CHAPTER 24

QUALITY CONTROL

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QUALITY CONTROL

24.1. OVERVIEW

Study-wide quality control is the ultimate responsibility of the LIFE field centers and the DMAQC center. The LIFE Program Coordinator at each clinical site must become familiar with LIFE requirements and schedule clinic activities so that there is adequate time for clinic staff to carry out their responsibilities while meeting quality standards.

24.2. TRAINING

Key clinic staff from each field center is trained at the initial LIFE central training session. LIFE uses a train-the-trainer model, i.e., the key staff who are trained at the central training session are responsible for training and re-training other staff members. Certification and recertification are required in order to assure that clinic staff have a clear understanding of the LIFE Protocol and Manual of Procedures (MOP) and procedures are standardized at all field centers. Training sessions are designed for those staff obtaining core measures and interviews, the interventionists, and the recruiters. In this chapter, both general and specific procedures are described.

Local refresher training sessions are held annually for all staff groups. These sessions focus on current issues facing the staff, new components implemented in the clinics, and problem areas.

24.2.1. Certification

Certification is required of LIFE staff that perform any of the activities listed below in Table 1. The Program Coordinator (or designee) is responsible for documenting that each of the certification tasks has been completed using the forms found in Appendix A. These forms and supporting documents (including data collection forms) are to be maintained at the field center in a certification file, and is reviewed at the time of the site visit. The completed Certification/Recertification Checklist documents should be sent to the Administrative Coordinating Center via email at LIFEACC@aging.ufl.edu. Completion of certification should also be documented on the Certification Form and subsequently entered in the study web-site in the certification database.

Table 1.

LIFE Components Requiring Certification
Telephone Screening
400 m walk test
Accelerometry
Short Physical Performance Battery
Blood Pressure Weight, Height Assessment
Weight, Height
ECG
Waist Circumference
Medication Inventory
Grip Strength
Ankle Brachial Index
Spirometry/MIP
Cognitive Tests
Blood/Urine Collection
Blood/Urine Processing
Interviewing (Disability Questionnaire)
CHAMPS
Data Entry
Physical Activity Intervention
Successful Aging Intervention

Note that for all components, the following tasks must be completed:

(1) Attendance at the LIFE centralized training session or training by someone certified in the measurement/procedure;

(2) Required reading: Manual of Procedures Chapters 1 (Protocol) and 24 (Quality Control).

(3) Plus additional items listed on the certification forms (Appendix A).

Attendance at central training is not sufficient for certification! Those who attended the central training session must also complete items #2 and #3 above.

Certification forms are contained in Appendix A. Additional information on certification for specific activities is often found in the respective MOP chapters.

24.2.2. Recertification

Recertification procedures facilitate compliance with the protocol and the maintenance of study skills over the course of the trial. They are designed to provide a review of the appropriate LIFE MOP chapters, as well as an opportunity to carefully review the required steps for various measurements and procedures.

Recertification is required annually for LIFE staff who perform any of the activities listed in Table 2. The Program Coordinator (or designee) is responsible for documenting that each of the recertification tasks has been completed using the forms found in Appendix A. These forms and supporting documents (including data collection forms) are to be maintained at the field center in the staff member's certification file and may be reviewed at site visits. The Certification/Recertification Checklist documents should be sent to the Administrative Coordinating Center. Completion of recertification should also be documented on the Staff ID and Certification Form and subsequently entered in the study web-site in the certification database.

Table 2.

LIFE Components Requiring Recertification
Telephone Screening
400 m walk test
Accelerometry
Short Physical Performance Battery
Blood Pressure Weight, Height Assessment
Waist Circumference
ECG
Medication Inventory
Grip Strength
Ankle Brachial Index
Spirometry/MIP
Cognitive Tests
Blood Collection
Blood Processing
Interviewing (Disability Questionnaire)
CHAMPS
Data Entry
Physical Activity Intervention
Successful Aging Intervention

Note that for all components, the following tasks must be completed:

(1) Required reading/review of designated chapters in the Manual of Procedures

(2) Observation and critique by a staff member certified in the measurement or procedure

(3) Additional items as listed on the recertification forms (Appendix B).

Supplementary information on recertification for specific activities is often found in the respective MOP chapters.

24.2.3 . New Program Coordinators

Field Centers notify the Administrative Coordinating Center when a new Program Coordinator (PC) is hired at a LIFE site. The new PC should read all chapters of the MOP and be very familiar with the protocol and visit procedures.

24.3. QUALITY CONTROL ACTIVITIES

24.3.1. Field Center Activities

Specific quality control activities to be carried out at the LIFE field center include:

1. Certificatio n/recertification of clinic staff in all components listed in Appendix A.
2. Monitoring of regular equipment calibration and maintenance
3. Recording of participant identifiers on the top of each questionnaire/data collection form prior to their completion at all clinic visits. Complete all form headers before participant leaves the clinic.
4. Regular observation and monitoring of clinical procedures including specimen collection.
5. Review of all questionnaires and data collection forms prior to data entry (and before the participant leaves the field center).
6. Compilation and review of data on lost laboratory samples, packaging problems, errors in packing, shipping, and labeling of specimens.
7. Reporting of quality control concerns or problems to the LIFE Administrative Coordinating Center and/or the appropriate central resource center for prompt resolution.

The Program Coordinator should regularly monitor field center procedures to be sure that they are being carried out properly and with consideration for the LIFE participant. Corrective action should be taken immediately if problems are observed.

The field center staff are encouraged to communicate with the Administrative Coordinating Center about quality control or other concerns or problems. The Certification Log is maintained on the study website. Please refer Chapter 4-General Procedures.

24.3.2. Equipment

The LIFE investigators have standardized much of the equipment for the trial. Such standardization (and the attendant maintenance and calibration of the equipment) assures one level of reliability across the LIFE field centers. Each field center is responsible for the proper operation and maintenance of equipment used in the LIFE trial. Some of the equipment is subject to standard calibrations and inspections (e.g., scales). It is suggested that responsibility for monitoring these standards be assumed by a specific individual, either the

Program Coordinator or a designated Quality Control Officer. Any real or suspected equipment problems should be reported promptly to the Administrative Coordinating Center. Details regarding equipment maintenance and calibration are contained in the respective MOP chapters. All fees associated with the maintenance and calibration requirements are paid directly by the clinic. A summary is provided below for standardized study equipment, i.e., equipment purchased and distributed by the Administrative Coordinating Center, and non-standardized equipment, i.e., equipment purchased by the clinic. Note that for non-standardized equipment, there are few calibration and/or maintenance checks required by LIFE, however, your clinic should practice all manufacturers recommended checks.

Table 3. Standardized study equipment

Study component	Standardized equipment	Calibration and/or maintenance required	Replacement Options
Physical Activity Measurement (Steps)	OMRON HJ112 (Pedometers)	None Same	Equipment
Physical Activity Measurement (Strength training)	Ironwear Fitness Ankle weights (2-5 lb pairs and 10 lbs)	None Same	Equipment
SPPB – 4m walk	Task Force (5meter) Metric Tape Measure	None	Standard Metric Tape Measure
400m walk	Orange marker cones and stop watches	None Same	Equipment
Hand Grip Strength	Jamar Handheld Dynamometer	None Same	Equipment
Distance Measurement	Redi-Measure Distance Measuring Wheel, Model 11-0755 (metric)	None Same	Equipment
Waist Circumference	Gulick II Tape Measure Model 67020	None Metric	Tape
Emergency Defibrillator		None Same	Equipment
Physical Activity Measurement	Accelerometry Units – GT3X Triaxial Activity monitor	None Same	Equipment
Physical Activity Measurement	Accelerometry Belts	None	Same Equipment
Physical Activity /Safety	Automatic Blood Pressure monitor	None Same	Equipment
Physical Exam/Safety	Glucometer None		Same Equipment
ECG	Philips Pagewriter Trim III	None Same	Equipment
ABI Nico	let Vascular Pocket-Dop II Doppler	None Same	Equipment
ABI Standard	Aneroid Sphygmomanometer	None Same	Equipment
Spirometry Easyone	PLUS spirometry Software	None Same	Equipment
Spirometry Adapter		None Same	Equipment

Spirometry	Easyone Spirettes	None	Same Equipment
Spirometry Rudolf	3-liter calibration syringes	Hans Rudolf, Inc.	Same Equipment
Spirometry MIP	gauges	None Same	Equipment
Spirometry Dispos	able mouthpieces	None Same	Equipment
Spirometry	Nose clips	None	Same Equipment

Table 4. Non-standardized study equipment

Study component	Recommended equipment	Calibration and/or maintenance required by LIFE
Timed Assessments	stopwatch None	
Height Wall	mounted stadiometer or wall mounted rule with level	None
Weight	Balance Beam Scale	20 kg weight
Blood Pressure	Aneroid BP Cuff	None
Sample processing and short-term storage	Refrigerated centrifuge -70°C freezer	Freezer temperatures should be recorded daily.

All standard maintenance should be documented by date in a permanent log at the field center. Problems and solutions should also be recorded. Copies of calibration records must be kept on file. The log and calibration records are inspected during periodic site visits, or copies may be requested by the LIFE Administrative Coordinating Center at periodic intervals.

24.3.3. Data Quality

Field center staff are asked to review all of the participants' questionnaires and data collection forms prior to ending each clinic visit. Forms must be completed neatly and accurately, and every question should be answered. Written responses to any items on the questionnaires/forms should be legible. After reviewing the forms, the reviewer's initials should be written in the form header (top of first page) as a confirmation that a review was done.

Throughout the study, the Administrative Coordinating Center (ACC) reviews copies of selected participant forms. Initially, a selected sample of forms from the first randomized participants will be reviewed. Details about which forms are to be sent to the ACC will be communicated to each site after randomization has begun. Any identifying information must be blacked out. This set of forms should be sent to the Administrative Coordinating Center as they are completed. Thereafter, forms are reviewed on a periodic basis, and may include a subset of forms or recognized "problem forms". The Administrative Coordinating Center staff verifies that the forms are legible and that they are filled out correctly and completely.

The data entry screens are designed to mirror the paper data collection forms to allow smooth flow from item to item and thereby minimize error with data entry. Verification of participant identifiers and visit numbers are incorporated into the data entry system, in addition to gross range checking of fields.

The DMAQC center regularly performs internal comparisons of the entered data to detect missing records or suspicious or invalid data. These comparisons include logical consistency checks of data within and across forms/questionnaires. When inconsistencies are detected, the field center is notified through edit reports, and is asked to verify, if possible, some entries. Prompt action with these verification requests is essential for an efficient quality control system.

24.3.4 Administrative Coordinating Center Activities

Quality assurance is a major activity of the Administrative Coordinating Center throughout the study. Activities include:

- Training/retraining of field center staff in data collection procedures
- Data control (filing, manual editing, special coding efforts)
- Monitoring of data entry activities and error rates.
- Documentation of database changes.

