Study: The Multi-Ethnic Study of Atherosclerosis (MESA)

Document: Quality Control (QC) Manual of Operations (MOP) Exam 5 Supplement

Date: 07/06/2010

Prelude

Quality Assurance and Quality Control elements from MESA Exams 1-4 are extended in this supplement for Exam 5 activities. Quality Control MOP and supplements from Exams 1-4 are posted on the MESA website at http://www.mesa-nhlbi.org/Mesa-Internal/manuals.asp and may be referred to as a reference.

Content of this Exam 5 QC supplement are divided into the following sections:

1. Quality Assurance
    A. Manual of Operations
    B. Technician Training
    C. Technician Certification
    D. Equipment maintenance and calibration
2. Quality Control
    A. Clinic visit component surveillance
        i. Anthropometry repeat measures
        ii. Ankle brachial Index (ABI) repeat measures
        iii. Audio recording
    B. Laboratory assay blind duplicate sampling
    C. High tech scan reread
        i. Cardiac MRI
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        iii. Carotid US
    D. Data collection (completeness and accuracy)
    E. Other

1 Quality Assurance

1.1 Manual of Operations

A Field Center Manual of Operations (MOP) section describing the detailed protocol for performing each component of the clinical exam will be maintained by the Operations Committee and Coordinating Center. All technicians will be required to study the sections of the MOP relevant to their responsibilities and demonstrate proficiency in following the procedures according to the MOP. Changes and clarifications will be documented via memorandum from the Coordinating Center to the Field Centers and the current version of the MOP will be posted on the MESA website at http://www.mesa-nhlbi.org/Mesa-Internal/manuals.asp.

Ancillary studies are required to produce a MOP that provides detailed instructions to the Field Center staff for performing ancillary procedures. Copies of these MOPs may be posted on the MESA website.

Laboratories and Reading Centers are required to maintain MOPs describing details related to the collection of specimens or images. Laboratories and Reading Centers are also required to maintain MOPs detailing internal procedures and activities for receipt and processing of the specimens and images as well as timely transfer of results to Coordinating Center.

Please contact Craig Johnson (wcraigj@uw.edu) at the Coordinating Center with any questions related to documentation or quality assurance or control activities.

1.2 Technician Training

The majority of Technician training occurs at the Field Centers under the direct supervision of the Study Coordinator or a designated lead technician. Technicians are encouraged to read the individual MOP sections, practice the procedures on fellow staff members, undergo critique by the Study Coordinator (or lead technician), and successfully complete the procedures on practice and/or pilot participants in preparation for formal certification and study authorization to perform the procedures on MESA participants. The Study Coordinator at each Field Center will work with Coordinating Center to ensure each Technician is appropriately trained and certified.

MESA provides central training for all technicians prior to the start of Pilot Exams. Exam 5 Central Training is hosted by Wake Forest University Field Center in Winston Salem February 16 – 19. While Central Training takes place over a week, it is noted that the majority of clinical staff members are new to MESA and likely will not be able to be certified at Central Training. Additional training and certification takes place at the Field Centers under the direction of the Study Coordinator.

1.3 Technician Certification

Certification is required prior to performing procedures on study participants. Technicians who are deemed proficient by the Study Coordinator (or a certified Lead Technician), but still require additional observations to formally meet the certification standard (i.e. perform the procedure on a minimal number of subjects) will be classified as Provisionally Certified. Provisionally Certified Technicians may perform study procedures under the direction of the study coordinator (or certified lead technician) only.

Certification requirements (and requirements for maintaining certification) are provided in the Certification Requirements Document included in this supplement.

Study Coordinators provide certification status for each Technician to the Coordinating Center. Coordinating Center maintains certification status records for the study.

1.4 Equipment maintenance and calibration

Field Center Study Coordinator (or designee) is responsible for ensuring routine inspection of all study equipment and material occurs. Clinical equipment will be checked according to the schedule laid out in this document. When equipment are deemed to be out of calibration or no longer in serviceable condition, the equipment will be serviced, recalibrated, or replaced. Damaged, broken, or worn equipment must be replaced (clinical exams will not be allowed to continue if materials are no longer useable). Study Coordinators will maintain an inspection and calibration log.

1.5 Site Visits

Each of the 6 Field Centers undergo Site Visit inspections in May and June of 2010. Field Center Site Visits consist of a tour of the facilities, observation of all Exam 5 procedures (including scans), review of computing systems, and review of retention strategies. Site Visit teams consist of one Project Office member and 1-2 Coordinating Center representatives. A representative from a Field Center (Investigator or Study Coordinator) may also be invited to join a site visit team. Representatives from ancillary studies may also be invited to attend if there is mutual agreement by all parties involved.

When convenient, Laboratories and Reading Centers are also visited. For Exam 5, Site Visits Centers include the MRI Reading Center (JHU), ECG Reading Center WFU), CT Reading Center (LA), and Clinical Laboratory (UMN).

2. Quality Control

2.1 Clinic visit component surveillance

QC surveillance of clinical exam components will be limited to repeat measures from anthropometry, ankle brachial index (ABI), and review of audio recordings of procedures (particularly interviews). QC repeat studies begin after the 2nd week (beginning 1st week of May 2010) and continue through the end of Exam 5 (September 2011).

2.1.1 Anthropometry repeat measures

Waist circumference and Hip circumference measurements (measured in centimeters) are repeated in 5% of participants at each of the Field Centers (2.5% intra-technician and 2.5% inter-technician). Participants are randomly selected for participation with slightly higher percentage being selected during the first 3 months. The Exam 5 Electronic Data Collection system will notify Field Center staff of selected participants for repeat procedures and will provide tracking.

Weight measurements are repeated on two different scales. Weight measured on a Balance Beam Scale (BBS) is accepted as the weight of record in the Exam 5 dataset in order to be consistent with measures at previous exams. Weight is also measured on the Body Composition Scale (BCS) which is a new procedure to Exam 5. The BCS weight is recorded in kilograms and will be converted to pounds by the Coordinating Center for comparison with the BBS measure.

Coordinating Center generates a report quarterly which includes a description summary of the measures and differences, estimates of correlation (r) and intraclass correlation coefficient (ICC), estimates of percent technical error of measurement (TEM%), and plots of the agreement/variability (Bland Altman). The report will also list individual observations which are deemed to be outliers (> 5 SD from the mean) in order to initiate feedback to Field Center Investigators and staff should follow-up or corrective action be indicated.

2.1.2 Ankle brachial Index (ABI) repeat measures

Participants are randomly selected for repeat procedure with slightly higher percentage being selected during the first 3 months. All six ABI component measurements will be collected along with the calculated ABI measurement itself. The Exam 5 Electronic Data Collection system will notify Field Center staff of selected participants for repeat procedures and will provide tracking.

Coordinating Center generates a report quarterly which includes a description summary of the measures and differences, estimates of correlation (r) and intraclass correlation coefficient (ICC), estimates of percent technical error of measurement (TEM%), and plots of the agreement/variability (Bland Altman). The report will also list individual observations which are deemed to be outliers (> 5 SD from the mean) in order to initiate feedback to Field Center Investigators and staff should follow-up or corrective action be indicated.

