigator any issues that may require review and/or adjudication. This notification should be made via email.

Scoring the CHAMPS PAQ

1. Scoring the CHAMPS for Screening

Participants are excluded from LIFE if they report greater than 125 minutes of physical activity per week at screening. Administrators must calculate the minutes of activity following the interview to determine eligibility. Eighteen items are used in the scoring for the CHAMPS for screening (8, 9, 14-16, 23-26, 29-33, 36-38, 40). The frequency of responses to categories 1 and 2 is summed and multiplied by the corresponding value (Category 1 = 30; Category 2 = 105). These values are then summed and produces a total score (minutes of physical activity). If the total score is greater than 125, the participant is not eligible for the study. Detailed instructions on the calculation of the total score for screening purposes are provided on the CHAMPS Screening Form. As noted on the CHAMPS Screening Form, a person is ineligible if he/she reports being active for 3 or more hours on any bolded box. This scoring procedure is only required during the administration of the CHAMPS during screening. Although scoring is done manually, CHAMPS data must be entered into the data management system.

Adjudication of Issues or Problems With CHAMPS PAQ Administration

When issues or problems with the CHAMPS administration are identified by an interviewer, the Principal Investigator will confer with co-investigators (principally the behavioral scientist on the study).

25.5.15 Assistive Device Questionnaire

The Assistive Device Questionnaire asks whether the participant usually requires a cane or walker when walking inside and outside the home, respectively. Responses to these questions may ultimately be used in the adjudication process for the major mobility disability outcome, when data on the 400 m walk are not available. If the participant is not available, the questionnaire should be administered as part of the Proxy ADL Questionnaire.

25.5.16. Health Related Quality of Life (HRQL)

The below key components of health related quality of life are assessed at baseline and after 12 month and 24 month follow-up clinic visit. The measures are self-administered (see 25.2 for details on Self-Administered Questionnaires). The administrator stresses that there are no right or wrong answers and that the participant should simply answer as openly and honestly as possible. The administrator is available to answer questions, but allows the participant to complete the questionnaires independently. The administrator reviews the questionnaires for completeness and requests the participant to complete any missed items.

1. Depressive symptomatology is assessed with the Center for Epidemiologic Studies-Depression Scale (CES-D). The CES-D is an 11-item scale with three answer categories and queries about depressive symptoms

experienced in the previous week. The response scale consists of "Rarely or Never" (0 points); "Some of the time" (1 point); and "Much or most of the time" (2 points). Three of the questions ask about the occurrence of symptoms and feelings associated with depressed affect (items 4, 6, & 9). Four items reflect somatic complaints (items 1-3 & 11). Two items reflect interpersonal problems (items 7 & 10). Two items reflect the frequency of positive feelings (items 5 & 8). For these questions participants get 2 points if they rarely or never experience the symptom and 0 points if the experience the feeling most or all of the time. Scores for this measure are transformed to coincide with the original 20-item version. Thus, the maximum score on the scale is 60. Scores of 24 and higher are used as a clinical alert.

2. Energy and fatigue level is assessed by the 6 fatigue and energy items from the Modified Exercise-induced Feeling Inventory. Each item is rated on a 6-point, which focuses on the amount of time that individuals experienced fatigue or energy related feelings during the past week.

3. **Stress** will be assessed by the Perceived Stress Scale (PSS). This psychological measure contains 10 items designed to measure the degree to which situations in one's life are appraised as stressful during the last month (e.g., feeling nervous or stressed, dealt successfully with irritating life hassles, able to control irritations in your life). Item response options range along a five-point continuum of Never (0), Almost Never (1), Sometimes (2), Fairly Often (3), Very Often (4). A total PSS score is obtained by summing item responses, and a higher score indicates greater perceived stress. This scale has been found to be valid in older adults, related to cognitive function, and responsive to physical activity interventions.

4. Please note: it is common for participants to view the above questionnaires as unusual or weird and may ask for clarification. The administrator may offer clarification by restating the item. Additionally, for items that require the participant to make a judgment about a vague item, the administrator instructs to the participant to respond according to his or her own perspective. For example, the administrator may ask, "What does it mean to you?" And, "You may respond according to your understanding of the item."

25.5.17. Pulmonary Questionnaires

25.5.17.1. Modified ATS-DLD-78-A questionnaire

The modified ATS-DLD-78-A questionnaire evaluates respiratory symptoms, respiratory history, and the use of oxygen and inhaled medications. There are 11 questions, each having several subsections. The questions are designed to collect information on respiratory symptoms, respiratory history, and use of oxygen and inhalers (i.e., "puffers"), including inhaled corticosteroids. All of the

11 questions are administered at SV2, while only 4 questions are administered at the 6, 18, and 30-month follow-up visits.