Monitoring of the LIFE study data takes place at the DMAQC center. These activities include validation, data control and report generation. Some of the monitoring and quality control reports are transmitted to the field centers for immediate action and attention; other quality control and monitoring reports are generated for the NIA Project Officer, the Steering Committee, the Field Centers and the Data and Safety Monitoring Board. For example, these reports include data on:

- Recruitment yields at each field center
- Summaries of certifications
- Problems observed or reported at site visits
- Serious adverse events
- Deviations from protocol
- Missed visits, refusals, losses to follow-up
- Adherence
- Errors in collection, labeling, storage, or shipping of laboratory specimens

It is the responsibility of Administrative Coordinating Center personnel to review these reports on a timely basis, to initiate action to remedy any problems as soon as possible, and, if necessary, to participate in site visits at the field centers, as well as to perform follow-up evaluations of actions taken.

24.3.5. Reports to NIA and Steering Committee

During the recruitment period of the trial, monthly reports on recruitment activities by each LIFE field center are provided to the Steering Committee, the Principal Investigators and the NIA Project Officer.

During all phases, monitoring reports and analyses are be generated for each field center and the whole study. These are reported to the Principal Investigators, the Steering Committee and the Program Directors.
Annual reports include a summary of quality control data by field center.

24.3.6. Data Safety Monitoring Board Activities

The Data Safety Monitoring Board (DSMB) is an independent panel of experts who review and advise on the scientific and operational progress of LIFE. The DSMB periodically reviews and evaluates data on recruitment, quality control, compliance, adverse events, and outcomes. This panel reports directly to the NIA and may recommend corrective action, changes in the protocol, or early stopping of the study. The DSMB also reviews and advises on proposed changes in the protocol originating from the Steering Committee and proposals for ancillary studies.

The charge of the DSMB is the following:

- Review the study protocol and the informed consent
- Identify modifications if needed
- Identify the relevant data and the format of the information to be regularly reported
- Review data (including masked data) relating to efficacy, recruitment, randomization, compliance, retention, protocol adherence, trial operating procedures, forms completion, intervention effects, gender and minority inclusion and subject safety
- Identify problems relating to safety. Inform study PI via written report, who, in turn, ensures that all Field Center PIs receive this report.
- Identify needs for additional data relevant to safety and request these data from the study investigators
- Propose appropriate analyses and periodically review developing data on safety and endpoints
- Make recommendations regarding recruitment, treatment effects, retention, compliance, safety issues and continuation of the study
- Send the Program Administrator and PI written reports following each DSMB meeting
- The study PI is be responsible for sending the reports to individual site PIs, who in turn are required to distribute the report to their local IRBs

- The DSMB may convene an executive session at any time. The PI and project officer would attend these meetings
- At any time, the DSMB may recommend discontinuation of any component/treatment group of the study for any of the following reasons:
    - Compelling evidence from this or any other study of
        - an adverse effect of the study treatment(s) that is sufficient to override any potential benefit for the interventions to the target population
        - a significant beneficial effect of the study treatment(s), such that its continued denial to other study group(s) would be unethical
    - A very low probability of addressing the study goals within a feasible time frame

24.3.7. Changes in the Manual of Procedures (MOP)

Changes in the MOP may need to be made from time to time. A draft of all changes to a MOP chapter is reviewed by a sub-committee of Administrative Coordinating Center before the revised version is posted on the LIFE website. New edits in a MOP chapter are underlined when the revised chapter is posted. Clinic staff is advised via E-mail when changes to the MOP are posted to the study web-site.

If a major procedural or design problem occurs, the Executive Committee is asked to make a recommendation, the change is made as above, and the Steering Committee is asked to approve these changes at the regularly scheduled meeting.

24.3.8. Changes in Forms

The LIFE Web site lists all of the study forms and identifies the current Version number and Date for each form. Minor changes in a form result in the same Version Number but a change in the date. In this case, the change to the form is not significant enough to warrant a reissue of the form and the current version is still valid. Any time that changes to a form are significant, a new Version Number is issued and the new form must be used.

Changes to forms are reviewed by a sub-committee of the Administrative Coordinating Center before the new version is distributed. Clinic staff are advised via E-mail when a new version of a form is posted to the study web-site.

24.4. SITE VISITS

During recruitment and follow-up, the Administrative Coordinating Center with other study personnel make site visits at each field center to promote communication, answer questions, and ensure that study procedures are understood and carried out correctly. The site visit program provides a mechanism to encourage the effective and standardized delivery of recruitment efforts, intervention programs, and the collection of appropriate and valid data

within each of the LIFE clinic sites. Site visits may also be performed if consistent departures from the Protocol and Manual of Procedures are detected. The decision for these site visits rests with the Administrative Coordinating Center. Retraining may be done as needed during these visits, depending on the availability of staff.

One of our most valuable resources is the LIFE clinic staff who are collecting the data and providing for the delivery of the intervention. It is these individuals who have the day to day experience, and first hand knowledge as well as a practical perspective to identify and help correct problems and/or variations in procedures that field centers may be having. Before the visit, the field centers are sent a proposed agenda and a schedule is worked out in advance. The Principal Investigator, Program Coordinator, and other key staff members, are involved. The first round of site visits occurs after experience is gained with the first wave of participants. This enables the Study to look at recruitment efforts, the methods of process and procedures, and any staffing problems clinics may be encountering.

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

After each site visit, two types of site visit reports are carried out. The first is a frank discussion at the end of the visit between the Site Visit Team, the Principal Investigator and key staff at the clinic site. A list of "Action Items" is provided. The Site Visit Team prepares written reports on the activities of the site visit. A detailed report of the team's observations and recommendations subsequently are then sent to the Principal Investigator of the clinic, and the Steering Committee. The Clinic PI is expected to respond in writing with the clinic plan for addressing the "Action Items".

24.4.1. Organization of the Site Visit

The site visits are designed to insure that each LIFE clinical site is recruiting appropriate individuals and collecting high quality data. Objectives for the site visitor are: a) to determine if the Protocol and Manual of Procedures are being followed, and if not, what measures should be taken to correct the problems; and b) to learn as much as possible from clinic center staff about how to improve effectiveness in meeting recruitment goals, collecting data, and facilitating a smooth clinic flow.

A key to a successful site visit is adequate preparation both from Administrative Coordinating Center and clinic centers. The visits should serve to enhance communication throughout the study, and to personalize interchange among clinic staff and investigators.

Questions for the Clinic Staff

During the site visit the visitor should seek answers to the following questions, review and discuss data reports provided by the Administrative Coordinating Center and explore any concerns or questions that arise.

1. Do clinics have an adequate number of appropriately trained staff members to provide for effective recruitment, data collection, data entry and intervention delivery?
2. Are staff roles clearly defined and is there communication and interaction between the various working groups?
3. How is information shared, for example, changes in the MOP or Protocol?
4. What is the overall view of clinic flow?
5. The clinic tracking/scheduling system is discussed and the following questions may be asked.
    a. What is the procedure followed when a participant does not show up for his/her appointment?
    b. How does the clinic keep track of where an individual is in the study flow so that the participant is scheduled within the appropriate window?
    c. How are problem participants handled?

During the site visit, the visitor may ask to follow a participant through an entire visit, observe a randomly selected interview and observe the collection of physical measurements. Questions are asked about where records are kept and how participant confidentially is assured. A site visitor conducts selected chart reviews to look at the following:

a. informed consent and appropriate signatures;
b. complete data forms and questionnaires; and
c. source documents.

Protocol and Manuals

The following questions concerning study documentation should be answered during the course of the site visit.

1. Where is the MOP located in the clinic and do clinic staff have easy access to it?
2. Do the Protocol and MOP have all the updates included?
3. What is the procedure for maintenance on equipment? Where are the quality control logs documenting that equipment is checked at

appropriate intervals?

4. Where is the IRB approval document? Has the IRB been informed of protocol changes?
5. A review of laboratory procedures and what OSHA regulations are being followed.
6. A review and discussion of data reports provided by the Administrative Coordinating Center, and exploration of any concerns or questions that arise. Possible items for discussion includes: data edits, missing/delinquent forms, missed visits and protocol violations.

Preparation for the site visit is valuable to the staff. Preparation should include:

1. Distribution of the site visit guidelines to all staff;
2. An explanation of the goals of the site visit to all staff;
3. A review of compliance with the guidelines during staff meetings prior to site visits; and
4. A self-evaluation of clinic strengths and weaknesses by each staff member in preparation for discussions with site visitor(s).

Post site-visit activities at the field center should include:

1. A staff meeting to debrief the field center staff regarding information and issues related to the site visit;
2. Review of the written site visit report when available;
3. Goal setting and planning based on site visit recommendations;
4. A written response from the PI to the Site Visit Team;
5. A follow-up progress report and discussion with the site visit team approximately three months after the site visit.

24.4.2. Site Visits to Central Laboratories and Reading Centers

Site visits are also conducted periodically at the central laboratory and reading centers. Site visit members include Administrative Coordinating Center staff, and other LIFE investigators.

24.5. Physical Activity/Successful Aging Intervention

Quality control across and within study field center is be achieved at several different levels. All centers in LIFE utilize the same Physical Activity and Successful Aging intervention. A set of manuals have been developed by LIFE and approved by the Steering Committee. These include a participant manual for the participants and an accompanying guide for the interventionists (see the Physical Activity Interventionist's manual and the Successful Aging Interventionist's training guides). All centers use these materials, which have

been designed to be appropriate for individuals of different backgrounds and educational levels. In addition, two counseling staff from each site are centrally trained by the Interventions and Operations Committee and monitored to ensure they deliver the intervention as designed. These individuals are responsible for training other staff members at their field centers who are to be involved in the intervention. Such training involves the following: (a) a review of the study protocol, (b) peer-tutored review of the lecture content presented during central training, (c) small group exercises similar to those offered during central training to practice exercise techniques and skills, and (d) the trainee's observation of the senior interventionist conducting several individual and group sessions.

To maintain the fidelity of the intervention, LIFE provides (a) strong initial and follow-up training for intervention staff, (b) monthly monitoring of center and participant behavior via a computerized tracking system, (c) Lifestyle Resource Core generated monthly contacts with each clinic concerning potential problems that may exist for specific groups or individuals in the LIFE intervention, and (d) site visits when required.

Central training is provided for intervention staff at the start of the study and onsite updates are provided on an annual basis. These training/review sessions contribute significantly to the quality of data by providing an opportunity for learning/updating intervention and data collection skills, recruiting skills, addressing specific problems related to adherence, and promoting study camaraderie. Since the need for replacement training is difficult to predict, the scheduling of these sessions are done on an *ad hoc* basis. Interventionists are asked to confirm in writing that they have read and are fully conversant with the training materials and study procedures.

