

## **CHAPTER 4**

### **GENERAL PROCEDURES**

<b>4.1.</b>	<b>General Guidelines.....</b>	<b>4-2</b>
<b>4.2.</b>	<b>Certification of Study Staff .....</b>	<b>4-2</b>
<b>4.3.</b>	<b>Assignment of Clinic Staff IDs .....</b>	<b>4-3</b>
<b>4.4.</b>	<b>Assignment of Field Center IDs .....</b>	<b>4-3</b>
<b>4.5.</b>	<b>LIFE Study Forms.....</b>	<b>4-4</b>
	<b>4.5.1. Downloading Forms from the LIFE Web Site .....</b>	<b>4-4</b>
	<b>4.5.2. Completion of LIFE Study Form Header.....</b>	<b>4-5</b>
	<b>4.5.3. General Rules for the Completion of Forms .....</b>	<b>4-7</b>
	<b>4.5.4. Missed Visit Forms.....</b>	<b>4-8</b>
<b>4.6.</b>	<b>Related Protocol and Procedural Processes .....</b>	<b>4-8</b>
	<b>4.6.1. Screening Log.....</b>	<b>4-8</b>
	<b>4.6.2. Study Charts .....</b>	<b>4-8</b>
	<b>4.6.3. Visit Checklists .....</b>	<b>4-9</b>
	<b>4.6.4 Site Personnel Log .....</b>	<b>4-10</b>
<b>4.7.</b>	<b>Resolution of Protocol/Procedural Questions.....</b>	<b>4-10</b>

#### **Study Documents/Items Referred to in this Chapter**

- Missed Visit
- Visit Checklists
- Participant Status Change
- Unscheduled Visit
- Adverse Event
- Outcome Tracking
- 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 on the LIFE website through a certification tracking system. This tracking 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 certification tracking system will also send email reminders to staff who require re-certification. The Program Coordinator at each site is responsible for making sure the certification of staff is current. The Program Coordinator is responsible for sending the ACC proper documentation of certification in order to keep the certification tracking system 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 IDS**

A five digit staff ID is automatically assigned when an individual is added to the LIFE website. To obtain a staff ID and access to the web site for a new staff member complete the New User Request form and email it to \_\_\_\_\_

and \_\_\_\_\_ at the DMAQC.

In most cases, the first two numbers of the Staff ID are the numeric portion of the Field Center ID (see Section 4.4.). Staff IDs will be listed under “Staff IDs” after navigating to “Operations > Committees > Field Center – XXX” and clicking on the tab labeled “Staff IDs”.

In the event of a staff resignation, please notify the DMAQC and the Administrative Coordinating Center in order to inactivate the staff ID.

#### **4.4. ASSIGNMENT OF FIELD CENTER IDS**

Each Field Center has been assigned a unique ID. This ID is used in multiple reports for identifying individual clinics. The field centers are also assigned unique series of participant IDs that, when appended to the field center ID, link the participant to a particular clinic. In the case of transfer, a participant always carries their unique participant ID with them; however, the Field Center ID changes 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 ID
Northwestern University, Chicago, IL	10	
Pennington Biomedical Research Center, Baton Rouge, LA		20
Pennington/Baton Rouge General Hospital, Baton Rouge, LA		21
Stanford University, Palo Alto, CA		30
Tufts University, Boston MA	40	
University of Florida, Gainesville, FL		50
University of Florida, Jacksonville, FL		51
University of Pittsburgh, Pittsburgh, PA		60
Wake Forest University, Winston Salem, NC		70
Yale University, New Haven, CT	80	

#### **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 under the Operations/Documents tab on the study website.
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, and an Interviewer/Examiner code. A description of these items is provided below.

##### **The Participant Identification (PatID) Number**

All Field Centers will use a set of unique 7 digit ID numbers.

A seven digit ID is assigned to each individual who completes a Telephone Screening 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 Participant ID label. Field Centers must provide their own labels but a web application will be provided for printing the labels. 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. Symbols should not be used in creating acrostics. If a participant's last name contains a symbol such as an apostrophe, then move to the next letter in the name to create the acrostic. For example, Delia O'Brien would have an acrostic of OBRDE. 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 CANNOT be corrected.

