Chapter 20

QUALITY CONTROL

OVERVIEW

Study-wide quality control is the ultimate responsibility of the LLFS field centers and the Data Management and Coordinating Center (DMCC). The LLFS Program Coordinator at each clinical site must become familiar with LLFS requirements and schedule clinical activities so that there is adequate time for assessment staff to carry out their responsibilities while meeting quality standards.

TRAINING

Key clinic staff from each field center is trained at the initial LLFS central training session. LLFS 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 LLFS 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 for all staff groups at the same time as training for new field staff at that field center. These sessions focus on current issues facing the staff, new components implemented in the clinics, and problem areas.

Certification: Certification is required of LLFS staff which performs 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 at the end of this chapter. 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 documents should not be sent to the Coordinating Center. Completion of certification should also be documented on the Staff ID and Certification Form and subsequently entered in the online LLFS REDCap data entry system certification database.

Table 1.

LLFS Components Requiring Certification
Grip strength
Performance measures (SPPB)
Blood pressure
Waist circumference
Height measurements (standing, seated, arm span, knee height)
Weight
Ankle Arm Index
Interviewing Skills for administered questionnaires
Spirometry
Medication Inventory panel
Blood Collection and Processing
Cognitive Measures (MMSE, Logical Memory, DSST, Category Fluency)
REDCap Data Entry
Carotid Ultrasound

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

1. Attendance at the LLFS centralized training session or training by someone certified in the measurement/procedure;
2. Required reading: Manual of Procedures (All Personnel should review the full Visit 2 Manual of Procedures as many sections/questionnaires have changed and there are a few new sections/questionnaires.)
3. Plus additional items listed on the certification forms (See forms at the end of this chapter).
4. Attendance at Carotid Ultrasound Training, followed by 8 weeks of practice at your field center and then the certification at your field center.

Attendance at central training is not sufficient for certification! Those who attended the central training session must also complete items #2, 3, and 4 above.

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

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 LLFS MOP chapters, as well as an opportunity to carefully review the required steps for various measurements and procedures.

Recertification for each of the measures listed in Table 1 will be conducted on an annual basis (within 1 month of the anniversary from last certification) or on an as needed basis when a Research Tech has not performed a measure at least twice in any calendar month. 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 documents should not be sent to the Coordinating Center. Completion of recertification should also be documented on the Staff ID and Certification Form and subsequently entered in the online LLFS REDCap Data entry system.

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

- Required reading/review of designated chapters in the Manual of Procedures
- Observation and critique by a staff member certified in the measurement or procedure
- Additional items as listed on the recertification forms (Appendix A).

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

QUALITY CONTROL ACTIVITIES

Field Center Activities: Specific quality control activities to be carried out at the LLFS field center include:

1. Certification/recertification of clinic staff in all components listed in Table 1.
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 visits.

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 end of the in person examination).
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 LLFS DMCC 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 LLFS participant. Corrective action should be taken immediately if problems are observed.

The field center staff is encouraged to communicate with the DMCC about quality control or other concerns or problems. The Certification Log is maintained in the LLFS REDCap Data Entry System.

Equipment: The LLFS investigators have standardized much of the equipment for the study. Such standardization (and the attendant maintenance and calibration of the equipment) assures one level of reliability across the LLFS field centers. Each field center is responsible for the proper operation and maintenance of equipment used in the LLFS 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 (clinical coordinator). Any real or suspected equipment problems should be reported promptly to the 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 corresponding field center.

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 LLFS DMCC at periodic intervals.

Data Quality: Field center staff is asked to review all of the participants' questionnaires and data collection forms prior to ending each in person 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 DMCC reviews copies of selected participant forms. Thereafter; forms are reviewed on a periodic basis, and may include a subset of forms or recognized "problem forms". The DMCC staff verifies that the forms are legible and that they are filled out correctly and completely. The REDCap online forms 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 REDCap forms, in addition to range checking of fields.

The DMCC 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.

Coordinating Center Activities: Quality assurance is a major activity of the Data Management and 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 LLFS study data takes place at the DMCC 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 Observational 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
- Errors in collection, labeling, storage, or shipping of laboratory specimens

It is the responsibility of DMCC 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.

Reports to NIA and Steering Committee: During all phases, monitoring reports and analyses are to 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.