2.1.3 Audio recording

Field Centers are requested to make a digital audio recording of all Exam 5 components with the exception of imaging (MRI, CT, US) and blood draw. Three digital audio recorders are provided to each Field Center for this purpose. Participants will be asked for permission to record audio of the clinic exam prior to any recording and in accordance with local institutional requirements. If a participant refuses recording of audio, the exam will proceed without audio recording. Any request (at any time) for the audio to be stopped will immediately be honored and any recorded material will be deleted if requested by the participant. If there is ever a doubt about whether it is appropriate to record or if the audio recorder is deemed as interfering with an exam component, the recording should stop.

Technicians will initiate an audio recording session for a participant by stating the participant ID Number, acrostic, and date/time the visit begins (one time at the beginning of the day). The recorder may be stopped between procedures. After the clinic exam is completed for the participant, the digital audio file will be uploaded to the Study Coordinator's computer for archival and subsequent use as defined below. Study Coordinators may organize the files as they wish, but it is recommended that the audio files be named such that the participant ID Number and date of exam are included (e.g. MESA5ID3010007DT04152010).

Study Coordinators (or designated Lead Technician) will review one randomly selected recording per month per Interview technician and will review for adherence to interview protocol and best practices (both for interviewer administered as well as for self administered forms). Results will be recorded on the appropriate supervisor's checklist and submitted to Coordinating Center for summarization. Study Coordinator will correct any deficiencies noted in a timely fashion. Coordinating Center will review one randomly selected recording every six months for each technician and will complete the appropriate supervisor's checklist. Coordinating Center will evaluate the individual technician adherence to protocol as well as assess consistency between the Field Centers. Technicians may be recommended for retraining or recertification at the discretion of the Study Coordinator or the Coordinating Center (after consultation with the Study Coordinator and Center PI).

Coordinating Center will monitor data completeness and quality throughout Exam 5. At any time, Coordinating Center may request audio recording files for audit of the EDC system and central study database. QC Committee will review the results of any such investigation.

2.2 Laboratory assay

2.2.1 Comparability study

The Central Lab performs comparability assays during the conduct of the study using a small number of stored MESA specimens. Results are provided to Coordinating Center for analyses and reporting to MESA QC Committee (subsequent calibration adjustment may be applied to the data at the discretion of QC Committee). Specific analyses to be performed will be drafted in a plan when the data are first available, but the report will consist of methods appropriate for identifying drift and differences in results and associated variability.

2.2.2 Blind duplicate sampling

Ten percent of participants are selected for laboratory assay replication (5% Lipids replication and 5% for the others). During specimen processing at the Field Center blind duplicate aliquots are prepared and labeled with ID numbers identical in format to the MESA ID Numbers. Field Centers and Coordinating Center maintain the linking file in order to prepare aliquots and analyze the results. The lab remains blinded throughout the process. Assays to be assessed are limited to Exam 5 Group 1 blood assays and include total cholesterol, HDL, LDL, triglycerides, glucose, creatinine, hemoglobin A1c, and insulin.

Coordinating Center generates a report quarterly which includes a description summary of the measures and differences, estimates of correlation (r) and intraclass correlation coefficient (ICC), estimates of percent technical error of measurement (TEM%), and plots of the agreement/variability (Bland Altman). The report will also list individual observations which are deemed to be outliers in order to initiate feedback to the Lab and Lab Committee.

2.3 High tech scan reread

Five percent of high tech scans are selected for a second reading (2.5% intra-reader and 2.5% inter-reader). Steps are taken to ensure readers are blinded as to whether the image is being read for QC purposes or not.

2.3.1 Cardiac MRI

Each of the first 100 scans are read by all three readers as a run in training and inter-reader quality assessment.

Structure and function measures (LV Mass, LV Volumes, and derived variables) will be of primary interest in these analyses. MRI and QC committees will discuss whether and which tagged results will undergo QC rereading.

2.3.2 Cardiac CT

The first 36 scans are read twice by the primary reader as a run in training and intra-reader quality assessment.

Agatston scores and component measures (Right Main CA, Left Main CA, Left Anterior Descending CA, and Circumflex CA) will be of primary interest in these analyses.

2.3.3 Carotid US

The University of Wisconsin US Reading Center maintains internal protocols for assessing reader training and quality.

Right Common Carotid Far Wall Mean IMT, Left Common Carotid Far Wall Mean IMT, Right ICA Far Wall Max IMT, Left ICA Far Wall Max IMT, carotid plaque presence or absence, and their longitudinal changes will be of primary interest in these analyses.

2.4 Data collection (completeness and accuracy)

MESA employs an Electronic Data Collection (EDC) system developed specifically for use during Exam 5 clinic visits. In this system, study data are entered by Field Center personnel directly into the central

database via tablet PCs that have been specifically configured with secure (encrypted) access to the Coordinating Center servers and database. The first place study examination data are recorded is in the central database making that location the source document/record. This obviates the need for Field Centers to maintain a separate paper record of the measurements. Due to this record keeping change (from prior exams), any auditing to be completed for Exam 5 will require comparison with information collected from direct observation of the procedure (routine Study Coordinator or site visitor observation) or from information collected from audio recording of the procedure (Section 2.1.3).

The system passed extensive performance testing prior to Central training (and pilot) and is updated according to requests and feedback from the general user base (Field Center staff, Operations Committee, Coordinating Center staff, and other users). At the request of and under the supervision of QC Committee, Coordinating Center will perform a data audit.

2.5 Other

2.5.1 ECG Reading Center

The Wake Forest University ECG Reading Center (EPICARE) maintains internal protocols for assessing reader training and quality. Regular (quarterly) scoring from a standard set of typical and difficult ECG tracings are key to this internal QC protocol. Extensive documentation of the results of these activities are on file at EPICARE.

2.5.2 Retinal Photography Reading Center

The University of Wisconsin Retinal Photography Reading Center maintains internal protocols for assessing reader training and quality.

The Reading Center provides regular quality assessment reports to QC Committee (quarterly).

2.5.3 Ancillary Studies

Ancillary studies are encouraged to establish QC plans and to share their results with QC Committee.

QC plan for MESA Lung ancillary study specifies a Lung CT reread protocol and a repeat spirometry protocol.

QC plan for MESA Air ancillary study specifies a questionnaire repeat protocol, CT reread protocol (Section 2.3.2), US repeat protocol (15 repeat scans per Sonographer), and an US reread protocol (Section 2.3.3).

