CHAPTER 4

GENERAL PROCEDURES

Study Documents/Items Referred to in this Chapter

- Missed Visit Form
- Visit Checklists
- Participant Status Change Form
- Death Report Form
- Unscheduled Visit Form
- Adverse Event
- Event Tracking
- Medical Records Abstraction
- Injurious Fall and/or Fracture Abstraction
- Vascular Outcomes Review
- Site Personnel Log

CHAPTER 4

GENERAL PROCEDURES

4.1. GENERAL GUIDELINES

The following sections provide information on staffing certification, assignment of staff ID's, Field Center ID's and standard procedures that are used for all forms during the data collection visits in the LIFE study.

4.2. CERTIFICATION OF STUDY STAFF

Each field center is responsible for designating staff to carry out data collection. These individuals are centrally trained or trained by someone who was centrally trained. Certification is required for assessors conducting study measurements (e.g., blood pressures, blood draws, interviews and physical performance). The interventionists are also certified. An individual may be certified in multiple study components within their masking designation. Detailed instructions for certification are provided in Chapter 24 - Quality Control.

The same data collection methods should be used at all LIFE sites during the course of the study. All data collectors in LIFE should establish how they collect data and how they respond to questions from participants. Sometimes factors that may seem unimportant, such as the order of forms, the setting, or the mood of the data collector can impact the quality of data. Field Centers should not have uncertified staff members collect data. Should this happen, it is considered a violation of the protocol. Multiple staff should be trained and certified so that back-ups are available. When a new staff member is added, they must be trained by a certified individual at the local clinic site or centrally trained at a LIFE training session.

Certification is tracked in the web-based data entry system. This system includes dates of certification and re-certification, and it includes the ability to

print a report of who is due for an annual recertification. The Program Coordinator at each site is responsible for making sure the certification of staff is current. Quality control checks are performed by the DMAQC center to assure that all study measurements and interventions are being conducted by certified personnel.

4.3. ASSIGNMENT OF CLINIC STAFF CODES

The staff ID will be assigned at the LIFE central training certification session, at the time a request is made to give the staff member access to the LIFE web site, or on email request to the DMAQC. To obtain access to the web site or a staff ID, sites should contact _L.C._.

Staff ID Assignment and Certification Forms are entered in the system. The Staff ID is a three-digit number. The first number is the numeric portion of the Field Center ID code (see Section 4.4.). A list of all active and inactive staff IDs at each Field Center can be viewed by clicking on the “List of Staff” tab on the home page of the website. . Notify _L.C._. at the DMAQC center in the event of staff resignation so that the staff person’s staff ID is closed out of the system.

4.4. ASSIGNMENT OF FIELD CENTER CODES

Each Field Center is assigned a clinic number. This number is used for multiple reports in identifying individual clinics. This Field Center number appears as the first two numbers on the participant’s ID thus tying the participant to a particular clinic. Field centers are also assigned unique series of participant IDs that, when appended to the field center number, constitute the LIFE participant ID. In the case of transfer, a participant always carries their unique ID with them; however, the first two digits of the LIFE participant ID can change to reflect the new Field Center (see Chapter 23 for details on transfers). The Field Center codes are listed below.

FIELD CENTER NAME	FIELD CENTER CODE
COI- Cooper Institute, Dallas, TX	_
STU - Stanford University, Palo Alto, CA	_
UPI - University of Pittsburgh, Pittsburgh, PA	_
WFU- Wake Forest University, Winston Salem, NC	_

4.5. LIFE STUDY FORMS

LIFE study forms are accessible via the study web site. Sites will need to make their own copies of the study forms. There are several advantages to this plan:

- The correct version of each form is immediately accessible
- Reduces the need for storage of large boxes of forms at each site
- Reduces expensive shipping costs to the study

We recognize that this procedure increases the burden of form preparation in the clinical centers; however, we hope that these many advantages outweigh this burden. Sites are encouraged to test their abilities to download and print forms well in advance of the first participant contact.

The forms are designed using the following format:

Type setting - Arial Font, 11 Size

Questions – Arial Font, 11, Size

Interviewer Script – Arial Font, Bold Font Style, 11 Size

Interviewer Note – Arial Font, Italics Font Style, 11 Size

4.5.1. Downloading Forms from the LIFE Web Site

Over the course of the study, changes are made to the study forms. A date of

issue and version number appears as the footer on all study forms. Forms can be located on the study web site and printed locally for reproduction. Instructions for locating study forms on the LIFE web site are as follows:

1. Locate the area of Forms on the Site Map
2. The Forms area provides a listing of all study forms and indicates their current valid version
3. Click on the selected (highlighted) form to open
4. Select print.

Sets of forms can also be downloaded as a group. For example, all of the 6 month follow-up forms will be grouped together and can be downloaded as a set.