Observation Study Monitoring Board Activities: The Observational Study Monitoring Board (OSMB) is an independent panel of experts who review and advise on the scientific and operational progress of LLFS. The OSMB 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 OSMB also reviews and advises on proposed changes in the protocol originating from the Steering Committee and proposals for ancillary studies.

The charge of the OSMB 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 relating to efficacy, recruitment, compliance, protocol adherence, study operating procedures, forms completion, 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
- Make recommendations regarding recruitment, compliance, safety issues and continuation of the study

- Send the Program Administrator and PI written reports following each OSMB meeting
- The study PI is responsible for sending the reports to individual site PIs, who in turn are required to distribute the report to their local IRBs
- The OSMB may convene an executive session at any time. The PI and Project Officer would attend these meetings
- At any time, the OSMB may recommend discontinuation of any component of the study for any of the following reasons:
    - Compelling evidence from this or any other study
    - A very low probability of addressing the study goals within a feasible time frame

Changes in the Manual of Procedures (MOP): Changes in the MOP may need to be made from time to time. A draft of all suggested changes to a MOP chapter is sent to the DMCC (LeAnne Kniepkamp, Program Manager). These changes will be forwarded to the prime mover of that chapter for Visit 2. If the prime mover agrees with the modifications, they will be reviewed by the Steering Committee before the revised version is posted on the LLFS 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 next regularly scheduled meeting.

Changes in Forms: The LLFS Web site lists all of the study forms and identifies the current Version number and Date for each form. Minor changes in a form will not change the Version Number but will change 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.

Suggested changes to forms should be sent to the DMCC (LeAnne Kniepkamp, Program Manager). These will then be forwarded to the prime mover for that form and chapter for Visit 2. If the prime mover agrees with the changes, they will be reviewed by the Steering Committee before the new version is distributed. Clinic staff is advised via E-mail when a new version of a form is posted to the study web-site.

SITE VISITS

The Data Management and Coordinating Center (DMCC), with other study personnel from other sites, will make site visits at each field center as warranted. The site visit program provides a mechanism to encourage the effective and standardized delivery of recruitment efforts and the collection of appropriate and valid data within each of the LLFS 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 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 LLFS clinic staff who are collecting the data. It is these individuals who have the day to day experience, and firsthand 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 Visit 2 participants. This enables the Study to look at 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".

Organization of the Site Visit: The site visits are designed to insure that each LLFS 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 collecting data and facilitating a smooth clinic flow.

A key to a successful site visit is adequate preparation both from 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 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 data collection and data entry?
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?

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:

1. Informed consent and appropriate signatures;
2. Complete data forms and questionnaires; and
3. 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 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.

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 LLFS investigators. Similarly, a periodic site visit of the Coordinating Center is made by investigators and staff from other LLFS sites.

APPENDIX A

LLFS Certification Checklist
Grip Strength

_____ ____ ____ ____
Name Staff ID

Observes the Following Procedural Steps:

1. ☐ Assembles proper materials and equipment: Jamar Handheld Dynamometer and a straight-backed chair
2. ☐ Greets participant and reviews procedure
3. ☐ Determines whether participant meets exclusion criteria
4. ☐ Has the participant seated comfortably on a standard chair.
5. ☐ Determines whether participant is right- or left-handed
6. ☐ Sets the dynamometer handgrip at position "2" (or other relevant position due to size of hand)
7. ☐ Checks that arrow of dynamometer is set at zero
8. ☐ Demonstrates how to properly grip bars of dynamometer and squeeze slowly and as hard as possible
9. ☐ Positions participant seated with his/her shoulder adducted and neutrally rotated.
10. ☐ Elbow flexed at 90^o, forearm flexed in neutral position and wrist between 0^o and 30^o and between 0^o and 15^o ulnar deviation.
11. ☐ Offers standard encouragement to participant
12. ☐ Shows dial to participant
13. ☐ Reads dynamometer at eye level
14. ☐ Records each value, rounding to the nearest 2 kg
15. ☐ Resets the arrow to zero after each reading
16. ☐ Allows 10 seconds of rest between trials
17. ☐ Performs 3 test with each hand (when possible)

Comments: _____

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Observer:_____ Date observed:_____

LLFS Certification Checklist

Short Physical Performance Battery (SPPB)