Appendix A: SUMMARY OF CERTIFICATION REQUIREMENTS

	Exam Component	Requirements*
1.	**Interviewer-Administered Questionnaires** (medical history, Eye history, MESA Lung questionnaire, MESA Air questionnaire)	1. Read the interviewing protocol in the Exam 5 MOP (Section 3.4) 2. Practice the questionnaire at least 5 times or as much as possible. 3. Conduct and audiotape 3 sets of interviews with 3 different volunteers. 4. Send all 3 sets of completed forms and tapes to the study certifier for review.
2.	**Self-Administered Questionnaires** (personal history, physical activity, health and life)	1. Read the sections in the Exam 5 MOP relating to the self-administered Questionnaire (Sections 3.4.7 – 3.4.10). Familiarize yourself with the questionnaires, especially the scripts of the instructions given to the participant. 2. Practice instructions for completing forms as needed. 3. Conduct and audiotape 3 sets of instructions for completing forms with 3 different volunteers. 4. Send tapes to study certifier for review.
3.	**Food Frequency Questionnaire**	1. Read the section in the Exam 5 MOP relating to the Food Frequency Questionnaire (Section 3.4.11). Familiarize yourself with the form, especially the script of the instructions given to the participant. 2. Complete and scan one Food Frequency Questionnaire. 3. Attend a training teleconference to review the form and the completion process.
4.	**Anthropometry**	1. Read Section 3.5.1 in the Exam 5 MOP and practice the procedure according to the MOP on volunteers as many times as necessary depending on previous experience. 2. Practice the procedures on at least 5 volunteers. 3. For Certification, obtain height, weight, hip and waist, and bioelectric impedance measurements on 5 volunteers in accordance with the MESA Anthropometry Certification / Supervisor Checklist. The readings must not differ from the trainer's by more than the following: ± 1 cm for height, ± 1 pound for weight (both for balance beam and body composition scale), and ± 2 cm for hip and waist girth. 4. Send checklists, completed by the trainer technician, to the CC.

	Exam Component	Requirements*
5.	**Seated Blood Pressure**	1. Read the blood pressure protocol in the Exam 5 MOP. 2. Practice the procedure according to the MOP as many times as necessary depending on previous experience. 3. Perform 5 blood pressure measurements in accordance with certification checklist under supervision of the lead staff person in the clinic. For re-certification, only 2 volunteers are required. 4. Send checklists, completed by the trainer technician, to the CC.
6.	**ABI**	1. Read the ABI protocol in the Exam 5 MOP. 2. Practice the procedure according to the MOP on at least 5 volunteers. 3. Perform 5 ABI measurements in accordance with certification checklist under supervision of the lead staff person in the clinic. 4. Send checklists, completed by the trainer technician, to the CC.
7.	**Phlebotomy**	1. Read MESA's Laboratory MOP and Section 3.6 of the Exam 5 MOP. 2. Observe the process performed by a certified technician. 3. Successfully perform 1 phlebotomy on a volunteer as described in the protocol and in accordance with certification checklist under supervision of the lead person in the clinic. 4. Pass written examination prepared by CBAL. 5. Send exams and checklists to CBAL and CC.
8.	**Blood Processing**	1. Read MESA's Laboratory MOP and section 3.6 of the Exam 5 MOP. 2. Observe the process performed by a certified technician. 3. Successfully process blood samples from 1 volunteer as described in the protocol and in accordance with the certification checklist under supervision of the lead person. 4. Pass written examination prepared by LCBR. 5. Send exams and checklists to LCBR and CC.
9.	**Cognitive Function**	1. Read and understand the Cognitive Function protocol in the FC MOP. 2. Practice each of the three cognitive assessment components (CASI, DSST, and Digit Span) on at least 5 volunteers. 3. Perform and audio tape 1 cognitive battery (CASI, DSST, and Digit Span). 4. Send completed forms and tape to the Coordinating Center along with the completed supervisor checklist. Cognitive Function Working Group Chair (or designee) will serve as certifying authority. 5. Take certification quiz and receive a passing score. If a passing score is not achieved, do additional training/practice and receive a passing score on a second certification quiz.

	Exam Component	Requirements*
10.	**MRI**	1. Read and understand the MRI protocol in the MRI MOP. 2. Perform 5 scans of excellent (E) quality (as determined by MRI RC staff following the certification checklist. (transmission required). 3. For non-centrally trained technicians, send checklists to MRI RC.
11.	**CT**	1. Read and understand the CT protocol in the CT MOP (both for cardiac CT and Lung CT). 2. Perform and transmit 5 scans of excellent (E) quality (as determined by CT RC staff or by the local physician investigator responsible for CT performance at their FC) following the protocols as described in the CT MOPs.
12.	**US**	1. Review the online training materials (at learn@wisc.edu), complete the post-test, and answer 100% of the questions correctly (multiple attempts are permitted). 2. Attend an in-person training session that includes - protocol lecture - phantom and QA lecture - scanning at least 2 subjects following the Exam 5 ultrasound protocol, with special emphasis on matching images with previously acquired reference images. - using the Exam 5 Carotid Ultrasound, DVD log, and phantom forms. - practicing storage of images on the MDR, sending them to the UW AIRP and burning DVDs. 3. After in-person training, each sonographer must submit a sample scan on a volunteer. The UW AIRP lab will provide initial feedback and reference images to match for a paired scan to be performed on the same subject within 10 days of the first scan. The sonographer will become certified after submitting 2 pairs following this process. Each scan must obtain a quality score above 85%. Additional scans might be necessary in some cases.
13.	**ECG**	1. Read and understand the ECG protocol in the ECG MOP. 2. Practice the procedure on at least 5 volunteers or as many as needed to become comfortable with the measurement of the chest, placement of the leads, and acquisition of the ECG. For technicians who have never performed the procedure, 20 practice ECGs are required before certification. 3. Perform and transmit 2 scans of excellent quality (as determined by ECG RC staff following the certification checklist either on two different volunteers or one volunteer with 30 minutes between tests. (transmission is required). 4. Send checklists to CC.

	Exam Component	Requirements*
14.	**Retinal Photography**	1. Read and understand the Retinal protocol in the Exam 5 MOP (Section 3.5.6). 2. Practice the procedure on at least 5 volunteers or as often as needed to become comfortable with the procedure. 3. Perform and transmit photographs on a minimum of 10 eyes (5 right and 5 left) in accordance with the certification checklist under the guidance of the primary retinal technician at the clinic. 4. Send checklists to CC.
15.	**Vision**	1. Read and understand the Vision protocol in the Exam 5 MOP (Section 3.5.7) 2. Practice the procedure on at least 5 volunteers or as often as needed to become comfortable with use of both the lensmeter and autorefractor. 3. Perform the procedure on 5 volunteers, including measurement of the glasses using the lensmeter, and ensuring data is sent to the computer in accordance with the certification checklist under the guidance of the primary vision technician at the clinic. 4. Transmit the data files from these tests to the CC 5. Send checklists to CC.
16.	**Spirometry**	1. Read and understand the Spirometry Protocol in the Spirometry MOP. 2. Practice the procedure (including albuteral inhalation) on at least 5 volunteers or as often as needed to become comfortable with the procedure. 3. Review web training. 4. Complete on-line test 5. Perform and transmit 5 good quality tests (as determined by Spirometry RC staff. If any are of poor quality, additional practice and transmission of 5 additional tests will be required.
17.	**Oximetry**	1. Read and understand the Oximetry Protocol in the Exam 5 MOP. 2. Practice the procedure on at least 5 volunteers or as often as needed to become comfortable with the procedure. 3. Perform 5 oximetry measurements in accordance with certification checklist. 4. Send checklists, completed by the trainer technician, to the CC.

*NOTE: In addition to the detailed requirements listed in the table by examination component, the following certification requirements apply to all components:

- Trainees must thoroughly read the relevant section in the MOP.
- Appropriate supporting documents (e.g. checklists and tests) must be completed when required.
- All certification documentation should be sent to the CC and to designated RCs when specified.
- A copy of the supporting certification documents should be retained at the FC for local records in a designated binder.