We view this plan as a way to use technology to improve the long-term operation of the LIFE study. We work carefully with each site to ensure a smooth implementation of this plan.

4.5.2 Completion of LIFE Study Form Header

All LIFE forms have a standard header that may include some or all of the following fields: Participant ID, Acrostic, Date of Visit; Visit Code, or Interviewer/Examiner code. A description of these items is provided below.

The Participant Identification (ID) Number

All Field Centers will use sequential 6 digit ID numbers. The ID number consists of the following sequence:

___ ___ - ___ ___ ___ ___

Field Center Code Participant ID

The first two digits are the Field Center code where the individual was first screened. The Field Center code is followed by a dash, and the four-digit participant number. For example, P3-0008 would represent a person screened

in clinic P3 (Pittsburgh)

This six-digit ID is assigned to each person who completes a pre-screen interview. The ID number is unique for that individual, that is, it is never assigned again. As the participant continues through the study, he or she keeps the same assigned ID number.

Participant ID Label

At the top left-hand corner of each form is a narrow box in which to place the label of the participant ID. Field Centers must provide their own labels but software for printing the labels will be provided. A discussion of printing labels is covered in Chapter 23.

Each page of the form should have a label with the participant ID number. This ensures that any pages that become separated are easily identifiable to clinic and data entry staff.

Assignment of Participant Acrostic

Participants are also identified by a code called an acrostic. The acrostic is comprised of the first three letters of the participant's last name and the first two letters of his/her first name. For example, the acrostic for Mary Jane Doe would be DOEMA. If the participant's first or last name is comprised of fewer than three letters, the letter Z is used to fill in each blank space. For example, Ray Ke would have an acrostic of KEZRA. Even if a participant changes their name during the course of the study, his/her acrostic remains the same. If an error is made in assigning the acrostic at the beginning of the trial and discovered later, the acrostic can NOT be corrected.

Date Form Completed

Clearly enter the date the form was completed. This is the date the participant came in for his/her visit.

Visit Code

The visit code is a three-digit code which represents the month of the visit. For example, the Month 9 follow-up visit would be entered as F09. Please refer to the following codes when filling in this number.

Screening Visit 1	SV1
Screening Visit 2	SV2
Follow-up Visits (F)	F03, F06, F09, F12, F15, F18, F21, F24
End-point Visit	E18, E21, E24

The Telephone Screening Interview form is precoded with the visit code TSI.

The forms used for the pre-intervention visits and the successful aging and physical activity intervention visits should be coded consecutively as follows:

Pre-intervention visits	PIV01, PIV02, etc
Successful Aging and Physical Activity Intervention	IV01, IV02, etc.

The forms listed below may be used at other times other than a regularly scheduled visit. The visit code used in these situations is PRN.

Participant Status Change

Death Report

Unscheduled Visit

Adverse Event

Event Tracking

Event Evaluation

Medical Record Abstraction

Injurious Fall and/or Fracture Abstraction

Vascular Outcomes Review

Interviewer/Examiner

The LIFE staff person who completes the form should record his/her LIFE ID in the space provided on the top of each form. This indicates that the form was reviewed, that all data have been completed, that permanently missing data have been clearly marked, and the form is ready for data entry.

Data Entry

All study forms including those forms of ineligible participants at pre-screen should be entered into the LIFE data base on a regular (preferably daily) basis. The DMAQC center monitors data entry activity and provides reports to the study committees.

4.5.3. General Rules for the Completion of Forms

1. Print in CAPITAL LETTERS. Much information is garbled simply by sloppy handwriting. This can result in inaccurate data, large numbers of queries, and time lost due to confusion during data entry.
2. Print clearly and use a black pen only. Do not use a pencil.
3. Clearly enter all dates numerically for month, day, and year using leading zeros as necessary. For example: July 5, 2004 would appear as 07 05 2004.
4. Record all numerical values carefully in the boxes provided, using leading zeros as necessary. In those rare cases where a value is not available, draw a line through the space(s) to indicate that the item is missing intentionally, and write PM (Permanently Missing) beside the response and initial and date next to “PM.” A designation for permanently missing data is also entered into the data system as described in Chapter 23-Data Management.
5. All corrections should be made by marking through the error and writing

the correct information above it. The staff member making the correction should sign her or his initials next to the corrected entry and date it. Do not attempt to erase or write over any entry. Do not use correction fluid.

6. Certain fields require dates. Participants may not always know the exact date of a procedure or event. When the year is known, but not the month or day, label these fields as missing using the procedures from #4 above.

7. In some cases, response options of "Other" will require free text entry. There is no limit to the number of characters allowed in the data entry system; however, participant responses should be recorded to enter the most pertinent information.

8. **Do not** use abbreviations. They are not standardized and are likely to cause data entry errors.