Field centers are provided with adherence and retention strategies and are encouraged to tailor these to the needs of their participants (based on factors such as ethnicity and geographical region) and to regularly monitor their performance. To monitor these variables, we have developed a computerized intervention tracking system to increase adherence by the interventionists to the study protocol. Elements of the LIFE computerized tracking system include demographic data on each participant, attendance records for both individual and group sessions, and exercise training parameters. Data are entered on each participant on a weekly basis and downloaded to the Administrative Coordinating Center. Data are used to generate monthly reports by the Administrative Coordinating Center for the Lifestyle Resource Core that are responsible for intervention fidelity. These reports include, but are not limited to the following:

- The average number of minutes of weekly physical activity for each participant. The distance covered during the onsite walking sessions, the reported perceived exertion, the weight used during strength training exercises. Average rates of attendance for the individual and group sessions for each field center in the LIFE trial.

- Interventionists query participants deemed intervention dropouts (i.e., those who refuse to participate in any further intervention activities) as to their reasons for discontinuing active participation. These reasons are documented in the tracking system. Participants who have withdrawn from the intervention are encouraged to remain active in follow-up data collection (i.e., discontinue intervention activities but continue in follow-up data collection). However, those individuals who elect to withdraw from both aspects of study participation continue to be contacted by the retention staff.

The Lifestyle Resource Core (LRC)

The Lifestyle Resource Core is responsible for the monthly monitoring of the interventions study-wide and for contacting individual sites that are failing to meet study goals. This core also serves as an expert panel for questions that may arise on the part of the individual interventionists throughout the course of the study. Members of this core are appointed by the steering committee in conjunction with the Lifestyle committee of LIFE. Some of the tasks of the LRC include: a) conducting conference calls on a monthly basis with region interventionist, b) reviewing monthly reports from the DMAQC, c) responding to email inquiries from sites.

Appendix A
Certification Forms

LIFE Certification/Recertification
Telephone Screening

_____ __ __ __ __ __
Name Staff ID

1. ☐ Attendance at LIFE training session _____ or
Date

☐ Local training by a staff member certified in the procedure.

_____ _____
Date Name of Trainer

Description of local training:
_____

_____

_____

2. ☐ Become familiar with LIFE Study website

3. Required Reading

☐ Chapter 1, Protocol
☐ Chapter 4, General Procedures
☐ Chapter 6, Screening
☐ Chapter 24, Quality Control
☐ Chapter 25, Interviewing

4. ☐ Conducts 3 interviews with older adults (70+y) via the telephone in the presence of an assessor certified in administering the CHAMPS Questionnaire.
5. ☐ Date of Certification _____

_____ _____
Signature of Program Coordinator & Date Signature of Principal Investigator & Date

LIFE Certification/Recertification Checklist
Telephone Screening

_____ __ __ __ __ __

Technician Name Staff ID

Observes the Following Procedural Steps:

1. ☐ Properly greets participant
2. ☐ Reads slowly in a natural conversational rhythm and in a normal tone of voice
3. ☐ Always reads the entire question before getting the participant's response
4. ☐ Asks every question
5. ☐ Repeats questions if it is answered inappropriately, but repeats it exactly as written.
6. ☐ Offers to reread a question if participants does not understand the question
7. ☐ Asks questionnaire items in order and exactly as worded
8. ☐ Took care to determine how many minutes the participant was actually involved in each activity (e.g., some people incorrectly count time getting ready to exercise and cool down into their estimate of time exercised)
9. ☐ Was careful not to double count any time spent walking hills into minutes spend walking briskly
10. ☐ Was careful not to count leisure walking as "walking briskly"
11. ☐ Correctly codes participant's responses on the data collection forms
12. ☐ Correctly records the total number of minutes of physical activity reported by the participant.

Comments:_____
_____
_____
_____
_____

Observer:_____ Date observed:_____

LIFE Certification/Recertification
Short Physical Performance Battery (SPPB)

_____ __ __ __ __ __
Name Staff ID

4. ☐ Attendance at LIFE training session _____ or
Date

☐ Local training by a staff member certified in the procedure.

_____ _____
Date Name of Trainer

Description of local training:
_____

_____

_____

5. ☐ Become familiar with LIFE Study website

6. Required Reading

☐ Chapter 1, Protocol
☐ Chapter 4, General Procedures
☐ Chapter 6, Screening
☐ Chapter 8, Follow-up Visits
☐ Chapter 16, Physical Measures
☐ Chapter 24, Quality Control
☐ Views Training CD-ROM entitled "Assessing Physical Performance in the Older Patient

4. ☐ Conducts 3 assessments, records on the Short Physical Performance Battery Form. Trainer uses and completes the SPPB Certification Checklist during observation of the procedure.

5. ☐ Date of Certification _____

_____ _____
Signature of Program Coordinator & Date Signature of Principal Investigator & Date

LIFE Certification/Recertification Checklist
Short Physical Performance Battery

_____ __ __ __ __ __

Technician Name Staff ID

During Procedure:

1. ☐ Ensures participant's safety at all times.

Observes the Following Procedural Steps:

2. ☐ Assembles proper materials and equipment: Stopwatch, masking tape, 5 meter tape measure, script, score sheet, and a straight-backed chair with a hard seat.
3. ☐ Properly sets up course layout for the gait speed test.
4. ☐ Greets participant and reviews procedures.
5. ☐ Ensures that participant is wearing proper footwear, i.e. not high heels.
6. ☐ Performs tests in their proper order.
7. ☐ Provides instructions exactly as they are written in the script.
8. ☐ Indicates location where SPPB was performed.
9. ☐ Properly demonstrates each maneuver.
10. ☐ Ensures that participant understands the instructions.
11. ☐ Scores each maneuver correctly.
12. ☐ Provides explanation when a specific maneuver is not attempted.
13. ☐ Positions participants correctly for each maneuver.
14. ☐ Positions himself/herself correctly for each maneuver.
15. ☐ For balance tests, stabilizes participant until feet are in correct position.
16. ☐ Times the balance tests correctly.
17. ☐ Properly determines whether cane or walker should be used for gait speed test.
18. ☐ Instructs participant to walk at their usual pace.
19. ☐ Times the gait speed test correctly (first and second trials)
20. ☐ Indicates length of walking course.
21. ☐ Records whether walking aid was used.
22. ☐ Positions chair properly against wall.
23. ☐ Determines whether participant feels safe standing from chair.
24. ☐ Determines whether participant feels safe standing from chair with arms folded.
25. ☐ Records whether participant was able to stand from chair without the use of their arms.
26. ☐ Determines whether participant feels safe standing from chair five times without using their arms.
27. ☐ Instructs participant that five chair stands should be done as quickly as possible.
28. ☐ Times the repeated chair stand test correctly.

29. ☐ Stops the repeated chair stand test properly, i.e. participant has to use their arms, is unable to complete the test after one minute, or stops and is unable to continue.
30. ☐ Correctly calculates summary score for balance tests
31. ☐ Correctly calculates composite score for SPPB.

Comments:_____
_____
_____
_____
_____

Observer:_____ Date observed:_____

LIFE Certification/Recertification
Seated Blood Pressure

_____ __ __ __ __ __
Name Staff ID

1. ☐ Attendance at LIFE training session _____ or
Date

☐ Local training by a staff member certified in the procedure.

_____ _____
Date Name of Trainer

Description of local training:
_____

_____

_____

2. ☐Become familiar LIFE Study website.

3. Required Reading

☐ Chapter 1, Protocol
☐ Chapter 4, General Procedures
☐ Chapter 6, Screening
☐ Chapter 8, Follow-up Visits
☐ Chapter 16, Physical Measures
☐ Chapter 24, Quality Control

4. ☐Conduct 3 blood pressures, record on the Blood Pressure, Radial Pulse & Weight Form. Trainer uses and complete the Seated BP Certification Checklist during observation of the procedure.
5. ☐ Date of Certification _____

_____ _____
Signature of Program Coordinator Date Signature of Principal Investigator Date

LIFE Certification/Recertification Checklist
Seated Blood Pressure

_____ __ __ __ __ __ __

Name Staff ID

During Procedure:

1. ☐ Keeps participant warm, relaxed and comfortable
2. ☐ Discourages participant from talking except to voice discomfort or confusion about instructions

Observes the Following Procedural Steps:

3. ☐ Assembles proper materials and equipment: standard mercury sphygmomanometer, 4 cuff sizes, measuring tape, cosmetic marking pencil
4. ☐ Greets participant and reviews purpose, time requirement and procedure.
5. ☐ Seats participant in proper position- both feet flat on floor, right forearm resting on table
6. ☐ Determines appropriate cuff size by following protocol for measurement of arm circumference. Measures length of arm from acromion to olecranon process, marks midpoint on arm. Measures arm circumference at mid point mark. Determines cuff size from MOP chart
7. ☐ Records arm circumference, cuff size and arm measured on data form
8. ☐ Measures and records radial pulse
9. ☐ Places cuff properly with center of bladder over the brachial artery and cuff at the level of participant's heart
10. ☐ Palpates brachial artery and estimates MIP
11. ☐ Confirms participant is relaxed and comfortable and reminds of the need to be seated quietly for 5 minutes prior to the measurement
12. ☐ Observes the 5 minutes of relaxed sitting
13. ☐ Obtains 2 blood pressure measures with a 30 second interval between end of first reading and beginning of second reading
14. ☐ Records both BP readings correctly on the data forms
15. ☐ Communicates appropriately with participant regarding a normal or an alert BP

Comments:_____
_____
_____
_____

Observer:_____ Date Observed:_____

LIFE Certification/Recertification
Weight, Height

_____ __ __ __ __ __
Name Staff ID

1. ☐ Attendance at LIFE training session _____ or
Date

☐Local training by a staff member certified in the procedure.

_____ _____
Date Name of Trainer

Description of local training:
_____

_____

2. ☐ Become familiar with LIFE Study website.