SUMMARY OF REQUIREMENTS FOR MAINTAINING CERTIFICATION

	Exam Component	Requirements*
1.	**Interviewer-Administered Questionnaires**	1. Administer questionnaires to at least 6 MESA participants every 2 months. 2. Be observed and evaluated by FC supervisor according to the supervisor checklist monthly quarterly. 3. Audiotape all sessions. Study coordinator (or FC interviewer supervisor) reviews 1 randomly selected taped session monthly. 4. Repeat certification process prior to each new examination cycle.
2.	**Self-Administered Questionnaires**	1. Administer questionnaires to at least 6 MESA participants every 2 months. 2. Be observed and evaluated by FC supervisor according to the supervisor checklist quarterly. 3. Audiotape all sessions. Study coordinator (or FC interviewer supervisor) reviews 1 randomly selected taped session monthly. 4. Repeat certification process prior to each new examination cycle.
3.	**Food Frequency Questionnaire**	1. Review questionnaire for at least 6 MESA participants every 2 months. 2. Be observed and evaluated by FC supervisor according to the supervisor checklist quarterly. 3. Audiotape all sessions. Study coordinator (or FC interviewer supervisor) reviews 1 randomly selected taped session monthly. 4. Repeat certification process prior to each new examination cycle.
4.	**Anthropometry**	1. Perform all anthropometric measurements on at least 6 MESA participants every 2 months. 2. Be observed and evaluated by FC supervisor according to the supervisor checklist monthly for the first 2 months, then quarterly. 3. Repeat certification process prior to each new examination cycle.
5.	**Seated Blood Pressure**	1. Perform seated blood pressure measurements on at least 6 MESA participants every 2 months. 2. Be observed and evaluated by FC supervisor according to the supervisor checklist monthly for the first 2 months, then quarterly. 3. Repeat certification process prior to each new examination cycle.
6.	**ABI**	1. Perform ABI measurements on at least 6 MESA participants every 2 months. 2. Be observed and evaluated by FC supervisor according to the supervisor checklist monthly for the first 2 months, then quarterly. 3. Repeat certification process prior to each new examination cycle.
7.	**Phlebotomy**	1. Perform Phlebotomy procedure on at least 6 MESA participants every 2 months. 2. Be observed and evaluated by FC supervisor according to the supervisor checklist monthly for the first 2 months, then quarterly. 3. Repeat certification process prior to each new examination cycle.

	Exam Component	Requirements*
8.	**Blood Processing**	1. Perform Blood Processing on at least 6 MESA participants every 2 months. 2. Be observed and evaluated by FC supervisor according to the supervisor checklist monthly for the first 2 months, then quarterly. 3. Repeat certification process prior to each new examination cycle.
9.	**Cognitive Assessment**	1. Administer questionnaires to at least 6 MESA participants every 2 months. 2. Be observed and evaluated by FC supervisor according to the supervisor checklist monthly quarterly. 3. Audiotape all sessions. Study coordinator (or FC interviewer supervisor) reviews 1 randomly selected taped session monthly. 4. Repeat certification process prior to each new examination cycle.
10.	**MRI**	1. Perform MRI procedures of acceptable quality on at least 6 MESA participants every 2 months. 2. Be observed and evaluated by the physician/ investigator responsible for MRI acquisitions at the FC according to the supervisor checklist quarterly. 3. Repeat certification process as needed if data quality is not acceptable based on MRI RC review.
11.	**CT**	1. Perform CT procedures of acceptable quality on at least 6 MESA participants every 2 months. 2. Be observed and evaluated by the physician/ investigator responsible for CT acquisitions at the FC according to the supervisor checklist quarterly. 3. Repeat certification process as needed if data quality is not acceptable based on CT RC review.
12.	**US**	1. Certification is renewed every 60 days. Each sonographer must submit a passing exam every 60 days. This usually will be achieved by scanning participants. 2. Sonographers not actively scanning MESA subjects will be asked to submit a single practice scan to maintain certification in this time window. 3. The quality scores of the sonographers will be monitored regularly. Frequent or repeated exams that do not achieve an 85% quality score may result in a sonographer being suspended from scanning and remedial training.
13.	**ECG**	1. Perform ECG procedures of acceptable quality on at least 6 MESA participants every 2 months. 2. Be observed and evaluated by the ECG Supervisor according to the supervisor checklist quarterly. 3. Repeat certification process as needed if data quality is not acceptable based on ECG RC review.

	Exam Component	Requirements*
14.	**Retinal Photography**	1. Perform Retinal Photographs of acceptable quality on at least 6 MESA participants every 2 months. 2. Be observed and evaluated by the Retinal Photography Supervisor according to the supervisor checklist quarterly 3. Repeat certification process as needed if photo quality is not acceptable based on Retinal RC review.
15.	**Vision**	1. Perform Vision Refraction tests of acceptable quality on at least 6 MESA participants every 2 months. 2. Be observed and evaluated by the Vision Supervisor according to the supervisor checklist quarterly 3. Repeat certification process as needed if data quality is not acceptable based on CC and NEI review.
16.	**Spirometry**	1. Perform Spirometry tests of acceptable quality on at least 6 MESA participants every 2 months. 2. Be observed and evaluated by the Spirometry Supervisor according to the supervisor checklist quarterly 3. Repeat certification process as needed if data quality is not acceptable based on Spirometry RC review.
17.	**Oximetry**	1. Perform oximetry measurements on at least 6 MESA participants every 2 months. 2. Be observed and evaluated by FC supervisor according to the supervisor checklist monthly for the first 2 months, then quarterly. 3. Repeat certification process prior to each new examination cycle.

Appendix B: Supervisor Checklists

MESA Interviewer-Administered Questionnaire Supervisor Checklist

DATE: ☐ ☐ ☐ **Field Center:** _____
mo **day** **year**

Interviewer: Name/ID _____

Interview/form reviewed: **Supervisor:** _____

Informed Consent ☐ **Medications** ☐ **Medical History** ☐ **Physical Activity** ☐ **Follow-up** ☐

MESA-Lung ☐

Purpose of Evaluation:

Certification ☐ **Supervisor QC Check** ☐ **Site Visit** ☐

Using the scale key below, evaluate the interviewer's performance based on each of the following criteria. Write any comments in the space provided at the bottom of the page. If rating is below 3 <u>OR</u> above 3, please explain in comment area. (Refer to appendix #.)

Answers respondent's questions and concerns.	*N/A*	*1*	*2*	*3*	*4*	*5*
Speaks slowly and distinctly reading the questions at neutral (but expressive) and even pace	*N/A*	*1*	*2*	*3*	*4*	*5*
Maintains the focus of the interview but allows participant to express thoughts.	*N/A*	*1*	*2*	*3*	*4*	*5*
Follows instructions/reads questions as written.	*N/A*	*1*	*2*	*3*	*4*	*5*
Initiates (where needed) appropriate, nonleading questions	*N/A*	*1*	*2*	*3*	*4*	*5*
Records/codes answers correctly (follows skip patterns as needed).	*N/A*	*1*	*2*	*3*	*4*	*5*
General Overall Rating	*N/A*	*1*	*2*	*3*	*4*	*5*

Key: *N/A – Not applicable*
1 – Unsatisfactory (failed to meet standards)
2 – Below expectation (did not meet some standards)
3 – At expectations (met standards)
4 – Above expectation (met all standards and in some cases exceeded them
5 – Outstanding (distinguished consistently exceeded all standards)

Comments: _____

_____

_____

_____

Corrective Action Taken: _____

_____

_____

_____

Supervisor Signature _____

WHEN CERTIFYING NEW INTERVIEWER - SEND COPY TO CC

FOR QC, COMPLETE THE WEB-BASED FORM ONLY!!!