Instructions
This is an interviewer-administered form. For most questions, possible responses are “Yes”, “No”, and/or filling in a bubble or a blank with a number or word. Please have the participants choose the appropriate responses for each question. If the participant asks about the meaning of any question, re-read the statement (or question) to them. Ask them to choose what seems to be the best option. The questions are otherwise self-explanatory.

The question on “breathlessness” of the modified ATS-DLD-78-A questionnaire does require, however, additional instructions. This question evaluates participant-perceived shortness of breath (i.e., dyspnea), according to a daily life answer to everyday experiences. There are six subsections, which are collectively referred to as the ATS Adult Dyspnea Questionnaire. The first subsection establishes whether the participant is disabled from walking by any condition other than heart or lung disease. If the participant’s response is “Yes”, the remaining 5 subsections are not administered. If the response is “No”, the remaining 5 subsections are then administered, with possible responses being “Yes” or “No”.

25.5.17.2. BORG Index. This dyspnea questionnaire is administered to participants immediately after the 400 meter walk at screening and at each of the follow-up clinic visits.

Instructions
Prior to administering the BORG Index, the participant is first instructed not to reveal the group to which they have been assigned since this information could influence the results of this evaluation.

Next, the participant is shown the BORG scale (show card) and is instructed as follows:

> **“**This is a scale that asks you to rate the difficulty of your breathing. It starts at number 0, where your breathing is causing you no difficulty at all, and progresses through to number 10, where your breathing difficulty is maximal. How much difficulty is your breathing causing you right now?”

At times, it may be necessary to instruct the participant to specifically choose a number between 0 and 10, rather than a verbal descriptor.

25.5.18. Spirometry Data Collection Form
This is a seven-item questionnaire, which is administered concurrent with spirometric and maximal inspiratory pressure (MIP) testing, at SV2 and at the 6, 18, and 30-month follow-up visits.

The first three questions (i.e., questions 1 through 3) are administered just prior to spirometric and MIP testing, in order to determine whether the participant can safely complete these tests. The instructions are self-explanatory.

The next three questions (i.e., questions 4 through 6), also administered prior to spirometric and MIP testing, evaluate the factors that may have a short-term influence on spirometric and MIP performance. These questions only inform subsequent interpretation of spirometry and MIP results. These three questions do not serve as a basis for exclusions. The instructions for these questions are self-explanatory.

The last question of the spirometry data collection form (i.e., question 7) documents the completion of the spirometric and MIP testing, as well as recording the best results for spirometry and MIP. Specific alert values for spirometry are included; none are required for the MIP. If the spirometric or MIP testing is not completed, the reason(s) why must be specified in the space provided. The instructions for this question are self-explanatory.

25.5.19. Sleep Questionnaires

Four sleep questionnaires will be used to evaluate insomnia symptoms (Insomnia Severity Index), daytime drowsiness (Epworth Sleepiness Scale), sleep quality (Pittsburgh Sleep Quality Index), and the risk for sleep apnea (Berlin Questionnaire). We will also record the use of caffeine and energy drinks. These questionnaires will be administered at SV2 and at the 6-, 18-, and 30-month follow-up clinic visits.

25.5.19.1. Insomnia Severity Index (ISI)

The ISI is a 7-item questionnaire scored on a 0-4 scale. It is important to note that the verbal descriptor for the 0-4 scale will differ depending on which question is being asked; the verbal descriptors are self-explanatory. The ISI evaluates various aspects of participant-perceived sleep quality on an average night, as experienced over the past 2 weeks.

25.5.19.2. Epworth Sleepiness Scale (ESS)

The ESS is a validated 8-item questionnaire scored on a 0-3 scale. The scale has corresponding verbal descriptors that remain the same for each of the 8 questions; the verbal descriptors are self-explanatory. The ESS evaluates the likelihood of the participant dozing off or falling asleep, as experienced during activities of everyday life and in “recent times”. If the participant requests clarification of “recent times”, please state the range as over the past 2 to 4 weeks.

Because some of the activities that are referred to in the ESS may no longer be performed (i.e., driving), a participant may need to be instructed “to evaluate how these activities would have been affected”, e.g. the likelihood of dozing off or falling asleep if they were still driving.

25.5.19.3. Pittsburgh Sleep Quality Index (PSQI)

The PSQI is an 18-item questionnaire that evaluates sleep quality and disturbances, as experienced over the prior 1-month. The first four items describe the participant's usual bedtime and arise time, including how long it takes to fall asleep and the quantity of the overnight sleep time. The responses to the remaining 14 items are scored on a 0-3 scale. It is important to note that the verbal descriptor for the 0-3 scale will differ depending on which question is asked; the verbal descriptors are self-explanatory.