3. Required Reading

- ☐ Chapter 1, Protocol
- ☐ Chapter 4, General Procedure
- ☐ Chapter 6, Screening
- ☐ Chapter 8, Follow-up Visits
- ☐ Chapter 16, Physical Measures
- ☐ Chapter 24, Quality Control

4. ☐ Conduct 3 sets of measures. Record on the Blood Pressure, Radial Pulse & Weight form. Observer uses and complete the Weight and Height Certification Checklist during observation of procedure.
5. ☐ Records height on the Height form. Observer uses and completes the Weight, Height Certification Checklist during observation of procedure.
6. ☐ Date of Certification _____

_____ _____
Signature of Program Coordinator Date

_____ _____
Signature of Principal Investigator Date

LIFE Certification/Recertification Checklist
Weight, Height

_____ __ __ __ __ __
Technician Name Staff ID

Observes the Following Procedural Steps:

1. ☐ Assembles proper materials and equipment:
   Balance beam scale for weight; wall-mounted stadiometer or wall-mounted ruler with level for height.
2. ☐ Greets participant and reviews procedure
3. ☐ Confirms participant is wearing light clothing, empty pockets and shoes removed
5. ☐ Positions participant correctly on the scale - head erect, eyes looking straight forward, stands still in middle of scale platform
5. ☐ Determines and records the weight to the nearest .1 kg on the study form
6. ☐ Articulates the requirements for Annual Commercial Calibration
7. ☐ For height, positions participant correctly and checks for kyphosis.
8. ☐ Determines and records the height to the nearest .1 cm on the study form

Comments:_____
_____
_____
_____

Observer:_____ Date Observed_____

LIFE Certification/Recertification
Waist Circumference

_____ __ __ __ __ __
Name Staff ID

1☐ Attendance at LIFE training session _____ or
Date

☐Local training by a staff member certified in the procedure.

_____ _____
Date Name of Trainer

Description of local training:
_____

_____

2 ☐ Become familiar with LIFE Study website.

3. ☐ View the Waist Circumference Training Video

4. Required Reading

- ☐ Chapter 1, Protocol
- ☐ Chapter 4, General Procedures
- ☐ Chapter 6, Screening
- ☐ Chapter 8, Follow-up Visits
- ☐ Chapter 16, Physical Measures
- ☐ Chapter 24, Quality Control

5. ☐ Conduct 3 sets of measures. Record on the Blood Pressure, Radial Pulse and Weight form. Observer uses and completes the Waist Circumference Certification Checklist during observation of procedure.

6 ☐ Date of Certification _____

_____ _____
Signature of Program Coordinator Date

_____ _____
Signature of Principal Investigator Date

LIFE Certification/Recertification Checklist
Waist Circumference

_____ __ __ __ __ __
Technician Name Staff ID

During procedure:

☐ Ensures participant safety at all times

Observes the Following Procedural Steps:

1. ☐ Assembles proper materials and equipment:
   Gulick II Tape measure, washable marker
2. ☐ Greets participant and reviews procedure
3. ☐ Instructs participant to remove clothing from abdomen.
4. ☐ Positions participant properly: standing with feet together.
5. ☐ Aligns the tape properly around the abdomen while articulating the anatomical landmarks used. Determines the midpoint between the highest point of the iliac crest and the lowest part of the costal margin in the mid-axillary line. Marks the midpoint on both sides with washable marker. .
6. ☐ Reads the measurement next to the "zero line" and records the measurement to the nearest 0.1 cm on the study form.
7. ☐ Demonstrates the procedure for determining the "calibration point."
8. ☐ Repeats measurement. Compares measurements and obtains third measurement if the first 2 measurements are not within 0.5 cm.

Comments:_____
_____
_____
_____

Observer:_____ Date Observed_____

LIFE Certification/Recertification
12 Lead ECG

_____ __ __ __ __
Name Staff ID

1. ☐ Attendance at LIFE training session _____ or
Date

☐ Local training by a staff member certified in the procedure.

_____ _____
Date Name of Trainer

Description of local training:
_____
_____
_____

2. ☐ Become familiar with LIFE Study website.

3. Required Reading
   - ☐ Chapter 1, Protocol
   - ☐ Chapter 4, General Procedures
   - ☐ Chapter 12, 12 lead ECG

4. ☐ Date of Certification _____

_____ _____
Signature of Program Coordinator & Date Signature of Principal Investigator & Date

LIFE Certification/Recertification Checklist
12 Lead ECG

_____ __ __ __
Technician Name Staff ID

During Procedure:

1. ☐ Ensures participant's safety at all times.

Observes the Following Procedural Steps:

2. ☐ Assembles proper materials and equipment:
    a) *Electrocardiograph, Phillips Pagewriter Trim III*
    b) ECG paper, disposable electrodes
    c) Isopropyl alcohol gauze pads and swabs
    d) Felt tip non-toxic washable markers
    e) Examining table disposable paper
3. ☐ Greets participant and explains procedure
4. ☐ Sets up participant on exam table-maintains privacy
5. ☐ Marks locations for electrodes
    Lead VI: Fourth ICS space at the right of the sternal border
    Lead V2: Fourth ICS space at the left of the sternal border
    Lead V3: Position equidistant between lead V2 and V 4
    Lead V 4: Fifth ICS space in the midclavicular line
    Lead V5: Fifth ICS space at the level of the anterior axillary line
    Lead V6: Fifth ICS space at the level of the midaxillary line
    Lead RL: Right lower leg above the inner ankle or as close as the electrode will reach
    Lead LL: Left lower leg above the inner ankle or as close as the electrode will reach
    Lead RA: Right inner right arm above the wrist
    Lead LA: Left inner right arm above the wrist
6. ☐ Preps skin
7. ☐ Obtain 12 lead ECG
8. ☐ Provide copy to participant
9. ☐ Complete ECG data form
10. ☐ Download ECG data to Tracemaster Vue system- assessed when back at site

Comments:_____
_____
_____
_____
_____

Observer:_____ Date Observed:_____

LIFE Certification/Recertification
400 Meter Walk (400 MW)

_____ __ __ __ __ __
Name Staff ID

5. ☐ Attendance at LIFE training session _____ or
Date

☐ Local training by a staff member certified in the procedure.

_____ _____
Date Name of Trainer

Description of local training:
_____
_____
_____

6. ☐ Become familiar with LIFE Study website.

7. Required Reading

☐ Chapter 1, Protocol

☐ Chapter 4, General Procedures

☐ Chapter 6, Screening

☐ Chapter 8, Follow-up Visits

☐ Chapter 16, Physical Measures

☐ Chapter 24, Quality Control

☐ Views Training CD-ROM on 400 MW

8. ☐ Conducts 1 assessment, records on the 400 meter walk Form. Trainer uses and completes the 400 meter walk Certification Checklist during observation of the procedure.

9. ☐ Date of Certification _____

_____ _____
Signature of Program Coordinator & Date Signature of Principal Investigator & Date

LIFE Certification/Recertification Checklist
400 M Walk

_____ __ __ __ __ __
Technician Name Staff ID

During Procedure:

1. ☐ Ensures participant's safety at all times.

Observes the Following Procedural Steps:

2. ☐ Assembles proper materials and equipment:
   Stopwatch, traffic cones, Redi-measure wheel, 2 standard chairs, script, data sheet.
3. ☐ Properly sets up course layout for the 400 M Walk test.
4. ☐ Greets participant and reviews procedures.
5. ☐ Ensures that participant is wearing proper footwear, i.e. not high heels.
6. ☐ Recites exclusion criteria for 400 M Walk.
7. ☐ Provides instructions exactly as they are written in the script.
8. ☐ Instructs participant to walk at his/her usual pace without overexerting himself/herself.
9. ☐ Properly demonstrates each maneuver.
10. ☐ Ensures that participant understands the instructions.
11. ☐ Records data properly.
12. ☐ Provides standard encouragement to participant.
13. ☐ Delivers key points from script clearly.
14. ☐ Positions himself/herself correctly for the walk
15. ☐ Records the distance covered correctly
16. ☐ Correctly records the time to completion or the time when participant stops.
17. ☐ Correctly enters data on collection forms
18. ☐ Correctly debriefs the participant.

Comments:_____
_____
_____
_____
_____

Observer:_____ Date Observed:_____

LIFE Certification/Recertification
Accelerometry

_____ __ __ __ __ __
Name Staff ID

1. ☐ Attendance at LIFE training session _____ or
Date

☐ Local training by a staff member certified in the procedure.

_____ _____
Date Name of Trainer

2. ☐ Become familiar with LIFE Study website.

3. Required Reading

☐ Chapter 1, Protocol

☐ Chapter 11, Accelerometry MOP

☐ Chapter 16, 400 meter walk

☐ Chapter 24, Quality Control

☐ Views Training CD-ROM entitled “Accelerometry”

4. ☐ Understands monitor will be worn during 400 m walk and at home.

5. ☐ Date of Certification _____

_____ _____
Signature of Program Coordinator & Date Signature of Principal Investigator & Date

LIFE Certification/Recertification Checklist
Accelerometry

_____ __ __ __ __ __
Technician Name Staff ID

Observes following procedure steps:

1. ☐ Properly connects monitor to computer and opens software for recognition of the monitor
2. ☐ Properly initializes the monitor with subject ID and demographics
3. ☐ Check marks the correct axes and steps
4. ☐ Places monitor on participant correctly (belt should be snug fit)
5. ☐ Explains instructions for caring of monitor while wearing at home
6. ☐ Downloads data
7. ☐ View data for quality and completeness
8. ☐ Converts data into a csv file
9. ☐ Understand data transfer to DMAQC

Comments:_____
_____
_____
_____

Observer:_____ Date observed:_____

LIFE Certification/Recertification
Medication Inventory

_____ __ __ __ __ __
Name Staff ID

1. ☐Attendance at LIFE training session _____ or
Date

☐Local training by a staff member certified in the procedure.

_____ _____
Date Name of Trainer

Description of local training:
_____

_____

_____

2. ☐ Become familiar with LIFE Study website.

3. Required Reading

☐ Chapter 1, Protocol
☐ Chapter 4, General Procedures
☐ Chapter 6, Screening
☐ Chapter 8, Follow-up Visits
☐ Chapter 24, Quality Control
☐ Chapter 25, Interviewing

4. ☐Complete review of 3 sets of medications, record on the Medication Inventory Form. Trainer uses and completes the Medication Inventory Certification Checklist during observation of the procedure.
5. ☐ Date of Certification _____

_____ _____
Signature of Program Coordinator Date Signature of Principal Investigator Date

LIFE Certification/Recertification Checklist
Medication Inventory

_____ __ __ __ __ __
Technician Name Staff ID

Observes the Following Procedural Steps:

1. ☐ Obtains proper form.
2. ☐ Greets participant and asks to see all prescription and over-the-counter medications taken during the past two weeks.
3. ☐ Writes the name of each medication on a separate line.
4. ☐ For each prescription medication, accurately and completely transcribes the name, strength, and units.
5. ☐ For each prescription medication, accurately indicates the formulation code, and whether or not the container was actually seen.
6. ☐ For each non-prescription medication, accurately and completely transcribes the name, strength, and units.
7. ☐ For each non-prescription medication, accurately indicates the formulation code and whether or not the container was actually seen
8. ☐ If participant did not bring in all their medications, asks participant for a medication list.
9. ☐ If participant did not bring in all their medications and a medication list is not available, asks participant to recall all the prescription and nonprescription medications that they have taken during the past two weeks.