MESA Self-Administered Questionnaire Supervisor Checklist

DATE: ☐ ☐ ☐ (mo day year) **Field Center:** _____

Interviewer: Name/ID _____

Interview/form reviewed: **Supervisor:** _____

Personal History ☐ **Health & Life** ☐ **Physical Activity** ☐ **Neighborhood** ☐ **Residential History** ☐

Purpose of Evaluation:

Certification ☐ **Supervisor QC Check** ☐ **Site Visit** ☐

Using the scale key below, evaluate the interviewer's performance based on each of the following criteria. Write any comments in the space provided at the bottom of the page. If rating is below 3 OR above 3, please explain in comment area. (Refer to appendix #.)

Answers respondent's questions and concerns	*N/A*	*1*	*2*	*3*	*4*	*5*
Speaks slowly and distinctly reading the script of the instructions to the participants at neutral (but expressive) and even pace	*N/A*	*1*	*2*	*3*	*4*	*5*
Reads script of instructions as written and ensures that participant understands how to correctly complete form	*N/A*	*1*	*2*	*3*	*4*	*5*
Completes the editing process and reviews forms.	*N/A*	*1*	*2*	*3*	*4*	*5*
General Overall Rating	*N/A*	*1*	*2*	*3*	*4*	*5*

Key: *N/A – Not applicable*
1 – Unsatisfactory (failed to meet standards)
2 – Below expectation (did not meet some standards)
3 – At expectations (met standards)
4 – Above expectation (met all standards and in some cases exceeded them
5 – Outstanding (distinguished consistently exceeded all standards)

Comments: _____

_____

_____

_____

Corrective Action Taken: _____

_____

_____

_____

Supervisor Signature _____

WHEN CERTIFYING NEW INTERVIEWER - SEND COPY TO CC

FOR QC, COMPLETE THE WEB-BASED FORM ONLY!!!

MESA Food Frequency Questionnaire Supervisor Checklist

DATE: ☐ ☐ ☐ (mo day year)

Field Center:

Interviewer: Name/ID

Supervisor:

Purpose of Evaluation:

Certification ☐ **Supervisor QC Check** ☐ **Site Visit** ☐

Using the scale key below, evaluate the interviewer's performance based on each of the following criteria. Write any comments in the space provided at the bottom of the page. If rating is below 3 OR above 3, please explain in comment area. (Refer to appendix #.)

Self Administration (bold applies to both self and interviewer administration)

Answers respondent's questions and concerns	*N/A*	*1*	*2*	*3*	*4*	*5*
Speaks slowly and distinctly reading the script of the instructions to the participants at neutral (but expressive) and even pace	*N/A*	*1*	*2*	*3*	*4*	*5*
Reads script of instructions as written and ensures that participant understands how to correctly complete form	*N/A*	*1*	*2*	*3*	*4*	*5*
Completes the editing process and reviews forms.	*N/A*	*1*	*2*	*3*	*4*	*5*
General Overall Rating	*N/A*	*1*	*2*	*3*	*4*	*5*

Interviewer Administration (rate in addition to self admin items in bold above)

Maintains the focus of the interview but allows participant to express thoughts.	*N/A*	*1*	*2*	*3*	*4*	*5*
Follows instructions/reads questions as written.	*N/A*	*1*	*2*	*3*	*4*	*5*
Initiates (where needed) appropriate, nonleading questions	*N/A*	*1*	*2*	*3*	*4*	*5*
Records/codes answers correctly (follows skip patterns as needed).	*N/A*	*1*	*2*	*3*	*4*	*5*

Key: *N/A – Not applicable*
1 – Unsatisfactory (failed to meet standards)
2 – Below expectation (did not meet some standards)
3 – At expectations (met standards)
4 – Above expectation (met all standards and in some cases exceeded them
5 – Outstanding (distinguished consistently exceeded all standards)

Comments: _____

_____

_____

Corrective Action Taken: _____

_____

Supervisor Signature _____

MESA Anthropometry Certification / Supervisor / Site Visit Checklist

DATE: ☐ ☐ ☐ (mo / day / year)

Field Center:

Technician: Name/ID

Supervisor:

Purpose of Evaluation:

Certification ☐ **Supervisor QC Check** ☐ **Site Visit** ☐

Please check the appropriate box if technician performance is satisfactory for each line item. Please note any comments or remedial action taken in 'Comments' section if performance was not satisfactory.

	S	U	
1.	☐	☐	Thoroughly explains the procedure to the participant.
2.	☐	☐	Insures the participant is wearing light gowns or scrubs.
3.	☐	☐	Gives instruction for the proper position to measure height.
4.	☐	☐	Reads and records the height measurement to the nearest 0.1 cm.
5.	☐	☐	Gives instruction to measure the weight.
6.	☐	☐	Reads and records the weight measurement to the nearest 0.5 lb.
7.	☐	☐	Locates the exact marking for the waist measurement.
8.	☐	☐	Reads and records the waist measurement to the nearest 0.1 cm.
9.	☐	☐	Locates the exact marking for the hip measurement.
10.	☐	☐	Reads and records the hip measurement to the nearest 0.1 cm.
11.	☐	☐	Gives instructions to stand on body comp scale and grip handles.
12.	☐	☐	Correctly enters participant height, gender, and age into scale.
13.	☐	☐	Prints report from body comp scale (BCS).
14.	☐	☐	Records values from printed BCS report.

Comments: _____

_____

_____

_____

Corrective Action Taken: _____

_____

_____

_____

Supervisor / Site Visitor Signature _____

WHEN CERTIFYING NEW TECHNICIAN - SEND COPY TO CC

FOR QC, COMPLETE THE WEB-BASED FORM ONLY!!!

MESA Seated Blood Pressure Certification / Supervisor / Site Visit Checklist

DATE: ☐ ☐ ☐ (mo day year) **Field Center:** _____

Technician name/ID: _____

Supervisor: _____

Purpose of Evaluation:

Certification ☐ **Supervisor QC Check** ☐ **Site Visit** ☐

Please check the appropriate box if technician performance is satisfactory for each line item. Please note any comments or remedial action taken in 'Comments' section if performance was not satisfactory.