25.5.20. Berlin Questionnaire (BQ)

The BQ is a 10-item questionnaire that evaluates the clinical risk for obstructive sleep apnea (OSA), an important cause of sleep-wake disturbances. The questions are self-explanatory, and include responses that are either yes/no or based on the frequency of occurrence (i.e., snoring). Question 10 regarding high blood pressure refers to a self-reported diagnosis of hypertension, either currently or previously, and includes hypertension that has subsequently resolved on medical therapy.

The BQ is administered to all participants, except those who report "treated" sleep apnea, defined as a prior diagnosis of sleep apnea, for which the participant is currently prescribed a device that delivers positive airway pressure via a nasal mask or face mask (CPAP, AutoPAP, BiPAP, or ASV). Participants who have untreated sleep apnea should be administered the Berlin Questionnaire.

If the BQ is not administered because the participant reports "treated" sleep apnea, please indicate this reason on the visit checklist, in the column "No, Other reason".

25.5.21. Napping, Caffeine, and Energy Drink Inventory

Based on a single question, participants are asked the number of cups or cans of caffeinated beverages, including soda, energy drinks, coffee, tea, iced coffee, or iced tea, that they typically drink each day. Response categories included none, less than one, one, two, or three or more cups/cans.

25.5.22. Social Cohesion and Trust Scale and Environmental Walkability Scale (NEWS-A)

To evaluate the potential impacts of perceptions of neighborhood cohesion and trust on participants' attempts to become more physically active, the 6-item social cohesion and trust scale will be collected on all participants enrolled in the study.[162] The scale, collected along with the abbreviated version of the Neighborhood Environmental Walkability Scale (NEWS-A),[163] will be given to all participants at randomization to complete at home and return at the first introductory intervention session. Each field center will send the completed forms

to the DMAQC for computer data entry. The social cohesion and trust scale and the NEWS-A perceived environment scale will be evaluated as potential moderators of physical activity intervention effects.

Instructions

1. Successful administration of the NEWS-A Environment Scale is the responsibility of the LIFE Project Coordinator at each LIFE site.
2. The Project Coordinator should ensure that copies of the NEWS-A Environment Scale are included in the packet of instructions and forms that are given to each participant at the end of the Randomization session.
3. Staff should instruct each participant that the Environment Scale should be completed at home and brought back with them to their introductory One-on-One Intervention Session.
4. Additional blank Environment Scale forms should be made readily available to Intervention staff conducting the One-on-One introductory intervention sessions, in case a participant forgets to bring back his/her completed form.
5. The Intervention staff member should collect the completed Scale at the beginning of the One-on-One session, and, if the scale was not brought in, should request that the Environment Scale be completed at the beginning of this session. The Intervention staff should also check over the returned scales for completeness, and have participants complete any omitted items as necessary at that time.
6. It is recommended that the Intervention staff conducting the one-on-one sessions use information obtained from the scale, as relevant, to identify any potential barriers in areas related to transportation to sessions, as well as (for the physical activity intervention) neighborhood barriers to walking.
7. The Study coordinator at each Site should identify a place to store the completed Environment Scales and instruct the intervention staff on where to put them.
8. Each Study coordinator should verify that each randomized participant returning for the One-on-One intervention session has completed the Scale.
9. The Environment Scales should be mailed on **a monthly basis to the DMAQC for data entry** to the following address:

   To the attention of: D
   LIFE DMAQC Project Manager
   Wake Forest University Health Sciences
   Division of Public Health Sciences
   Department of Biostatistical Sciences
   Medical Center Blvd.
   Winston Salem, NC, 27157

25.5.23. Outcome Events Questionnaire

Sites should refer to MOP Chapter 20 (Outcomes) for instructions on the completion of the Outcome Events Questionnaire and other associated study outcomes forms and procedures.

25.5.24. Cost-Effectiveness Analysis

In order to conduct the cost-effectiveness analysis the following steps are taken.

1. Quality of life assessment.
    a. QWB-SA scores are used at each follow-up.
    b. In the case of death, 0.0 is obtained as the QWB-SA score for each successive follow-up.
    c. Missing data is estimated using the last observation carried forward (LOCF) or the least squares estimation procedure.
    d. Quality adjusted life years are calculated by summing the difference between the QWB-SA scores for participation in the two arms of the study.
2. Cost: Administrative cost for the study is estimated using the method using the ACTIVE trial.
    a. Personal cost is estimated by multiplying the amount of time dedicated to the intervention activities by the prevailing hourly wage rate at the Wake Forest School of Medicine.
    b. Cost is estimated for program components including the computerized tracking system, peripheral materials, printing and postage, facilities costs, and health club membership.
    c. Direct cost to participants will include cost of athletic equipment, costs of treating injuries (based on prevailing charges from medical service at the Wake Forest School of Medicine) and other incidental costs.
    d. Time spent exercising is estimated from questionnaire information.
    e. Value of time spent in the program is calculated on the basis of the average wage of workers 20-64 years of age as reported by the Bureau of Labor Statistics. For participants older than 65 years of age, time spent exercising is valued on the basis of the average wage for workers 65 years or older according to the Bureau of Labor Statistics.
    f. Travel distances are estimated using software that calculates the distance traveled from the zip code of the patient's residence to the facilities. Travel costs are estimated using the Federal Government's Reimbursement Rate per mile.
3. Health Care Utilization is estimated from the UCSD Health Care Utilization Questionnaire.
    a. The value of service is adjusted to 2004 dollars using the Medicare component of the consumer price index.
    b. Costs of medications are estimated on the basis of wholesale price in 2004 discounted by 15% (in order to adjust for typical retail