Comments:_____
_____
_____
_____

Observer:_____ Date observed:_____

LIFE Certification/Recertification
Grip Strength

_____ __ __ __ __ __
Name Staff ID

1. ☐Attendance at LIFE training session _____ or
Date
☐Local training by a staff member certified in the procedure.

_____ _____
Date Name of Trainer

Description of local training:
_____

_____

_____

2. ☐ Become familiar with LIFE Study website.

3. Required Reading
   - ☐ Chapter 1, Protocol
   - ☐ Chapter 4, General Procedures
   - ☐ Chapter 6, Screening
   - ☐ Chapter 8, Follow-up Visits
   - ☐ Chapter 16, Physical Measures
   - ☐ Chapter 24, Quality Control

4. ☐Conduct 3 sets of measures, record on Grip Strength Form. Trainer uses and completes the Grip Strength Certification Checklist during observation of the procedure.
5. ☐ Date of Certification _____

_____ _____ _____
Signature of Program Coordinator &Date Signature of Principal Investigator & Date

LIFE Certification/Recertification Checklist
Grip Strength

_____ __ __ __ __ __
Name Staff ID

Observes the Following Procedural Steps:

1. ☐ Assembles proper materials and equipment: Jamar Handheld Dynamometer
2. ☐ Greets participant and reviews procedure.
3. ☐ Determines whether participant is right- or left-handed.
4. ☐ Determines whether participant has had a current flare-up of pain in his/her dominant wrist or hand or any surgery on his/her dominant hand or wrist in the past three months.
5. ☐ Sets the dynamometer handgrip at position appropriate for participant. Adjusts position for a smaller or larger hand when necessary.
6. ☐ Checks that arrow of dynamometer is set at ZERO.
7. ☐ Positions participant's arm properly on the table, with elbow bent, while seated in a chair.
8. ☐ Demonstrates how to properly grip bars of dynamometer and squeeze slowly and as hard as possible.
9. ☐ Allows one practice try to familiarize participant with the feel of the instrument.
10. ☐ Ensures that the bars are the right distance apart for a comfortable grip.
11. ☐ Shows dial to participant.
12. ☐ Tests the appropriate hand
13. ☐ Allows ten seconds of rest between the two trials.
14. ☐ Records each value to the nearest 2 kilograms.
15. ☐ Resets the arrow to zero after each reading.

Comments:_____
_____
_____
_____
_____

Observer:_____ Date observed:_____

_____ _____
Signature of Program Coordinator & Date Signature of Principal Investigator & Date

LIFE Certification/Recertification
Blood/Urine Collection

_____ __ __ __ __ __
Name Staff ID

1. ☐ Attendance at LIFE training session _____ or
Date

☐ Local training by a staff member certified in the procedure

_____ _____
Date Name of Trainer

Description of local training:
_____

_____

_____

2. ☐ Become familiar with LIFE Study website.

3. ☐ Required Reading: Chapter 13, Biological Sample Collection and Processing

4. ☐ Completes Blood Collection Certification Checklist and Urine Collection Certification Checklist Forms.

5. ☐ Date of Certification _____

Observer:_____ Date observed:_____

_____ _____
Signature of Program Coordinator & Date Signature of Principal Investigator & Date

LIFE Certification/Recertification Checklist
Blood Collection

_____ __ __ __ __ __
Name Staff ID

Observes/completes the following procedural steps on one volunteer:

1. ☐ Ensures informed consent has been given and the participant's safety at all times.
2. ☐ Assembles proper materials and equipment.
3. ☐ Completes the Phlebotomy Log.
4. ☐ Labels tubes and Phlebotomy Form.
5. ☐ Completes the Phlebotomy Form, covering all questions.
6. ☐ Performs venipuncture per proper technique, in the assigned tube order, timing the procedure with a stopwatch.
7. ☐ Places the appropriate tubes on ice after gentle mixing.
8. ☐ Inspects and provides a bandage to venipuncture site.
9. ☐ Delivers tubes to processing station at the appropriated temperatures.
10. ☐ Inputs data from the Phlebotomy Form into the LIFE web based data entry system.
    ☐ Data entry performed by other study personal.

Comments:_____

_____

Observer:_____ Date Observed:_____

LIFE Certification/Recertification Checklist
Urine Collection

_____ __ __ __ __ __
Name Staff ID

Observes/completes the following procedural steps on one volunteer:

1. ☐ Instructs the participant to drink a full glass of water 1 hour prior to the scheduled visit.
2. ☐ Ensures participant's safety at all times.
3. ☐ Labels Urine Collection Form and collection container
4. ☐ Gender-specific procedures explained to the participant.
5. ☐ Delivers container to processing station.
6. ☐ Inputs data from the Urine Collection Form into the LIFE web based data entry system.
   ☐ Data entry performed by other study personal.

Comments:_____

_____

Observer:_____ Date Observed:_____

LIFE Certification/Recertification
Blood/Urine Processing

_____ __ __ __ __ __
Name Staff ID

1. ☐Attendance at LIFE training session _____ or
Date
☐Local training by a staff member certified in the procedure

_____ _____
Date Name of Trainer

Description of local training:
_____

_____

_____

2. ☐ Become familiar with LIFE Study website.

3. ☐Required Reading: Chapter 13, Biological Sample Collection and Processing

4. ☐Required Reading: Investigator Manual from Diagnostic Testing Lab

5. ☐ Completes Blood Processing Certification and Urine Processing Certification Checklist Forms.

6. ☐ Date of Certification _____

_____ _____
Signature of Program Coordinator & Date Signature of Principal Investigator & Date

LIFE Certification/Recertification Checklist
Blood Processing

_____ __ __ __ __ __
Name Staff

During the procedure:

1. ☐ Ensures blood samples are handled appropriately on ice or in a sample tube Bench-top cooler during processing.

Observes the Following Procedural Steps:

2. ☐ Assembles proper materials and equipment:
3. ☐ Confirms Participant ID and Biological Specimen ID on Phlebotomy Log.
4. ☐ Labels all tubes/cryovials (so that the barcode runs vertically) and Blood Processing Form.
5. ☐ Processes 2ml lavender top tube and SST per diagnostic testing lab instructions.
6. ☐ Serum tubes are kept at room temperature for at least 30 minutes but no longer than 60 minutes prior to centrifugation.
7. ☐ Keeps tubes and cryovials at their appropriate temperatures at all times.
8. ☐ Process all tubes immediately after centrifugation.
9. ☐ Follows all steps in the Life Study Blood Processing chart.
10. ☐ Places the cryovials into a 2” labeled storage box and stores in a -70°C freezer.
11. ☐ Cleans processing area with 10% bleach or appropriate viral cleanser.
12. ☐ Records freezer and centrifuge temperatures.
13. ☐ Inputs data from the Blood Processing Form into the LIFE web based data entry system.
    ☐ Data entry performed by other study personal.

Comments: _____
_____

Observer:_____ Date Observed_____

LIFE Certification/Recertification Checklist
Urine Processing

_____ __ __ __ __ __
Name Staff

Observes the Following Procedural Steps:

1. ☐ Assembles proper materials and equipment
2. ☐ Labels all tubes/cryovials and Urine Collection Form.
3. ☐ Follows all steps in the LIFE MOP section on Urine Processing.
4. ☐ Centrifuges urine prior to aliquoting.
5. ☐ Places the cryovials into a 2" labeled storage box and stores in a -70°C.
6. ☐ Cleans processing area with 10% bleach or appropriate viral cleanser. Stocks
   processing area for the next day.
7. ☐ Inputs data from the Urine Processing Form into the LIFE web based data entry
   system.
   ☐ Data entry performed by other study personal.

Comments: _____

_____

Observer:_____ Date Observed_____

LIFE Certification/Recertification
Ankle Brachial Index

_____ __ __ __ __ __ __
Name Staff ID

1. ☐ Attendance at LIFE training session _____ or
Date
☐ Local training by a staff member certified in the procedure.

_____ _____
Date Name of Trainer

Description of local training (Include dates of at least 3 practice ABIs prior to certification:

_____

_____

2. Required Reading

☐ Chapter 1, Protocol
☐ Chapter 4 General Procedures
☐ Chapter 6, Screening
☐ Chapter 8, Follow-up Visits
☐ Chapter 14, Ankle Brachial Index
☐ Chapter 24, Quality Control
☐ Chapter 25, Interviewing

3. ☐ Views on-line video link (http://content.nejm.org/cgi/content/short/361/19/e40) of measurement.
4. ☐ Successfully completes quiz of ABI/PAD measurement (posted on the LIFE Study website: www.thelifestudy.org).
5. ☐ Conducts 3 practice ABIs
6. ☐ Successfully performs an ABI on one volunteer and meets all criteria on the ABI certification checklist.
7. ☐ Date of Certification _____

_____ _____
Signature of Trainer & Date Signature of Principal Investigator & Date

LIFE Certification/Recertification Checklist
Ankle Brachial Index

_____ __ __ ___ __ __
Name Staff

Observes the Following Procedural Steps:

Supine Ankle-Brachial Index

1. ☐ Directs patient to lie down in supine position, with a head pillow for comfort if needed.
2. ☐ Allows patient to relax in this position for at least 5 minutes before starting ABI test.
3. ☐ Advises patient that we will not talk during the ABI because we would like the patient to be completely relaxed.

(Right Brachial Artery)

4. ☐ Places blood pressure cuff of appropriate size over right brachial artery.
5. ☐ Locates brachial artery by palpation.
6. ☐ Applies ultrasound jelly over brachial artery.
7. ☐ Locates brachial artery using Doppler probe.
8. ☐ Locates maximum flow of brachial artery with Doppler probe.
9. ☐ Positions the Doppler probe so that it is pointed in the direction of oncoming flow.
10. ☐ Inflates cuff quickly to at least 20 mm Hg above maximal pressure.
11. ☐ Deflates at 2 mm Hg/second until a **sustained** systolic pressure is audible.
12. ☐ Deflates cuff quickly and completely.
13. ☐ Records systolic blood pressure at which a **sustained** pulse was first audible.

(Right Posterior Tibial Artery)

14. ☐ Locates right posterior tibial artery by palpation.
15. ☐ Applies ultrasound jelly over posterior tibial artery.
16. ☐ Locates right posterior tibial artery using Doppler probe.
17. ☐ Locates maximum flow of posterior tibial artery with Doppler probe.
18. ☐ Positions the Doppler probe so that it is pointed in the direction of oncoming flow.
19. ☐ Inflates cuff quickly to at least 20 mm Hg above maximal pressure.
20. ☐ Deflates cuff at 2 mm Hg/second until a **sustained** systolic pressure is audible.
21. ☐ Deflates cuff quickly and completely.
22. ☐ Records systolic blood pressure at which a **sustained** pulse was first audible.