Throughout Exam:

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

Steps in Exam:

3.	☐	☐	Greets the subject and communicates appropriately with participant regarding purpose, time requirement, and process of blood pressure measurement.
4.	☐	☐	Seats participant in proper position.
5.	☐	☐	Insures that participant was not chewing gum.
6.	☐	☐	Places right arm on table in proper position.
7.	☐	☐	Bares participant arm to above point of shoulder.
8.	☐	☐	Measures and records arm circumference according to protocol.
9.	☐	☐	Selects proper size cuff using table in protocol.
10.	☐	☐	Palpates brachial artery.
11.	☐	☐	Places cuff directly on skin (no sleeve or rolled-up), with center of bladder over brachial art.
12.	☐	☐	Places cuff at level of participant's heart.
13.	☐	☐	Asks if participant was relaxed and helped subject to relax if needed.
14.	☐	☐	Instructs participant on posture.
15.	☐	☐	Times 5 minutes of relaxed sitting.
16.	☐	☐	Obtains 3 blood pressure measures with 1-minute intervals between end and restart.
17.	☐	☐	Records all three blood pressures correctly.
18.	☐	☐	Correctly identifies and records blood pressure for participant.
19.	☐	☐	Communicates appropriately with participant regarding an alert level blood pressure.
20.	☐	☐	Communicates appropriately with participant regarding a normal blood pressure.
21.	☐	☐	Communicates appropriately with participant regarding completion of blood pressure procedure.

Comments/Corrective Actions: _____

_____

_____

Supervisor /Site Visitor Signature _____

FOR QC ACTIVITY, MAKE SURE TO COMPLETE THE WEB-BASED QC PROCEDURES/ACTIVITIES FORM

MESA Supine ABI Certification / Supervisor / Site Visit Checklist

DATE: ☐ ☐ ☐ **mo** **day** **year**

Field Center: ☐

Technician: Name/ID ☐

Supervisor: ☐

Purpose of Evaluation:

Certification ☐ **Supervisor QC Check** ☐ **Site Visit** ☐

Please check the appropriate box if technician performance is satisfactory for each line item. Please note any comments or remedial action taken in 'Comments' section if performance was not satisfactory.

General:

	S	U	
1.	☐	☐	Thoroughly explains the procedure to the participant.
2.	☐	☐	Insures that the participant is relaxed and lying completely supine (legs straight with feet rolled outward) on the examination table, and that entire table is flat.
3.	☐	☐	Has participant rest quietly for at least 5 minutes prior to the procedure.
4.	☐	☐	Informs participant just before inflating cuff to avoid startling the participant.
5.	☐	☐	Records correct (i.e. pressure that observing trainer would record) pulse obliteration pressure.
6.	☐	☐	Read all pressure measurements.
7.	☐	☐	Records correct (i.e. pressures that observing trainer would record) pressures for all arteries.
8.	☐	☐	Can articulate alternative ABI protocol if unable to obtain brachial measurement in one arm (due to surgical procedure, for example).
9.	☐	☐	Can articulate protocol for ABI procedure when right and left artery pressures differ by more than 6 mmHg.

Right Brachial Artery:

10.	☐	☐	Places blood pressure cuff of appropriate size over right brachial artery.
11.	☐	☐	Locates brachial artery by palpation.
12.	☐	☐	Marks the location of the artery with a black marker.
13.	☐	☐	Applies ultrasound jelly over brachial artery.
14.	☐	☐	Locates brachial artery using Doppler probe.
15.	☐	☐	Inflates cuff quickly to at least 20 mm Hg above maximal pressure.
16.	☐	☐	Deflates at 2 mm Hg/second until a **sustained** systolic pressure is audible.
17.	☐	☐	Reads and records first systolic blood pressure at which a **sustained** pulse was first audible.
18.	☐	☐	Deflates cuff quickly and completely after measurement is obtained.
19.	☐	☐	Enters measurement into ABI data entry screen.

MESA Exam 5 Phlebotomy Certification / Supervisor Checklist

DATE: ☐ **mo** ☐ **day** ☐ **year**

Field Center:

Technician Name/ID:

Supervisor:

Please check the appropriate box if technician performance is satisfactory for each line item. Please note any comments or remedial action taken in 'Comments' section if performance was not satisfactory.

Preparation:

1. ☐ Blood collection trays properly prepared.
2. ☐ Blood draw tubes correctly labeled.
3. ☐ Questions on Phlebotomy / Processing Form asked.

Venipuncture:

5. ☐ Script properly delivered
6. ☐ Non-permeable lab coat, gloves, and face shields used.
7. ☐ Correct preparation of venipuncture site.
8. ☐ Venipuncture smoothly executed.
9. ☐ Tubes filled in correct priority order.
10. ☐ Plasma tubes <1/2 filled discarded.
11. ☐ Tourniquet released within 2 minutes; time noted on Phlebotomy form.
12. ☐ Proper appropriate care of venipuncture site after needle is removed.
13. ☐ Needle & tubing appropriately disposed.

Handling of filled draw tubes:

14. ☐ Tubes 1, 3, 4, & 6 mixed for ~30 seconds, then placed in ice bath.
15. ☐ Tubes 2 & 5 NOT mixed, placed directly in rack at room temperature.
16. ☐ If tubes < ½ full, discard, unless they are serum

P/P Form:

17. ☐ Correct sample ID labels on both pages of Phlebotomy/Processing form.
18. ☐ Venipuncture starts and end times noted on Phlebotomy form.
19. ☐ Elapsed tourniquet time noted on form.
20. ☐ Form completely filled out, and any comments noted in comment section.

Comments: _____

_____

_____

For QC activity, Make sure to complete the Web-based QC Procedures/Activities form

MESA Laboratory Processing Certification / Supervisor Checklist

DATE: ☐ ☐ ☐ **Field Center:**
mo **day** **year**

Technician Name/ID:

Supervisor:

Please check the appropriate box if technician performance is satisfactory for each line item. Please note any comments or remedial action taken in 'Comments' section if performance was not satisfactory.

Preparation:

1. ☐ Aliquot racks organized and cryovials correctly labeled
2. ☐ Non-permeable lab coats, gloves, and face shields used.

Stage 1:

3. ☐ Time checked to ensure tubes 1,3,4 & 6 are processed within 30 minutes of venipuncture – tubes centrifuged at 4 ^{o}C for 30,000 g-minutes.
4. ☐ EDTA plasma pooled and aliquoted into purpl-coded cryovials #1 - 7.
5. ☐ Citrate plasma correctly aliquoted into blue-coded cryovials #8 – 11.
6. ☐ SCAT-1 plasma correctly aliquoted into yellow-coded cryovials #12 – 15.
7. ☐ New pipet tip used for each sample type.
8. ☐ Filled cryovials checked off on form and frozen upright @ -70 ^{o}C

Stage 2:

12. ☐ Time monitored to ensure tubes 2 & 5 held at room temperature for > 40 minutes and < 90 minutes.
13. ☐ Centrifuged tubes 2 & 5 @ 4 ^{o}C for 30,000 g-minutes.
14. ☐ Serum pooled and aliquoted into red-coded cryovials #16 - 22. Filled cryovials checked off on form and frozen upright @ -70 ^{o}C.

Processing Completion:

15. ☐ All used draw tubes, used pipet tips, any excess blood products, used gloves, etc discarded in biohazardous waste container.
16. ☐ Centrifuge, and blood processing areas wiped down with 10% bleach solution or equivalent disinfectant.
17. ☐ Processing form completely filled out, confirm all start times, cryovials obtained, and any comments noted in comment section.