_____ ____ ____ ____

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, 15 foot chain, script, score sheet, and a straight-backed chair, standard for all sites
3. ☐ Properly sets up course layout for the measured walk
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: (balance, gait speed, chair stand)
7. ☐ Provides instructions exactly as they are written in the script
8. ☐ Properly demonstrates each maneuver
9. ☐ Ensures that participant understands the instructions
10. ☐ Scores each maneuver correctly
11. ☐ Provides explanation when a specific maneuver is not attempted
12. ☐ Positions participants correctly for each maneuver
13. ☐ Positions himself/herself correctly for each maneuver
14. ☐ For balance tests, stabilizes participant until feet are in correct position
15. ☐ Times the balance tests correctly
16. ☐ Records length of walking course
17. ☐ Instructs participant to walk at their usual pace
18. ☐ Times the measured walk correctly
19. ☐ Positions chair properly against wall
20. ☐ Determines whether participant feels safe standing from chair with arms folded
21. ☐ Records whether participant was able to stand from chair without the use of their arms
22. ☐ Determines whether participant feels safe standing from chair five times without using their arms
23. ☐ Instructs participant that five chair stands should be done as quickly as possible
24. ☐ Times the repeated chair stand test correctly

Comments:_____

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Observer:_____ Date observed:_____

LLFS Certification Checklist
Seated Blood Pressure and Radial Pulse

_____ ____ ____
Name Staff ID

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: Omron HBP-1300 automated sphygmomanometer, 4 cuff sizes, measuring tape, cosmetic marking pencil.
4. ☐ Greets participant and reviews procedure.
5. ☐ Determines appropriate cuff size by following protocol for measurement of arm circumference:
   a. Measures length of arm from acromion to olecranon process, marks midpoint on arm.
   b. Measures arm circumference at mid-point mark.
   c. Determines cuff size from MOP and records arm circumference on data form.
6. ☐ Seats participant in proper position- both feet flat on floor, right forearm resting on table.
7. ☐ Marks cuff size on data form.
8. ☐ Places cuff properly with center of bladder over the brachial artery and cuff at the level of participant's heart.
   a. Mark cuff placement on form.
9. ☐ Confirms participant is relaxed and comfortable and reminds of the need to be seated quietly for 5 minutes prior to the measurement.
10. ☐ Observes the 5 minutes of relaxed sitting.
11. ☐ Obtains 3 BP measurements and records values correctly onto form.
12. ☐ Observes 1 minute between-measurement periods.
13. ☐ Records radial pulse on form
14. ☐ Does not inform participant of measures until all measurements have been taken and provides all three measures to participant, if asked.
15. ☐ Communicates appropriately with participant regarding a normal or an alert BP.

Comments:_____

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Observer:_____ Date observed:_____

LLFS Certification Checklist
Waist Circumference

_____ _____ _____
Name Staff ID

Observes the Following Procedural Steps:

1. ☐ Greets participant and reviews procedure
2. ☐ Positions participant correctly, standing erect, with arms hanging loosely at the sides, weight equally distributed on both feet and with head facing straight ahead
3. ☐ Places tape at the level of the umbilicus underneath the shirt
4. ☐ Applies the tape snugly but not tight
5. ☐ Assures the tape is horizontal all of the way around
6. ☐ Reads measurement at mid-respiration with the participant breathing quietly
7. ☐ Records measurement to the nearest tenth of a centimeter, rounding down

Comments:_____

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Observer:_____ Date observed:_____

LLFS Certification Checklist
Standing Height Measurement

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Name Staff ID

Observes the Following Procedural Steps:

1. ☐ Greets participant and reviews procedure
2. ☐ Selects appropriate setting for height measurement
3. ☐ Asks participant to take of his/her shoes or offers help to do it when needed.
4. ☐ Positions participant correctly, with feet flat on the floor, heels together, with heels, hips and shoulders directly against the wall.
   a. Checks for Frankfort plane and positions head as need to achieve correct measurement.
5. ☐ Positions Handi-stat wooden measuring triangle correctly:
   a. Rests the wooden base of the set square against the wall above the participant's head with the right angle toward the floor.
   b. Slides down slowly until it touches the top of the participant's scalp, carefully centered with their nose.
   c. Ensures one wooden edge is flat and held steadily against the wall.
   d. Marks the tape exactly where the corner of the right angle touches the tape.
   e. Marks the tape from underneath the set square with the pencil angled upward.
6. ☐ Removes the square and asks the participant to step away from the wall:
   a. Opens the metal measuring tape and ensures it is straight.
   b. Secures it against the wall by pressing it with foot at the "0" end, or by taping it.
   c. Keeping the tape flat against the wall and vertical, reads the measurement closest to the mark on the tape
7. ☐ Records measurement to the nearest 0.1cm and converts to feet and inches for the participant