(Left Posterior Tibial Artery)

23. ☐ Locates left posterior tibial artery by palpation.
24. ☐ Applies ultrasound jelly over posterior tibial artery.
25. ☐ Locates left posterior tibial artery using Doppler probe.
26. ☐ Locates maximum flow of posterior tibial artery with Doppler probe.
27. ☐ Positions the Doppler probe so that it is pointed in the direction of oncoming flow.
28. ☐ Inflates cuff quickly to at least 20 mm Hg above maximal pressure.
29. ☐ Deflates at 2 mm Hg/second until a **sustained** systolic pressure is audible.

30. ☐ Deflates cuff quickly and completely.
31. ☐ Records systolic blood pressure at which a **sustained** pulse was first audible.

(Left Brachial Artery)

32. ☐ Places blood pressure cuff of appropriate size over left brachial artery.
33. ☐ Locates left brachial artery by palpation.
34. ☐ Applies ultrasound jelly over brachial artery.
35. ☐ Locates brachial artery using Doppler probe.
36. ☐ Locates maximum flow of brachial artery with Doppler probe.
37. ☐ Positions the Doppler probe so that it is pointed in the direction of oncoming flow.
38. ☐ Inflates cuff quickly to at least 20 mm Hg above maximal pressure.
39. ☐ Deflates at 2 mm Hg/second until a **sustained** systolic pressure is audible.
40. ☐ Deflates cuff quickly and completely.
41. ☐ Records systolic blood pressure at which a **sustained** pulse was first audible.

(Repeat Readings)

42. ☐ Repeats entire set of ABI measurements in reverse order (Left brachial, left posterior tibial, right posterior tibial, right brachial arteries).
43. ☐ Calculates the ABI using the LIFE data entry software.

Observer: _____ Date Observed: _____

LIFE Certification/Recertification
Spirometry

_____ __ __ __ __ __
Name Staff ID

1. ☐ Attendance at LIFE training session _____ or
Date

☐ Local training by a staff member certified in the procedure.

_____ _____
Date Name of Trainer

Description of local training:
_____
_____
_____

2. ☐ Become familiar with LIFE Study website.

3. Required Reading

☐ Chapter 16, Physical Measures

☐ Viewed on-line didactic programs (see Spirometry Certification Checklist)

4. ☐ Received verification from Gail Flynn of the Yale Spirometry Reading Center that all components of required training have been successfully completed as indicated on the Spirometry Certification/Recertification Checklist.

5. ☐ Date of Certification _____

_____ _____
Signature of Program Coordinator & Date Signature of Principal Investigator & Date

LIFE Certification/Recertification Checklist
Spirometry

_____ __ __ __ __ __
Name Staff ID

Spirometry certification and recertification requires completion of three training phases.

Phase I. Didactic On-Line Training – *

1. ☐ Completes the on-line educational program, 'Spirometry Fundamentals' administered on-line at the University of Washington website: http://depts.washington.edu/spirofun/online/ (Please contact the Administrative Coordinating Center at LIFEACC@aging.ufl.edu to obtain a User Account to access the site for completion of the course.)
2. ☐ Completes online Spirometry training course at: http://spirotrain.com administered by __. (Please contact to obtain a User Account.)

* Routine annual recertification will only require item 1 above.

Phase II. Hands-on Training by Spirometry-trained LIFE Assessor at Local Field Center–

3. ☐ Asks exclusion questions
4. ☐ Explains procedure to participant
5. ☐ Asks participants if they use inhaler medications
6. ☐ Asks participant to loosen tight fitting clothing
7. ☐ Follows universal precautions
8. ☐ Properly enters ID information on computer
9. ☐ Positions participant properly (sitting position and head position)
10. ☐ Obtains three acceptable quality FVC maneuvers
    a. ☐ Effectively demonstrates the FVC maneuver
    b. ☐ Places a nose clip during the FVC maneuver
    c. ☐ Watches for maximum effort
    d. ☐ Enthusiastically coaches
    e. ☐ Evaluates for reproducibility and retests if necessary
11. ☐ Prints results
12. ☐ Exits program properly

Phase III. Follow-up training at the field centers –

13a. ☐ For the initial certification, completes 10 additional practice spirometries that meet ATS criteria and sends to __ for review.

13b. ☐ For recertification of assessors with suboptimal QC scores and at the discretion of QC supervisor (__), completes 5 additional practice spirometries that meet ATS criteria and sends to __ for review.

13c. ☐ For annual recertification, __of the Yale Spirometry Reading Center will review at least 5 spirometries that the LIFE assessor performed during the month subsequent to the completion of phase 1 and 2 training.

Please note: For initial certification or recertification of assessors with suboptimal QC scores, after completion of Phases I, II, and III training, this form should be submitted to LIFEACC@aging.ufl.edu. The ACC will forward this to __for further review.

For annual recertification, after completion of Phases I and II training, this form should be submitted to LIFEACC@aging.ufl.edu. The ACC will forward this to __ of the Yale Spirometry Reading Center for further review.

Comments:_____
_____
_____
_____

_____ _____
Observer Date observed

_____ _____ _ _

LIFE Certification/Recertification
Maximal Inspiratory Pressure (MIP) Certification

_____ __ __ __ __ __
Name Staff ID

1. ☐ Attendance at LIFE training session _____ or
Date

☐ Local training by a staff member certified in the procedure.

_____ _____
Date Name of Trainer

Description of local training:
_____
_____
_____

2. ☐ Become familiar with LIFE Study website.

3. Required Reading

☐ Chapter 16, Physical Measures

☐ Conducts 1 assessment, records on the maximal inspiratory pressure (MIP) data collection form. Trainer uses and completes the MIP Certification Checklist during observation of the procedure.

☐ Received confirmation from Gail Flynn of the Yale Spirometry Reading Center that all steps of the required training have been completed as indicated on the MIP Certification/Recertification Checklist.

4. ☐ Date of Certification _____

_____ _____
Signature of Program Coordinator & Date Signature of Principal Investigator & Date

LIFE Certification/Recertification Checklist
Maximal Inspiratory Pressure (MIP) Certification

_____ __ __ __ __ __
Name Staff ID

Hands-on MIP Central Training (Procedural Steps) –

1. ☐ Aware that MIP testing is performed after completion of spirometry.
2. ☐ Positions participant properly (sitting position and head position)
3. ☐ Obtains five MIP maneuvers,
   a. ☐ Demonstrates the MIP maneuver
   b. ☐ Places a nose clip during the MIP maneuver
   c. ☐ Watches for maximum effort
   d. ☐ Enthusiastically coaches
   e. ☐ Evaluates for reproducibility (i.e. the highest two readings are within 10 cm H2O) and retests if necessary
4. ☐ Docum ents results
5. ☐ Upon completion of Items 1-4, this form should be submitted to LIFEACC@aging.ufl.edu. The ACC will forward to __ of the Yale Spirometry Reading Center to determine that training requirements have been met as indicated on the MIP Certification/Recertification Checklist.

Comments:_____
_____
_____
_____

_____ _____
Observer: Date Observed:

_____ _____
Gail Flynn Date

LIFE Cognitive Assessment
Certification

Complete this form and mail it, along with your mock test administration, to the LIFE Cognition Coordinating Center.

_____ _____ __ __ __ __ __

Technician Name Field Site Staff ID

1. ☐ Attendance at LIFE training session _____ OR
Date

☐ Local training by a staff member certified in the procedure.

_____ _____
Date Name of Trainer

Description of local training:

_____

_____

2. ☐ Become familiar with LIFE Study website

3. Required Reading:
☐ Protocol
☐ LIFE MOP Chapter 15: Cognitive Assessment

4. ☐ Administer the cognitive test battery on at least four volunteers according to the description in the training manual.

5. ☐ Conduct a mock administration on an age appropriate volunteer and mail the mock administration (forms and tape) to:

LIFE Cognition Coordinating Center
Wake Forest University School of Medicine
Medical Center Boulevard
Winston-Salem, NC 27157-1207

To be completed by the Coordinating Center:

Date of Certification _____

_____
Signature of Coordinating Center Reviewer

LIFE Certification/Recertification
Interviewing

_____ __ __ __ __ __ __
Name Staff ID

6. ☐ Attendance at LIFE training session _____ or
Date
☐ Local training by a staff member certified in the procedure.

_____ _____
Date Name of Trainer

Description of local training:
_____

_____

7. Required Reading

☐Chapter 1, Protocol
☐Chapter 4 General Procedures
☐Chapter 6, Screening
☐Chapter 8, Follow-up Visits
☐Chapter 24, Quality Control
☐Chapter 25, Interviewing

8. ☐Conducts interviews on one volunteer according to the description in Chapter 25. This includes administering the Disability and HRQL Questionnaires. The interviews are observed directly by the trainer.

9. ☐Date of Certification _____

_____ _____
Signature of Program Coordinators & Date Signature of Principal Investigator & Date

LIFE Certification/Recertification Checklist
Interviewing

_____ ___ ___ ___ __ __
Name Staff

Observes the Following Procedural Steps:

1. ☐ Properly greets participant
2. ☐ Reads slowly in a natural conversational rhythm and in a normal tone of voice
3. ☐ Always reads the entire question before getting the participant's response
4. ☐ Is aware of the participant's facial expressions, e.g. puzzled, confused
5. ☐ Asks every question
6. ☐ Repeats questions if it is answered inappropriately, but repeats it exactly as written.
7. ☐ Offers to reread a question if participants does not understand the question
8. ☐ Asks questionnaire items in order and exactly as worded
9. ☐ Correctly codes participant's responses on the data collection forms

Observer: _____ Date Observed: _____

LIFE Certification/Recertification
CHAMPS

_____ __ __ __ __ __ __
Name Staff ID

1. ☐ Attendance at LIFE training session _____ or
Date
☐ Local training by a staff member certified in the procedure.

_____ _____
Date Name of Trainer

2. Required Reading

☐Chapter 1, Protocol
☐Chapter 4 General Procedures
☐Chapter 6, Screening
☐Chapter 8, Follow-up Visits
☐Chapter 24, Quality Control
☐Chapter 25, Interviewing

3. ☐Conducts practice interviews on 3-5 older volunteers and then conducts a final interview while being evaluated by the designated site investigator. The site investigator must complete the LIFE certification/recertification checklist for CHAMPS on the interviewer being certified.

4. ☐Date of Certification _____

_____ _____
Signature of Program Coordinator & Date Signature of Principal Investigator & Date

LIFE Certification/Recertification Checklist
CHAMPS

_____ ___ ___ ___ __ __
Name Staff

Observes the Following Procedural Steps:

1. ☐Read required material
2. ☐Is knowledgeable about MET capacity and MET demands of the activities in the CHAMPS Questionnaire
3. ☐Is not judgmental in relation to participant responses
4. ☐Is not biased in asking questions
5. ☐Is accurate in his/her determination of the frequency spent in various physical activities on a weekly basis
6. ☐Demonstrates skill in probing time spent in various activities
7. ☐Is effective in discriminating between single and multiple bouts of physical activity
8. ☐Does not give credit for single activity in two different categories

Observer: _____Date Observed: _____

LIFE Certification/Recertification
Data Entry

_____ __ __ __ __ __
Name Staff ID

1. ☐ Attendance at LIFE training session _____ or
Date

☐ Local training by a staff member certified in the procedure.