Comments: _____

_____

_____

Supervisor Signature _____

For QC activity, Make sure to complete the Web-based QC procedures/activities form

MESA Cognitive Assessment Supervisor Checklist

DATE: ☐ ☐ ☐ **Field Center:** ☐
mo **day** **year**

Interviewer: Name/ID ☐

Interview/form reviewed: **Supervisor:** ☐

Informed Consent ☐ **Medications** ☐ **Medical History** ☐ **Physical Activity** ☐ **Follow-up** ☐

MESA-Lung ☐

Purpose of Evaluation:

Certification ☐ **Supervisor QC Check** ☐ **Site Visit** ☐

Using the scale key below, evaluate the interviewer's performance based on each of the following criteria. Write any comments in the space provided at the bottom of the page. If rating is below 3 <u>OR</u> above 3, please explain in comment area. (Refer to appendix #.)

Answers respondent's questions and concerns.	*N/A*	*1*	*2*	*3*	*4*	*5*
Speaks slowly and distinctly reading the questions at neutral (but expressive) and even pace	*N/A*	*1*	*2*	*3*	*4*	*5*
Maintains the focus of the interview.	*N/A*	*1*	*2*	*3*	*4*	*5*
Follows instructions/reads questions as written.	*N/A*	*1*	*2*	*3*	*4*	*5*
Initiates appropriate, nonleading questions only where permitted	*N/A*	*1*	*2*	*3*	*4*	*5*
Records/codes answers correctly.	*N/A*	*1*	*2*	*3*	*4*	*5*
Completes the scoring process where appropriate.	*N/A*	*1*	*2*	*3*	*4*	*5*
General Overall Rating	*N/A*	*1*	*2*	*3*	*4*	*5*

Key: *N/A – Not applicable*
1 – Unsatisfactory (failed to meet standards)
2 – Below expectation (did not meet some standards)
3 – At expectations (met standards)
4 – Above expectation (met all standards and in some cases exceeded them
5 – Outstanding (distinguished consistently exceeded all standards)

Comments: _____

_____

_____

_____

Corrective Action Taken: _____

_____

_____

Supervisor Signature _____

WHEN CERTIFYING NEW INTERVIEWER - SEND COPY TO CC
FOR QC, COMPLETE THE WEB-BASED FORM ONLY!!!

MESA Cardiac MRI Quality Control Form

1. Participant ID number: ____ ____ ____ ____ ____ ____ ____

2. Acrostic: ____ ____ ____ ____ ____ ____ ____

3. Date of MRI: ____ ____ / ____ ____ / ____ ____

4. Field Center (circle one)
   3 - Wake Forest
   4 - Columbia
   5 - Johns Hopkins
   6 - Minnesota
   7 - Northwestern and Loyola
   8 – UCLA

5. Date QC form completed: ____ ____ / ____ ____ / ____ ____

6. Name of person completing form (circle one): Chia-Ying Liu
   Other: _____

7. Quality Control Scores: 0=missing; 1=non-diagnostic; 2=acceptable; 3=good

Description of the Series	**Score**	**Comments**
Cine 4 chamber	0 1 2 3	
Tagging	0 1 2 3	
Short Axis cine	0 1 2 3	
Cine 2 chamber	0 1 2 3	
Short axis delay	0 1 2 3	
4 chamber delay (FGRE)	0 1 2 3	
2 chamber delay (FGRE)	0 1 2 3	
Cine 4 chamber (FGRE)	0 1 2 3	
Short axis cine (FGRE)	0 1 2 3	
Cine 2 chamber (FGRE)	0 1 2 3	

8. Corrective actions (specify): _____

   _____

9. Overall Assessment (circle one):
   a. Accepted
   b. Not accepted

Field Center MRI Technologist Training Checklist

DATE: mo day year **Field Center:**

Technologist: Name/ID

FC MR Physician or Principal Investigator:

A check indicates yes to the questions below:

1. The technologist meets the requirements as specified in the FC MOP: ☐
   Completion of a two-year AMA approved program and two to three years MRI experience
2. Reviewed the overall MESA Protocol and Study Design: ☐
3. Reviewed the MESA MRI protocol Lecture: ☐
4. Presented the Cardiac Anatomy Lecture: ☐
5. Presented the Cardiac Gating Lecture: ☐
6. Presented the Physics Lecture: ☐
7. Reviewed the FC MOP: ☐
8. Reviewed the procedure for Alerts: ☐
9. The technologist completed the written examination under direct supervision: ☐
10. The technologist completed an examination under my direction and demonstrated all items listed on the MESA MRI Certification/ Supervisor Checklist: ☐

FC MR Physician or Principal Investigator Signature:

SEND COPY TO MRC (WHEN NEW TECHNOLOGIST IS CERTIFIED)

MESA CT Certification / Supervisor / Site Visit Checklist

DATE: ☐ ☐ ☐ **Field Center:** ☐

mo **day** **year**

Technician Name/ID: ☐

Supervisor: ☐

Purpose of Evaluation:

Certification ☐ **Supervisor QC Check** ☐ **Site Visit** ☐

Please check the appropriate box if technician performance is satisfactory for each line item. Please note any comments or remedial action taken in 'Comments' section if performance was not satisfactory.

During examination:

1. ☐ Greets participant professionally.
2. ☐ Places calibration pad phantom correctly.
3. ☐ Teaches participant breath-holding technique (at end-inspiration).
4. ☐ Checks that participant is centered prior to the scan.
5. ☐ Selects correct field of view (35 cm) including the phantom.
6. ☐ Selects appropriate ECG triggering (80% per protocol).
7. ☐ Scans entire heart (at least 35 slices per scan, preferably 40).
8. ☐ Instructs participant to relax between scans.
9. ☐ Assesses the adequacy of positioning, ECG gating, and lack of respiratory motion.

Data transmission and quality control:

11. ☐ Transmits images successfully via Internet.
12. ☐ Uses proper MESA ID labeling on study form.
13. ☐ Demonstrates understanding of QA procedure and frequency of CT calibration using the Calibration and Torso phantoms.
14 ☐ Documents any problems (if they occurred) in obtaining either scan.

Comments: _____

_____

Corrective Action Taken: _____

_____

_____

Supervisor / Site Visitor Signature _____

COMPLETE THE WEB-BASED QC ACTIVITIES/PROCEDURES FORM

Ultrasound Reading Center at University of Wisconsin Recommends a revision to this checklist which is not reflected in this document. Please contact Claudia Korcarz for additional information prior to reviewing local sonographer activities.

MESA Carotid IMT Certification / Supervisor / Site Visit Checklist

DATE: ☐ ☐ ☐ **mo day year**

Field Center: ☐

Technician: Name/ID ☐

Supervisor: ☐

Purpose of Evaluation:

Certification ☐ **Supervisor QC Check** ☐ **Site Visit** ☐

Please check the appropriate box if technician performance is satisfactory for each line item. Please note any comments or remedial action taken in 'Comments' section if performance was not satisfactory.

General/Initial Scan:

1. ☐ Completes the Sonographer Log Sheet.
2. ☐ Completes the MESA Carotid IMT form.
3. ☐ Enters proper participant, study, and image annotations.
4. ☐ Selects proper pre-sets, and changes pre-set for ICA images.
5. ☐ Locates the bifurcation, distinguishes the internal from the external carotid artery.
6. ☐ Identifies the site of maximal wall thickening/plaque on the near and far wall, in the bulb or internal carotid artery.
7. ☐ Places focal zones at or just below the far wall to optimize far wall interfaces.
8. ☐ Uses color and pulse wave Doppler imaging as identification aids.
9. ☐ Adjusts gain controls to maximize wall and lesion interfaces.