These same rules should be adhered to by participants who are completing questionnaires.

Once a participant has completed the self-administered forms, a staff member should check all forms immediately to ensure that they are complete and legible throughout.

For forms and questionnaires completed by staff, another staff member should review the forms immediately following the clinic visit. The staff member that completed the form should clarify illegible sections

4.5.4. Missed Visit Forms

If no data on a participant can be collected for an intended visit within the visit window, a missed visit form should be filled out. Complete the form indicating which visit was missed and why the visit was missed.

Missed visit forms should be completed for missed intervention visits as well as missed clinic visits. Complete a missed visit form for an intervention visit that is missed and not made up.

4.6 Related Protocol and Procedural Processes

4.6.1 Screening Log

Each Field Center should keep a Screening Log of all persons screened over the phone or seen in the clinic as per their site Standard Operating Procedures. The Screening Log is for clinic use and organization only, and is not entered into the LIFE database. To insure confidentiality, LIFE staff must keep the log locked in a secure place.

4.6.2. Study Charts

Study charts must be stored in a secure location, accessible only to study staff. During non-clinic hours, the files should be locked. These requirements are necessary to protect the confidentiality of the participant data.

All LIFE clinic visit material should be accurate, detailed, signed, and dated. Each Field Center should follow their own institution's guidelines for charting requirements. The clinic chart should be labeled with the Participant ID and acrostic. Each study form and other clinic material should include the participant ID and acrostic. Any documents that contain the participant's identification must be placed in a separate participant file and placed in a secure location.

Examples of materials that may be included in the study participant charts, but are not limited to the following:

1. Participant identification and demographics such as: name, address, phone, date of birth, age, race and gender.
2. Information on the contact information sheet.
3. Social Security number or Medicare number.
4. All informed consents, which should be signed and dated. Some IRB's may require the time that the informed consent was signed. If the individual is participating in multiple substudies or ancillary studies, there may be multiple informed consents. If the participant refuses certain parts of the study, this should be noted.

5. Print outs of LIFE ECG tracing, blood pressure, and other reports.

6. Eligibility worksheet with inclusion/exclusion criteria, or clinic flow chart or clinic checklist of completed procedures.

7. Information on serious adverse events and study outcomes should include details of the event, the date(s) of the event, and copies of materials collected for event verification such as hospital records, labs and discharge summaries for all hospitalizations.

9. Clinic visit information on general medical history, physical exam form, review of systems, current medications, behaviors, dates of visits, randomization and group assignments. Any documentation of noncompliance, missed visits, telephone calls to or from the participant etc. Clinic notes include notes written by the physician, nurse, or other clinic staff. A visit checklist is provided with the participant forms for each visit to serve as an inventory of the items required in the participant chart.

4.6.3. Visit Checklists

For each participant at each scheduled visit a visit checklist should be completed.

The visit checklist provides an inventory of all measurements and forms that are to be completed at that visit.

There are visit checklists for:

- Screening Visit 1
- Screening Visit 2
- 3 month Telephone Follow-up
- 6 month Visit
- 9 month Telephone Follow-up
- 12 month Visit
- 15 month Telephone Follow-up
- 18 month Follow-up/Close-Out
- End-point Follow-up

Each checklist should be filled out during the course of the visit to document the assessments that have been completed. As visit components are completed the assessor marks the appropriate box with an "X". If components aren't completed because of participant refusal, then the "No, participant refused/ineligible" box is marked. If the element is missed for any other reason, the "No, Other Reason" box is marked and the reason is noted on the form.

Reasons for marking the "No", "Other Reason" could be:

- Only a proxy is available so only the disability and health events questionnaires could be completed
- The visit was done off-site, so only certain components could be completed.

4.6.4 Site Personnel Log

The Site Personnel Log is used for tracking study staff and their roles and certifications. The Program Coordinator at each site is responsible for regularly updating this document. The form does not require data entry and should be filed in the Staff Certification Log, which is kept on site. The form is posted on the Forms page of the study website.

4.7. Resolution of Protocol/Procedural Questions that Arise During the Course of the LIFE Study

Since protocol questions are certain to arise during the course of the study, it is important that these questions be resolved in a manner that allows a single authoritative answer to be disseminated across the entire study in a systematic fashion.

When questions regarding the protocol, the administration of tests or interview instruments arise, the following system should be followed:

1. A query detailing the problem should be e-mailed to _T.H._
2. _T.H._ will identify which LIFE Study investigator(s) is (are) qualified to respond most authoritatively and forward the query.

3. The LIFE expert(s) will reply back to _T.H._

4. A numbered LIFE Study Memo will be issued to all relevant study personnel.

5. If the MOP needs to be changed, an amended MOP chapter will be posted on the web.

6. Protocol changes will be discussed by the study Steering Committee.