_____ _____
Date Name of Trainer

Description of local training:
_____

_____

_____

2. ☐Become familiar with LIFE Study website.

3. Required Reading

☐ Chapter 1, Protocol

☐ Chapter 4, General Procedures

☐ Chapter 7, Randomization

☐ Chapter 23, Data Management

☐ Chapter 24, Quality Control

☐ Chapter 26, Study Organization and Policies

3. ☐Enter information to and print participant labels using label application. Assign acrostic to participant. Complete entry of 3 sets data entry forms: Telephone Screener, 400 M Walk, and SPPB. Trainer uses and completes the Data Entry Certification Checklist during observation of the procedure. The program verifies data entered.

4. Data verified by (Program Coordinator):_____

5. Date of Certification _____

_____ _____
Signature of Program Coordinator & Date Signature of Principal Investigator & Date

LIFE Certification/Recertification Checklist
Data Entry

_____ __ __ __ __ __
Name Staff ID

Observes the Following Procedural Steps:

1. ☐ Obtains telephone screener and enters data into label application.
2. ☐ Correctly prints labels for participant entered.
3. ☐ Correctly assigns acrostic for participant.
4. ☐ Opens data entry application on website and enters Telephone Screening Interview, CHAMPS, and SPPB.
5. ☐ Files completed forms as required by site.
6. ☐ Verified data entered.

Comments:_____
_____
_____
_____
_____

Observer:_____ Date Observed:_____

LIFE Certification/Recertification
Physical Activity Intervention Specialist

_____ __ __ __ __ __
Name Staff ID

1. ☐ Attendance at LIFE training session _____ or
Date

☐ Local training by a staff member certified in the procedure.

_____ _____
Date Name of Trainer

Description of local training:
_____

_____

2. ☐ Become familiar with LIFE Study website.

3. Required Reading
   - ☐ Chapter 1, Protocol
   - ☐ Chapter 4, General Procedures
   - ☐ Chapter 8, Follow-up Visits
   - ☐ Chapter 9, Retention Activities
   - ☐ Chapter 10, Physical Activity and Successful Aging Education Intervention
   - ☐ Chapter 21, Safety Management
   - ☐ Chapter 22, Adverse Events
   - ☐ Chapter 24, Quality Control
   - ☐ Appendix D, Exercise Interventionist's Training Guide

4. ☐ Date of Certification _____

_____ _____
Signature of Program Coordinator & Date Signature of Principal Investigator & Date

LIFE Certification/Recertification Checklist
Physical Activity Intervention Specialist

_____ __ __ __ __ __ __ __
Name Staff ID

During Procedure:

1. ☐ Ensures participant's safety at all times.

Observes the Following Procedural Steps:

2. ☐ Properly greets and orients new participant to exercise program

3. ☐ Familiar with exercise training form and log
4. ☐ Can complete baseline assessment of vital signs, RPE instructions, and pedometer use
5. ☐ Records walking data appropriately and monitors participant
6. ☐ Successfully obtains post-walking vital signs and completes all forms completely
7. ☐ Instructs flexibility exercises appropriately
8. ☐ Can properly instruct and supervise resistance training, records weights and RPE for each exercise
9. ☐ Administers balance training appropriately
10. ☐ Logs all attendance sheets and missed forms appropriately
11. ☐ Familiar with Field Center emergency procedures and reporting of all Events
12. ☐ Can adequately review "home-based participant log" and inform the participant

Behavioral, Group, and Counseling Skills

1. ☐ Demonstrates competence in initial contact and telephone contact counseling
2. ☐ Demonstrates appropriate basic counseling skills

Data Entry

1. ☐ Physical Activity Session form

Comments:

_____
_____
_____
_____

Observer: _____ Date Observed: _____

LIFE Certification/Recertification
Successful Aging Workshop Leader / Intervention Specialist

_____ __ __ __ __ __
Name Staff ID

1. ☐Attendance at LIFE training session _____ or
Date

☐Local training by a staff member certified in the procedure.

_____ _____
Date Name of Trainer

Description of local training:
_____

_____

2. ☐Become familiar with LIFE Study website.

3. Required Reading
   - ☐ Chapter 1, Protocol
   - ☐ Chapter 4, General Procedures
   - ☐ Chapter 8, Follow-up Visits
   - ☐ Chapter 9, Retention Activities
   - ☐ Chapter 10, Physical Exercise and Health Education Intervention
   - ☐ Chapter 21, Safety Management
   - ☐ Chapter 22, Adverse Events
   - ☐ Chapter 24, Quality Control
   - ☐ Appendix E, Workshop Interventionist's Training Guide

4. ☐Date of Certification _____

_____ _____
Signature of Program Coordinator & Date Signature of Principal Investigator & Date

LIFE Certification/Recertification Checklist
Successful Aging Workshop Leader / Intervention Specialist

_____ __ __ __ __ __ __
Name Staff ID

During Procedure:

1. ☐ Ensures participant's safety at all times

Interpersonal Skills:

1. ☐ Enthusiasm towards participants
2. ☐ Listens actively to participant

Observes the Following Procedural Steps:

1. ☐ Properly greets and orients new participants to the workshops
2. ☐ Conducts Check-In with each participant
2. ☐ Familiar with protocols and forms
3. ☐ Demonstrates working knowledge of workshop scheduling procedures (i.e., when calendar schedule should be finalized, when presentations should be confirmed, when participants should be informed of class schedule)
4. ☐ Demonstrates proficiency in developing workshop series (i.e., can draft initial schedule, create list of contacts & activity ideas, etc.)
5. ☐ Demonstrates proficiency in executing scheduled telephone contacts
6. ☐ Creates and presents a minimum of one workshop class with original presentation content, handouts and activities (can be waived if classroom instruction was performed in previous work role and has been observed by site coordinators.)
7. ☐ Instructs upper extremity stretching exercises appropriately
8. ☐ Familiar with Field Center emergency procedures and reporting of all Events

Data Entry

1. ☐ Successful Aging Attendance Form

Observer: _____ Date Observed:_____

Appendix B

Program Coordinator Training Guide

Program Coordinator Training Guide

Site:_____ Date: _____

Site ID:_____

Staff:

Principal Investigator: _____

Program Coordinator:
_____

Recruitment Coordinator: _____

Medical Safety
Officer:_____

MD/Study
Physician:_____

Phlebotomist (s)
:_____

Interventionists: Successful Aging:

_____

Physical Activity:

Other Staff:

Name	Primary Role
_____	_____
_____	_____
_____	_____

1. **Suggested Meetings**

These meetings should already be in place or should be scheduled within the first week.

General Staff (weekly)
Attendees: PC, screening staff, phlebotomist, medical safety officer, assessor, interventionists, PI (if available)

Meeting time/day:_____

Usual Attendees:_____

_____

_____

- This meeting should focus on the status of current clinic operations (i.e., is your clinic currently screening? randomizing?); pay special attention to screening/randomization windows.

Notes:_____

_____

_____

Recruitment (conduct as needed)
Attendees: PC, RC, PI

Usual Attendees:_____

_____

_____

- Your initial recruitment meeting should educate you on where your clinic is at in terms of recruitment (numbers).
- What forms of advertising are currently in effect?
- What are the procedures for orientations (staffing, materials)?
- How many participants are currently awaiting orientation or are in the screening process?
- How does your clinic follow up on ineligibles and re-screens? Is this handled by phone call and/or letter?

Notes:_____

_____ _____

_____ _____

Phlebotomy (conduct as needed)

Attendees: PC, phlebotomist

- Review the responsibilities of your phlebotomist
- Who handles specimen processing and shipping?

_____ _____

- Does your phlebotomist maintain all blood processing supplies with the central laboratory?

_____

Notes:_____ _____

_____

2. Clinic Operations

Screening

- Identify which staff are involved in screening visits; how and when is the data that is collected (including the pre-screen) data entered?

_____

_____

_____

- Who handles scheduling and re-scheduling?

_____

- Become familiar with the space in your clinic where various measures are carried out.

- Do you have a protocol for when a participant has high blood pressure or scores high on CES-D and low on the MMSE?

_____ _____

_____

Notes:_____

_____

_____

Randomization

- Who randomizes participants at your center?

- When do you administer the pre-randomization review?

_____

- Who insures that the eligibility form is entered prior to randomization?

_____

- Who delivers the randomization instructions

- _____ _____

- Remember: when randomizing, don't forget to print the screen that tells the randomization status!
-
- Is a confirmation letter sent out to participants after randomization reminding participants of the date and time of their first intervention visit?_____

Notes:_____

_____

_____

Semi Annuals

- Who schedules participants for their semi annual visits?

_____

- How are participants paid their honorarium?

_____

- Is there a good system for data entry?

_____

_____

Notes:_____ _____

_____

Data Management

- Where are participants charts located?

_____

- Who is responsible for filing source documents?

_____

- Is there a quality control procedure for the data in the charts to insure completeness and accuracy?_____

  _____
- Is their a data “manager” who can oversee data entry and timeliness?_____

  _____

- Become familiar with the forms that are currently in use; know where master copies are kept and who manages the upkeep of current forms.
- Who insures that the appropriate version of forms is always in use? Are copies always available and does staff know where they are located?_____

  _____

  _____
- Review the flow of forms (i.e., how do all source documents arrive in a chart when some are handled by intervention, nurse, phlebotomist, screening staff, etc.?)_____

  _____

Notes:_____ _____

_____ _____

_____ _____

Equipment/Supplies

- Review your clinic’s procedures for equipment calibration
- Who manages supplies?_____
  - Exam table paper
  - ECG paper
  - Participant snacks
  - Run-in diaries
  - Forms, binders
- Locate the LIFE incentive items
  - Is there an inventory list? Tracking system for what is given out and when?

    _____

    _____

3. Items for Independent Training

- Complete any certification that may be required with your IRB
  - Become familiar with your own IRB procedures (i.e., when does your IRB meet to review changes to protocol?)
  - Locate the institutional forms on which changes to protocol should be submitted.

  Notes: _____
  _____
  _____

  - Where are current copies of consents kept? Who insures that approvals from IRB are received?

    _____

    _____

- Adverse Event Reporting
  - Insure that all staff are aware of what events should be classified as "adverse" (your IRB may require submission of certain events that LIFE does not, and vice versa).
  - Who submits adverse events to IRB?