Comments:_____

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Observer: _____ Date observed:_____

LLFS Certification Checklist
Seated Height Measurement

_____ _____ _____

Name Staff ID

Observes the Following Procedural Steps:

1. ☐ Greets participant and reviews procedure.
2. ☐ Selects appropriate setting for seated height measurement.
3. ☐ Positions participant correctly, with legs hanging unsupported or if touching the floor the weight is supported by the buttocks, heels together, with back of knees near edge of seat, and knees directed straight ahead Thighs and buttocks are relaxed.
4. ☐ Sits erect with head in a Frankfort position.
5. ☐ Places piece of tape approximately at seated height level.
6. ☐ Positions base correctly:
   a. Rests the wooden base of the set square against the wall above the participant's head with the right angle toward the floor.
   b. Slides down slowly until it touches the top of the participant's scalp, carefully centered with their nose.
   c. Ensures one wooden edge is flat and held steadily against the wall.
   d. Marks the tape exactly where the corner of the right angle touches the tape.
   e. Marks the tape from underneath the set square with the pencil angled upward.
7. ☐ Removes the square and asks the participant to get up from the chair:
   a. Opens the metal measuring tape and ensures it is straight.
   b. Secures it against the wall by pressing it with foot at the "0" end, or by taping it.
   c. Keeping the tape flat against the wall and vertical, reads the measurement closest to the mark on the tape
8. ☐ Records measurement to the nearest 0.1cm and converts to feet and inches for the participant

Comments:_____

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Observer: _____ Date Observed:_____

LLFS Certification Visit Checklist

Arm Span Measurement

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Name Staff ID

Observes the Following Procedural Steps:

1. ☐ Greets participant and reviews procedure
2. ☐ Selects appropriate setting for arm span measurement. An unobstructed wall wide enough to accommodate the participant's outstretched arms ideally with a corner.
3. ☐ Positions participant correctly.
    a. Stands erect back to the wall or sit if unable to stand
    b. With arms fully extended at shoulder height (at a 90 degree angle to the trunk of the body, use carpenter's square to get 90 degree angle)
    c. Places piece of painter's tape at shoulder height level approximately where longest fingertip ends. One side can be extended to touch the corner of the wall and tape need only be used for the other side.
4. ☐ Positions base correctly: Rests the wooden base of the set square perpendicular to the wall at the participant's outstretch fingertip. Mark the tape exactly where the set square touches the fingertip.
5. ☐ Removes the square and asks the participant to step away. Opens the metal measuring tape and ensures it is straight. Secures it against the wall by taping it. Keeping the tape flat against the wall and horizontal, reads the measurement closest to the mark on the tape
6. ☐ Records measurement to the nearest 0.1cm rounding down

Comments:_____

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Observer:_____ Date Observed: _____

LLFS Certification Checklist
Knee Height Measurement

_____ _____ _____
Name Staff ID

Observes the Following Procedural Steps:

1. ☐ Greets participant and reviews procedure
2. ☐ Selects appropriate setting for knee height measurement
3. ☐ Positions participant correctly, with legs hanging unsupported, shoes and socks removed and leg bare past the knee
4. ☐ Positions sliding caliper correctly. Fixed blade of sliding caliper under heel of right foot, just below the lateral malleolus of the fibula. The knee and ankle are at a 90 degree angle.
5. ☐ The moveable blade of the caliper is placed on the anterior surface of the right thigh, above the condyles of the femur, at the edge of the patella.
6. ☐ The shaft of the caliper is held parallel to the shaft of the tibia. Pressure is applied to the skin.
7. ☐ Records measurement to the nearest 0.1cm.

Comments:_____

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Observer:_____ Date observed: _____

LLFS Certification Checklist

Weight Measurement

_____ ____ ____ ____

Name Staff ID

Observes the Following Procedural Steps:

1. ☐ Greets participant and reviews procedure
2. ☐ Places scale on a hard floor surface rather than on a carpet
3. ☐ Ensures participant is wearing light indoor clothing. Asks participant to remove shoes as well as any heavy sweater, coat, etc. prior to the weigh-in.
4. ☐ Directs the participant to step onto the scale as soon as the number 0.0 appears on the display
5. ☐ Waits about four seconds for the numbers to stabilize
6. ☐ Record in kg, to the nearest tenth (one decimal place)

Comments:_____

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Observer:_____ Date Observed:_____

LLFS Certification Checklist

Ankle-Arm Index Measurement –Cont.