### **Date of Visit (Date Form Completed)**

A record of the date the data was collected for a specific form is required on each form. This date is recorded on the form as a "date of visit" or "date of notification" (i.e. Adverse Event Form). Each form must be completed at the time of administration. This will ensure accurate data documentation.

Clearly enter the date in the format of 2-digit Month/2-digit Day/4-digit Year (MM/DD/YYYY).

### **Visit Code**

The visit code is a three-digit code which represents the month of the visit. For example, the Month 6 follow-up visit would be entered as F06. Please refer to the following codes when completing the form header.

Screening Visit 1     SV1

Screening Visit 2     SV2

Follow-up Visits     F06, F12, F18, F24, F30, F36, F42

Closeout Visit        CLS

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

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

Successful Aging and Physical Activity Intervention     IV001, IV002, 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 NSV (non-scheduled visit).

- Participant Status Change
- Unscheduled Visit
- Adverse Event
- Outcome Event Tracking
- Adverse Event Evaluation
- News-A

### **Interviewer/Examiner**

The LIFE staff member who completes the form should record his/her 5-digit Staff ID in the header. 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 database on a regular (preferably daily) basis. The DMAQC center monitors data entry activity and provides reports to the study committees and field centers.

#### **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, 2010 would appear as 07 05 2010.
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."
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. Record the dates in the format listed above. Dates are critical for outcome and safety monitoring. These dates will be required on the respective forms. In the event that the participant does not know the exact date of a procedure or event, record as much of the date as possible. For example when the year is known, but not the month or day, enter the year on the form and label the month and day as missing

using the procedures from #4 above. During data entry of the form the ability to leave a date field missing is limited to outcome and safety monitoring forms.

7. In some cases, response options of “Other” will require free text entry. Participant responses should be as complete as possible and staff should record 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 assessment visit within the assessment 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 intervention visits are documented on the session attendance logs. Staff indicates on the session attendance log that the participant did not attend the session as well as the reason for the missed visit.

### **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 Protected Health Information (PHI) Chart and placed in a secure location.

Documents or study forms linking participants' names and demographic information with Participant ID numbers are to be stored separately from participants' coded research data charts in a separate room and in a locked filing cabinet accessible only to LIFE Study staff. Examples of materials/study documents to be included in PHI charts are:

1. All signed/dated Informed Consent Forms
2. Telephone Screening Interview
3. Contact Information Form

Adverse event evaluation forms should be stored separate from both the coded research data chart and the PHI chart. Access to these documents should be limited to unmasked study staff.

#### **4.6.3. Visit Checklists**

For each participant at each scheduled assessment 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
- 6 month follow-up visit
- 12 month follow-up visit
- 18 month follow-up visit
- 24 month follow-up visit
- 36 month follow-up visit
- 42 month follow-up visit
- Close out visit

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 proxy administered questionnaire, and the Quality of Well Being and Health Care Utilization questionnaires could be completed (See **MOP Chapter 8 – Follow Up Visits** for questionnaires to be administered to proxies.)
- 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 the Administrative Coordinating Center at the central email address LIFEACC@aging.ufl.edu., which will be received by \_\_\_, project manager, \_\_\_, assistant project manager, \_\_\_, assistant project manager, \_\_\_, program assistant; \_\_\_, program assistant; and \_\_\_, assistant project director.
2. \_\_\_ will be first responder and will identify which LIFE Study investigator(s) is (are) qualified to respond most authoritatively and forward the query. In the event, that \_\_\_y is not available to respond, the assistant project managers, program assistant and/or project director will respond to the query as indicated above.
3. The LIFE expert(s) will reply back to central email LIFEACC@aging.ufl.edu.
4. A numbered LIFE Study Memo will be issued to all relevant study personnel with the appropriate response and posted on the FAQ page of the study website.
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.