    _____

  - Who enters adverse events in the LIFE web-based data entry system? Who data enters the event into the LIFE database?

    _____

    _____

  - Who insures "approval" from IRB?

    _____

  - Where are these forms filed?

    _____

- Staff Certifications
  - Review current staff certifications; is the LIFE website up to date?
  - Is there a staff person in charge of overseeing certifications?

    _____

  - How does your clinic staff stay current and prevent expirations?_____

    _____

  - Where are the hard copy certification forms located? Are PC/PI sign-offs up to date?

    _____

- Committee Involvement
  - Is the PC a member of any committees?

    _____
    _____
  - What are his/her responsibilities?

    _____
    _____
    _____

- LIFE Website
  - Become familiar with the LIFE website; make sure you have access to what you need
  - Become familiar with all of the reports that are available to you; these reports can be useful in helping you to determine how your clinic is doing.

- Ancillary Studies
  - Which ancillary studies are being conducted at your site?

    _____
    _____
  - Who coordinates the ancillary studies?

    _____
  - How are you informed of activities and issues?

    _____
    _____
  - Who handles IRB issues related to ancillary studies(updating consents, submitting AE's, etc.)_____

    _____

Suggested Databases

Your clinic may want to consider establishing some of the following databases and files to help with clinic flow:

- Participant Tracking Log: this is a database containing the name of anyone who fills out a pre-screen; you may want to include columns such as work and home phone number, DOB, address, and eligibility status; this database helps determine the number of participants your clinic needs to screen before starting a group.

- Randomiz ation Databases: you may want to include columns such as address, PID, acrostic, phone numbers, date of randomization, and randomization status; since this is a good place to keep patient addresses current, you may want to mask the column listing randomization status (in case blinded staff have access)
- Medical Mailings: This database would list the names, addresses, and phone numbers of participants' primary care doctors; this database can be used to document that patient results are sent at appropriate times.
- Outcomes Tracking: Keep a separate outcomes database for participants; columns should include the window in which the measure should be completed and a notes column for any special comments about the patient.
- Recruitment Activity Database
- Labels (names and addresses of participants)
- Master LIFE Calendar: You may want to post a monthly calendar that includes all meetings, group times for intervention and staff vacations.

Suggested Letters

The following form letters may be helpful so that customized letters do not need to be recreated for every occasion:

- Participant Instruction Letters: These letters notify participants about how to prepare for certain screening visits, randomization visit, and semi annual f/u visit.
- Inelig ible Letters: These letters may follow a personal phone call to notify the participants that they are ineligible due to age, physical performance or health conditions; it is also helpful to have some sort of "generic" ineligible letter.
- Rescreen Letters: For temporary exclusion criteria.
- Invitations: For first intervention group
- Results Letters: For participants' screening and annual results; for doctors re: CES-D results
- Outcomes: Letters that accompany questionnaires that are mailed out.

Appendix C

Physical Activity Interventionist Training Guide

Physical Activity Interventionist Training Guide

Site:_____
Clinic ID:_____

Exercise Staff:

Name	Primary Role
_____	_____
_____	_____
_____	_____
_____	_____
_____	_____
_____	_____
_____	_____

Required Reading

LIFE MOP

Chapter 1, Protocol

Chapter 4, General Procedures

Chapter 8, Follow-up Visits

Chapter 9, Retention Activities

Chapter 10, Physical Exercise and Health Education Intervention

Chapter 21, Safety Management

Chapter 22, Adverse Events

Chapter 24, Quality Control

Appendix D, Exercise Interventionist's Training Guide

- R eview Protocol
- Revie w MOP

2. Suggested Meetings

These meetings should already be in place or should be scheduled within the first week.
Intervention meeting (weekly)
Attendees: PC, Medical monitor, Intervention Staff, Recruiter, study MD, PI (if available)

Meeting time/day:_____

Usual Attendees:_____
_____ _____
_____

This meeting should focus on the status of current intervention operations (i.e., progress of the intervention groups); pay special attention to issues surrounding delivery of the intervention, exercise training capacity, tracking attendance and compliance with the intervention.

Notes:_____
_____
_____

How (and where) are visits scheduled? Which staff person schedules the visits? Who insures that participants are attending all required visits?_____
_____

How are adverse events/side effects handled?
_____
_____

Notes:_____
_____

. Field Center Operations

Exercise facility

Identify which staff are involved in exercise training; how and when is the training data that is collected (including the participant logs) data entered?
_____
_____
_____

Are the behavioral sessions being scheduled properly?

_____

Become familiar with the space in your clinic where the exercise and "successful aging" interventions are carried out.

_____

Are there adequate steps taken to minimize contamination of the control group?

_____

Notes:_____

_____

_____

Are steps taken to ensure blinding of the assessment group from the intervention randomization?

_____

Who is responsible for scheduling exercise sessions and reviewing attendance and compliance with the intervention?

Notes:_____

_____

_____

Data Management

Where are participants exercise training forms located?_____

Who is responsible for filing source documents?

Who is responsible for reviewing the "Participant Logs"?

Who is responsible for ensuring the return of "Participant Logs"

_____

Who is responsible for the monthly behavioral telephone calls?

_____

Is there a quality control procedure for the data in the charts to insure completeness and accuracy?_____

_____

Is their a data "manager" who can review data entry and timeliness?_____

_____

Become familiar with the training forms that are currently in use; know where master copies are kept and who manages the upkeep of current forms.

Who insures that the appropriate version of forms is always in use? Are copies always available and does staff know where they are located?_____

_____

_____

Notes:_____

_____

_____

Equipment/Supplies

Review your clinic's procedures for maintaining exercise equipment

Who manages supplies?_____
Pedometers
Sphygmomanometers
Stethoscopes
Stopwatches
Training logs
Training forms
Ankle Weights

3. Items for Independent Training

Complete any certification that may be required
Are all intervention staff familiar with all emergency procedures
-
Have all staff completed Basic Life Support Training
-
Have all intervention staff completed the LIFE exercise interventionist certification and re-certification training.
Notes: _____
_____
_____

Are all staff familiar with the LIFE exercise training protocol and trained in delivering and monitoring the exercise intervention with the participants.

Notes: _____
_____
_____

Are all behavioral staff familiar with the LIFE behavioral intervention protocol and trained in delivering the behavioral content.

Notes: _____
_____
_____

Adverse Event Reporting
Insure that all intervention staff are aware of what events should be classified as "adverse" (your IRB may require submission of certain events that LIFE does not, and vice versa).
Who submits adverse events to IRB?
_____

Who submits adverse events to the Administrative Coordinating Center? Who data enters the event into the LIFE database?
_____
_____

Many AE's have an accompanying intervention modification form; this should be obtained by the interventionists and then data entered.
_____
_____

Are intervention staff familiar with the intervention modification form and how it is to be completed?

_____

Where are these forms filed?

_____

Staff Certifications
Review current intervention staff certifications; is the LIFE website up to date?

_____

How does your clinic staff stay current and prevent expirations?_____

_____

Where are the hard copy certification forms located? Are PC/PI sign-offs up to date?

_____

_____

Suggested Databases

The intervention staff interfaces and accesses the following databases:
Participant Tracking System: this is a database containing the data obtained from intervention visits, study milestones, attendance and compliance tracking, some demographic information.

Medical Mailings: This database has the names, addresses, and phone numbers of participants' primary care doctors; this database can be used to document that patient results are sent at appropriate times.

Suggested Letters

The following form letters may be helpful so that customized letters do not need to be recreated for every occasion:

Participant Instruction Letters: These letters describes the process to report any abnormal physical signs and symptoms to the intervention and provides staff contact information.

Appendix D

Successful Aging Workshop Leader Training Guide

Successful Aging Workshop Leader
Training Guide

Site:_____

Clinic ID:_____

Staff:

Workshop Leader: _____

Workshop Assistant:_____

LIFE Program Coordinator:_____

_____

Direct Supervisor for Workshop Leader:_____

Items for Independent Training at Field Centers

□ Revie w MOP
□ Review Protocol Forms
□ Assess potential classroom/meeting space and A/V equipment (see suggested items in MOP: Workshop Format)
□ Develop initial interest list of Workshop Topics & presenters
□ Complete any certification that may be required with your institution and IRB (e.g., HIPAA, health and safety)
□ Review Adverse Event Reporting: Insure that all staff are aware of what events should be classified as "adverse" (your IRB may require submission of certain events that LIFE does not, and vice versa).
□ LIFE Website
Become familiar with the LIFE website; make sure you have access to what you need (i.e., intervention, etc.)

Suggested Meetings at Field Centers

□ Screening/Randomization staff: The Workshop Leader should meet with the staffers who explain the content of the interventions to prospective participants to ensure they have a full understanding of the Workshops and can properly explain/describe it.
□ Program Coordinator/Workshop Aide: The Workshop Leader should meet with these staffers on a regular basis to discuss items related to the general operation of the condition (workshop calendar, scheduling difficulties, participant issues, space or equipment needs, etc).

Data You Need to access to operate the Workshops at Field Centers:
Review with your site the systems in place to record and access the following data.

□ Participant Contact Information: Name, phone numbers, DOB, address.
□ Randomiz ation Information: Study ID of participants actually randomized, date of randomization, and randomization outcome (i.e., which condition).
□ Mailin gs: This database should track the date and content of mailed materials sent to participants pertaining to the workshop condition (i.e., calendar schedules and project newsletters).
□ Workshop Attendance/ Adherence Tracking: Keep up-to-date information on participant attendance at workshops & executed telephone contacts.
□ Master LIFE Calendar: A monthly calendar that includes all meetings, recruitment and screening activities, intervention contacts, assessments and staff vacations helps keep the Workshop operations coordinated with other study activities.

CENTRALIZED TRAINING ACTIVITIES

1. Conduct of the Successful Aging Workshops (see Workshop MOP).
□ Review class format, class time breakdown, resources required.
□ Review guidelines for timing and scheduling of workshop topics.
□ Clarify/confirm criteria for class presenters/speakers.
□ Review timeline for scheduling guest speakers.
□ Review forms and sample letters for guest speaker contacts.
□ Confirm workshop topics (i.e., allowable vs. unallowable topics, potential for contamination)
□ Review & practice Upper Extremity Stretching Protocol
- Certification on performance

2. Additional Intervention contacts with Participants
□ Review & practice protocol for Post-Randomization session
- Rehearse with "Description and Expectations" Form

□ Telephone Contacts (TONE)
- Review script and protocol guidelines

□ Post-Intervention DeBriefing Session
- Review/rehearse protocol
- Determine post-intervention options for participants

3. Participant Mailings
□ Review suggested mailings (newsletters, calendar schedules)
□ Review/clarify appropriateness of content, format, frequency of mailing

4. Participant Safety
□ Review MOP Chapter 21 for guidelines