[Page 1 of 2]

_____ _____ _____

Name Staff ID

Certification Requirements:

1. ☐ Complete training requirements
2. ☐ Recite exclusion criteria
3. ☐ Conduct exam on two volunteers while being observed by QC officer listening with Doppler
4. ☐ Performs exam according to protocol as demonstrated on completed QC checklist
5. ☐ Three simultaneous readings of systolic measurements recorded by the staff member agree with those of the QC officer within ± 4 mm Hg, with the average of the three readings within ± 3 mm Hg.
6. ☐ Ten simultaneous readings of age eligible participants recorded by the staff member agree with another staff member within ± 4 mm Hg, with the average of the three readings within ± 3 mm Hg.

General Procedural Steps:

1. ☐ Explains procedure
2. ☐ Determines reference arm correctly
3. ☐ Applies blood pressure cuffs to reference arm, right ankle and left ankle
4. ☐ Observes five minute rest period before measurement
5. ☐ Uses Doppler to locate brachial artery and right and left posterior tibial arteries and marks them with a wax marker

Observes the Following Procedural Steps:

Reference Arm Systolic BP Measurement

1. ☐ Turns unit on
2. ☐ Anchors Doppler at marked location to achieve best sound quality
3. ☐ Measures the systolic blood pressure using the Doppler and digital Omron HBP-1300
4. ☐ Presses cancel when 10 mmHG below the appearance of systolic pressure
5. ☐ Records measurement

Ankle Systolic BP Measurement

1. ☐ Moves to the end of the table

Right Ankle:

1. ☐ Anchors Doppler at marked location to achieve best sound quality
2. ☐ Measures the systolic blood pressure using the Doppler and digital Omron HBP-1300
3. ☐ Presses cancel when 10 mmHg below the appearance of systolic pressure
4. ☐ Records measurement

Left Ankle:

1. ☐ Anchors Doppler at marked location to achieve best sound quality
2. ☐ Measures the systolic blood pressure using the Doppler and digital Omron HBP-1300
3. ☐ Presses cancel when 10 mmHg below the appearance of systolic pressure
4. ☐ Records measurement

LLFS Certification Checklist

Ankle-Arm Index Measurement –Cont.

[Page 2 of 2]

_____ ____ ____ ____

Name Staff ID

Repeat of Ankle-Arm Measurements:

1. ☐ Repeats sequence of measures in reverse order: Left ankle Right ankle Reference arm

Completion:

1. ☐ Removes cuffs and conducting jelly
2. ☐ Turns Doppler unit off immediately
3. ☐ Reviews form for completeness
4. ☐ Correctly completes form

Comments:_____

_____

_____

_____

Observer:_____ Date Observed:_____

LLFS Certification Checklist

Interviewing Certification

_____ ____ ____ ____
Name Staff ID

During Procedure:

1. ☐ Reads slowly, speaks clearly and uses appropriate inflection when speaking
2. ☐ Reduces the chance of bias by maintaining a neutral attitude toward participant's answers
3. ☐ Elicits accurate and complete information by using non-directive probes
4. ☐ Keeps interview on track by presenting questions at a regular pace
5. ☐ Focuses participant's attention on questions while always being polite
6. ☐ Treats participant with respect
7. ☐ Maintains a professional and friendly manner; leaves participant with an overall feeling of well being

Observes the Following Procedural Steps:

8. ☐ Reads script and questions exactly as written on the questionnaires (same order, same wording)
9. ☐ Appropriately reads/does not read response options
10. ☐ Uses all mandatory response forms with the appropriate questions
11. ☐ Uses optional response forms appropriately
12. ☐ Follows skip patterns in questionnaires
13. ☐ Accurately records participant's responses on questionnaire
14. ☐ Follows the guidelines for recording data on forms/laptop
15. ☐ Reviews participant forms for completeness when returned during in-person visit

Comments:_____

_____

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Observer:_____ Date observed:_____

LLFS Certification Checklist
Spirometry

_____ ___ ___ ___
Name Staff ID

Observes the Following Procedural Steps:

1. ☐ Explains procedure to participant
2. ☐ Asks anamnesis and exclusion questions
3. ☐ Asks participant if they use beta agonist inhaler and follows procedure if the answer is yes
4. ☐ Asks participant to loosen tight clothing
5. ☐ Follows universal precautions
6. ☐ Properly enters ID information, basic critical values and follows instructions given by the EasyOne Diagnostic spirometer.
7. ☐ Positions participant properly (sitting position and head position)
8. ☐ Obtains three acceptable quality FVC maneuvers
    a. ☐ Enthusiastically coaches
    b. ☐ Does exaggerated demonstration of the maneuver
    c. ☐ Watches for maximum effort
    d. ☐ Evaluates for reproducibility and retests if necessary
9. ☐ Records results on form (and prints results)
10. ☐ Exits program properly

Comments:_____

_____

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Observer:_____ Date observed:_____

LLFS Certification Checklist
Medical Inventory Certification

Name Staff ID

1. ☐ 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.

Observes the Following Procedural Steps:

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

_____

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_____

Observer:_____ Date observed:_____

LLFS Certification Checklist
Blood Collection Procedure

_____ ___-___-___
Name Staff ID

VENIPUNCTURE

	Satisfactory/ Unsatisfactory	Comments
1. Ensures participant's safety at all times	____	_____
2. Assembles proper supplies	____	_____
3. Participant prepared and procedure explained; covers "bleeding disorder" question	____	_____
4. Participant is fasting, if possible	____	_____
5. Tubes labeled and checked	____	_____
6. Venipuncture Form completed	____	_____
7. Tourniquet application and release	____	_____
8. Venipuncture technique	____	_____
9. Tube collection sequence	____	_____
10. Inversion technique	____	_____
11. PAXgene tube collection	____	_____
12. Stasis obtained	____	_____
13. Needle disposal	____	_____
14. Alternative DNA collection	____	_____
15. Collection of phantom QC samples	____	_____

Comments:_____

_____

_____

_____

Observer:_____ Date observed:_____

LLFS Certification Checklist
Blood Processing and Shipping Procedure

_____ ____ ____
Name Staff ID

PROCESSING

	Satisfactory/ Unsatisfactory	Comments
1. Required reading completed	____	_____
2. Knowledge of centrifuge/powerpack operation	____	_____
3. SST centrifugation	____	_____
4. Venipuncture Form completed	____	_____

PACKAGING AND SHIPPING

	Satisfactory/ Unsatisfactory	Comments
1. CPT and PAXgene tubes in 5-place styro	____	_____
2. 5-place box in sleeve and biohazard bag	____	_____
3. Gel packs above/below 5-place styro	____	_____
4. SST, EDTA, Na citrate tubes wrapped, in biohazard bag	____	_____
5. Absorbent material in both boxes	____	_____
6. Frozen gel pack in small styro box	____	_____
7. Return of unused tubes	____	_____
9. Delivery of package to FedexOffice	____	_____
10. Shipping phantom QC samples	_____	_____

MISCELLANEOUS

	Satisfactory/ Unsatisfactory	Comments
1. Incident Form Completed	_____	_____
2. Containers correctly labeled for shipping	____	_____
3. Freezer stocked with small styro box with gel pack	____	_____

Comments:_____

_____

_____

_____

Observer:_____ Date observed _____

LLFS Certification Checklist
Blood Processing and Shipping Procedure

_____ _____

Name of Staff Member to be Certified Staff ID

_____ _____ _____

Name of Certifier Signature of Completed Certification Date

General Procedures Certification

1. ☐ Knows that exam should be performed in quiet, private area without interruptions
2. ☐ Provides instructions in a clear, slow, and easily audible voice
3. ☐ Reads ALL instructions as written without deletion or addition of information
4. ☐ Uses stopwatch discretely
5. ☐ Records scores in an accurate and timely manner
6. ☐ Encourages participant to guess if response is “I don’t know”

MMSE

1. ☐ Queries for additional information regarding date when appropriate
2. ☐ Repeats three words up to five times for registration item
3. ☐ Allows immediate correction of responses
4. ☐ Administers pentagon drawing after WORLD backwards
5. ☐ Presents paper at subject’s midline for three step command
6. ☐ Introduces digital pen before administering the pentagon task
7. ☐ Scores sentence and pentagons correctly