Image Collection: Right and Left Side:

10. ☐ Records 15 seconds of a real time transverse (short-axis) sweep of the carotid from the base of the common, up through the bulb, into the internal, and back down to the base of the common carotid.
11. ☐ Records five seconds of the pulse-wave Doppler measurement of the peak systolic velocity in the internal carotid.
12. ☐ Insure that Pulse Wave Doppler angle correction does not exceed 60 degrees.
13. ☐ Displays placement of the Doppler gate and records the velocity in cm/sec.
14. ☐ Captures a cine loop of the distal 10-mm of the common carotid artery.
15. ☐ Cycles through the cine loop images and selects the one that best displays the intimal walls.
16. ☐ Records five seconds of the best frozen image of the common carotid artery.
17. ☐ Records five seconds of common carotid cine loop.

MESA Retina Supervisor Checklist

DATE: ☐ ☐ ☐ **Field Center:**
mo **day** **year**

Technician Name/ID:

Supervisor:

Please check the appropriate box if technician performance is satisfactory for each line item. Please note any comments or remedial action taken in 'Comments' section if performance was not satisfactory.

Preparation:

1. ☐ Lens is clean
2. ☐ Chin and forehead rest is cleaned
3. ☐ Explains photography procedure to participant
4. ☐ Photographer adjusts table and chin rest if necessary

Procedure:

5. ☐ Followed photography script
6. ☐ Remind participant to rest in between photo shoot
7. ☐ Photographs are reviewed at end of session
8. ☐ Procedure completed smoothly
9. ☐ Procedure completed is acceptable time range i.e. 10-15mins

Handling of participant comfort and ease:

10. ☐ Maintains communication with participants throughout session
11. ☐ Advising participants of steps/action about to occur e.g. prior to shooting photographs
12. ☐ Answer participant questions appropriately

Form Completion:

13. ☐ Uses correct sample ID on both completion form and laptop data entry screen.
14. ☐ Photography completion form is filled out correctly, during or immediately after session.

Complete Processing & Shipping to OERC

14. ☐ Successfully creates Photo CD sets (1 for file and 1 to send to OERC)
15. ☐ Successfully transmits Eye History Form to OERC
16. ☐ Successfully prepares the photo log, shipping manifest, and CD package to send to OERC

Comments: _____

Make sure to complete the Web-based QC Procedures/Activities form

MESA Vision Supervisor Checklist

DATE: ☐ ☐ ☐ **Field Center:** ☐

mo **day** **year**

Technician Name/ID: ☐

Supervisor: ☐

Please check the appropriate box if technician performance is satisfactory for each line item. Please note any comments or remedial action taken in 'Comments' section if performance was not satisfactory.

Preparation:

1. ☐ Lens is cleaned
2. ☐ Chin and forehead rest are cleaned
3. ☐ Explains Vision procedure to participant
4. ☐ Adjusts table and chin rest if necessary

Procedure:

5. ☐ Followed Vision script on form and computer screen
6. ☐ Ask for and return the participant's glasses for the lensmeter component
7. ☐ Complete the refraction component appropriately i.e. with or without glasses, contact lens
8. ☐ Entire examination process completed smoothly
9. ☐ Examination completed in an acceptable time range i.e. 10-15mins

Handling of participant comfort and ease:

10. ☐ Maintains communication with participants throughout session
11. ☐ Advising participants of steps/action about to occur
12. ☐ Answer participant questions appropriately

Form Completion:

13. ☐ Uses correct ID on both completion form and computer data entry screen.
14. ☐ Vision completion form is filled out correctly, during or immediately after session.

Complete Processing

14. ☐ Successfully upload data from refraction machine to computer
15. ☐ Successfully print refraction report for participant

Comments: _____

Make sure to complete the Web-based QC Procedures/Activities form

MESA Spirometry Certification / Supervisor / Site Visit Checklist

DATE: ☐ ☐ ☐ (mo day year) **Field Center:**

Technician name/ID:

Supervisor:

Purpose of Evaluation:

Certification ☐ **Supervisor QC Check** ☐ **Site Visit** ☐

Please check the appropriate box if technician performance is satisfactory for each line item. Please note any comments or remedial action taken in 'Comments' section if performance was not satisfactory.

Steps in Exam:

1. ☐ ☐ Greets the subject and communicates appropriately with participant regarding purpose, time requirement, and process of spirometry measurement.
2. ☐ ☐ Completes questions 1-4 on the Spirometry Completion Form before starting the procedure.
3. ☐ ☐ Insures that participant is wearing loose clothing, has removed objects from the mouth including unsecured dentures, and has used the restroom prior to spirometry exam.
4. ☐ ☐ Opens spirometry software and locates the correct participant
5. ☐ ☐ Follows scripted instructions
6. ☐ ☐ Asks participant to sit straight up with head up during the examination (standing is OK if more comfortable for the participant).
7. ☐ ☐ Places nose clips on the nose
8. ☐ ☐ With a new mouth piece, has the participant do a trial exhalation and appropriately corrects any problems.
9. ☐ ☐ Attaches mouthpiece to spirometry hose/machine and conducts the examination
10. ☐ ☐ Demonstrates and properly coaches the participant during the procedure
11. ☐ ☐ Coaches participant until both "6 second" and "Plateau Achieved" messages are displayed
12. ☐ ☐ Appropriately uses curves on the screen to coach and provide feedback
13. ☐ ☐ Indicates testing position and impression of test quality.
14. ☐ ☐ Only rejects curves that are completely unusable and achieves three acceptable maneuvers from participant (in 8 attempts or fewer).
15. ☐ ☐ Monitors participant for headache, dizziness, lightheadedness, fainting, shortness of breath, or significant cough.
16. ☐ ☐ Correctly administers albuterol where appropriate.
17. ☐ ☐ Records appropriate comments.
18. ☐ ☐ Prints a hard copy of the spirometry report
19. ☐ ☐ Transmits data to Spirometry Reading Center

Comments/Corrective Actions: _____

_____

_____

Supervisor /Site Visitor Signature _____

FOR QC ACTIVITY, MAKE SURE TO COMPLETE THE WEB-BASED QC PROCEDURES/ACTIVITIES FORM

MESA Oximetry Certification / Supervisor / Site Visit Checklist

DATE: ☐ ☐ ☐ **Field Center:**
mo **day** **year**

Technician name/ID:

Supervisor:

Purpose of Evaluation:

Certification ☐ **Supervisor QC Check** ☐ **Site Visit** ☐

Please check the appropriate box if technician performance is satisfactory for each line item. Please note any comments or remedial action taken in 'Comments' section if performance was not satisfactory.

Steps in Exam:

1. ☐ ☐ Places probe correctly.
2. ☐ ☐ Confirms good signal (pulse) is obtained
3. ☐ ☐ Observes for one minute
4. ☐ ☐ Accurately estimates apparent median value (+/- 1%)
5. ☐ ☐ Records value on form or computer screen

Comments/Corrective Actions: _____

_____

_____

Supervisor /Site Visitor Signature _____

FOR QC ACTIVITY, MAKE SURE TO COMPLETE THE WEB-BASED QC PROCEDURES/ACTIVITIES FORM