acquisition costs). A dispensing fee of $2.50 is added for each 30-day period a medication is used.

c. The costs of physician visits, ER visits, and hospital stays are valued at the prevailing charge rates for Wake Forest University.

4. Cost-Effectiveness Analysis
    a. The analysis we'll use an intention to treat principle.
    b. The average cost and the mean number of quality-adjusted life years gained and the associated 95% cost fund intervals are determined for each group.
    c. A ratio of cost/quality-adjusted life years is created.

(See Direct Cost Tracking Form in Appendix B.)

Appendix A

Dear LIFE Participant:

Thank you for participating in the LIFE research study. We sincerely appreciate your involvement in this important program.

In an effort to decrease the amount of time you need to spend at each assessment visit, we would like you to complete the 2 enclosed questionnaires prior to your next assessment visit. Please complete the questionnaires during the week prior to your next assessment visit and the forms are collected from you at that time.

Both questionnaires should take about 15 minutes or so but please take your time and do not hesitate to call us toll-free if you have questions. The toll-free phone number is 1-800-662-2437. A questionnaire specialist can answer your questions between the hours of 10AM – 7PM Eastern Standard Time (7AM – 4PM Pacific). If no one is available at the time you call, please leave a message stating your name, phone number, and the best time to call you and your call will be returned within 1 business day or sooner if possible.

On both questionnaires there are general instructions but it is very important to read each question carefully since the pattern of questions may change suddenly. Some questions may seem to repeat previous material but each one is unique in some way and is necessary.

Some tips are as follows:

Quality of Well-Being Scale

1. Do not fill in any of the blank squares in the box at the top of the page that say “LIFE.”

2. Please complete all questions on this questionnaire in the same day.

Health Care Utilization Questionnaire

1. Do not fill in any of the blank squares in the box at the top of the page that says “LIFE.”

2. Please note that this asks only about the past **6 months**. Please tell us about the health care you received in the 6 months prior to completing the form.

3. You don’t have to be 100% accurate so try to complete the questionnaire from memory. It is not necessary to review all of your medical receipts or records to answer these questions.

4. It is OK to have another person help you to complete the questionnaire if that works better for you.

Thanks again for your participation and we look forward to seeing you at your next visit.

Sincerely,

LIFE study staff

Appendix B

LIFE Direct Costs Tracking Form

Physical Activity Intervention

Site: _____ Date Completed: _____
Completed by: _____

Approximate Dates Covered: _____ to _____

Materials

Please include all materials, gifts, incentives, and refreshments (pamphlets, water bottles, etc.) associated with the physical activity intervention

Item	Number used/obtained	Estimated Value
1)		
2)		
3)		
4)		
5)		
6)		
7)		
8)		

Transportation Costs

Please include all costs associated with transport of participants to **intervention** sessions, including parking fees. Do not include any cost for travel to assessments.

Item	Number used/obtained	Estimated Value
1)		
2)		
3)		
4)		
5)		

Successful Aging Intervention

Site: _____ Date Completed: _____

Completed by: _____

Approximate Dates Covered: _____ to _____

Materials

Please include all materials, gifts, incentives, and refreshments (pamphlets, water bottles, etc.) associated with the physical activity intervention

Item	Number used/obtained	Estimated Value
1)		
2)		
3)		
4)		
5)		
6)		
7)		
8)		

Transportation Costs

Please include all costs associated with transport of participants to **intervention** sessions, including parking fees. Do not include any cost for travel to assessments.

Item	Number used/obtained	Estimated Value
1)		
2)		
3)		
4)		
5)		

LIFE Direct Costs Tracking Form

Marketing & Recruitment Costs: Please include all expenditures associated with marketing/recruitment for The LIFE Study (e.g., newspaper ads, brochures, mailings, informational talks, radio or TV commercials, etc.)

Item	Number used/obtained	Estimated Value
1)		
2)		
3)		
4)		
5)		