HVLT-R Immediate and Delay

1. ☐ Reads list at 2-second inter-stimulus interval
2. ☐ Quickly repeats a word if the participant does not understand on Trial 1 only
3. ☐ Records words in correct order
4. ☐ Leaves appropriate amount of time for delayed trial
5. ☐ Reads words from recognition form at appropriate pace allowing as much time as needed

LLFS Certification Checklist
Blood Processing and Shipping Procedure

Digital Clock Drawing Test

1. ☐ Checks the appropriate box to activate the digital task
2. ☐ Does not show drawing of the clock prior to copy condition
3. ☐ Provides correct responses to queries about the time
4. ☐ Writes subject ID in appropriate space immediately following copy condition
5. ☐ Checks the appropriate box to end the digital task

Trail Making Test

1. ☐ Points clearly to circles while explaining task
2. ☐ Provides appropriate corrections to mistakes during practice trials
3. ☐ Provides appropriate corrections to mistakes during test
4. ☐ Records time to completion
5. ☐ Records subject ID and test ID on each page

Logical Memory I and II

1. ☐ Records subjects responses verbatim
2. ☐ Does not repeat any portions of the story
3. ☐ Awards appropriate number of points for elements recalled
4. ☐ Alerts subject that he or she will be asked to recall the story at a later time
5. ☐ Leaves appropriate amount of time for delayed trial

Number Span

1. ☐ Reads numbers at rate of one per second
2. ☐ Does not repeat a number sequence when requested
3. ☐ Discontinues test after two consecutive failures at the same level
4. ☐ Corrects subject when needed on practice items for digits backwards

Digital Digit Symbol Test

1. ☐ Demonstrates three sample boxes
2. ☐ Provides feedback as necessary during practice
3. ☐ Provides appropriate correction if subject skips boxes during test
4. ☐ Does not correct if subject places incorrect symbol in box during tests
5. ☐ Allows 90 seconds
6. ☐ Records subject ID and test ID on bottom of page

LLFS Certification Checklist
Blood Processing and Shipping Procedure

Animal Fluency

1. ☐ Provides correct feedback for errors during practice trial
2. ☐ Provides one prompt if participant makes no response for 15 seconds
3. ☐ Correctly records data in 15 second intervals on record form

Letter Fluency

1. ☐ Records answers in correct time frames
2. ☐ Provides encouragement if the participant indicates that they are finished
3. ☐ Provides correct prompt after 2nd error in a row
4. ☐ Queries unfamiliar words after test

LLFS Certification Checklist
REDCap Data Entry System

_____ _____ _____
Name Staff ID

. . . Successfully logs onto REDCap

. . . Can change own password.

. . . Can log onto REDCap web server and retrieve output.

. . . Can use data entry subject menu (schedule appointments and assign recruitment status)

. . . Can enter data accurately.

. . . Understand and use ReportBuilder Templates.

. . . Successfully enters ‘test participant’ data.

Comments:_____

_____ _____
_
_____

LLFS Certification Checklist
8 Image Carotid Ultrasound

_____ _____ _____ _____ _____
Name Staff ID URL Tech ID

1. ☐ Attend scheduled training session. (Assigned dates:_____ to _____)

2. ☐ Practice *at least* 10 full scans where protocol is demonstrated correctly. A certified technologist observed at *least* half of the practice scans and gave direct verbal and/or written feedback.

3. ☐ 5 full pre-certification scans demonstrating correct protocol and captured images reviewed and approved by a certified technologist.
   Note: Pre-certification scans rejected due to image quality will be reviewed by a second reader.

4. ☐ Practice for a minimum of 2 months (upon completion of training session) with 3-5 scans per week performed and submitted to the URL Reading Center for evaluation and feedback.

5. ☐ Attend scheduled certification session. (Assigned dates: _____ to _____)

6. ☐ No less than 10 one-sided full certification scans by both trainee and a certified technologist.

7. ☐ Accurate documentation on all certification scans.

8. ☐ Read results and execution of the certification scans met the following criteria:
   a. ≥80% images with overall image quality of good or better
   b. Intraclass correlation of ≥0.80 in CCA_IMT between site staff scans and URL certifying sonographer scans.
   c. Mean absolute difference in CCA_IMT of ≤0.05 between site staff scans and URL certifying sonographer scans.
   d. At least 20 scout scans obtained per protocol for verification of best image selection and plaque identification.
   e. All worksheets accurately completed.

Comments_____

_____

_____

_____

Certification approved by: _____ Date: _____