

SECTION 4 OBSERVATIONS

INTRODUCTION

Observations of staff performing activities ensures staff received adequate training and perform tasks using approved and/or standardized procedures. Observations help identify procedures that are not clearly understood and/or need improvement as well as identify where additional training is needed. In the same way, monitoring the performance and condition of equipment helps identify the need for equipment maintenance and/or additional training on the appropriate use of the equipment.

Clinical Center (CC) lead staff, certified peers, and Clinical Coordinating Center (CCC) Quality Assurance (QA) staff are all responsible for observing routine activities using the standard Training/QA Checklists. Observations by CC lead staff and certified peers occur during initial local training, recertification, and routine quality assurance monitoring. The CCC observations occur during initial central training and at the initial and regular follow-up QA visits.

This section describes:

- Clinical Center responsibilities for observations,
- Clinical Center responsibilities for equipment monitoring, and
- Clinical Coordinating Center QA Visits.

4.1 CC Observations

Clinical Center lead staff are responsible for observing non-lead staff performing procedures. Observations by peers or other staff members also helps promote discussion of the procedures and consistency in performing the activities.

4.1.1 Observations for Certification

Clinical Centers must use the Training/QA Checklists for initial certification and annual recertification observations. Ideally, lead staff complete the Training/QA Checklists on non-lead staff. However, lead staff may choose other appropriate certified staff to do the observations. In addition, staff members may complete the checklists themselves if other staff are not available to make the observations. Observations by other lead staff are strongly encouraged, particularly in those activities than involve interactions with participants.

After the observation, the lead staff or peer observer and staff observed should meet to identify strengths as well as areas needing improvement. If areas of improvement are major, lead staff should outline an individualized plan for correction. The lead staff monitor the implementation of the plan as dictated by the degree of improvement needed. For example, the lead staff may choose to follow-up only verbally if areas needing improvement are minor. On the other hand, the lead staff may observe the task a second time if the areas needing improvement are significant.

4.1.2 Observations for Quality Assurance

In addition to the initial certification and recertification observations, some tasks have more frequent observation requirements as noted on the Training/QA Checklist. Perform the observations according to the schedule on the Checklists.

On a quarterly basis, the Lead (DA) Nutritionist must observe and evaluate staff who do not meet the Four-Day Food Record (*4DFR*) documentation performance standards using *Form 567 - Food Record Documentation*. See *Vol. 2, Section 10.1.8 - QA of 4DFRs* for more details.

4.2 Equipment Checks

Equipment checks and routine maintenance help identify both short-term and long-term problems with equipment performance. Each CC is responsible for the appropriate functioning and maintenance of equipment used to carry out WHI procedures. Clinical Centers need to maintain logs of equipment checks and maintenance following both the manufacturer and WHI requirements. *Table 4.1 - CC Equipment Maintenance* lists the type and frequency of the required equipment checks

It also strongly recommended that CCs keep a maintenance log for other equipment in the CC, including the Personal Computers (PCs), scan guns and pens, and scanner. See *Vol. 5, Section 10 - Maintenance and Support*.

Table 4.1
CC Equipment Maintenance

Equipment Description (Vol. 2 - Procedures references)	Check	Each Use	Dail y	Monthly	Semi- Annually	Annually
Blood Pressure Cuffs ; 4 sizes available (See <i>Sec. 2.3.2.3</i> and <i>9.2.5</i>)	Inspect for wear and tear.	X				
Sphygmomanometer ; conventional mercury (See <i>Sec. 2.3.2.3</i> and <i>9.2.5</i>)	Check for zero reading before measurement.	X				
	Local inspection and cleaning; inspect cap.					X
Stadiometer ; Recommend: Perspective Enterprises, model #PE-WM-60-84-PL (See <i>Sec. 2.3.2.3</i> and <i>9.3.3</i>) Alternative equipment models must be approved by CCC (calibration requirements may vary).	Check ease of movement, pressure of head piece, measuring board for accuracy.					X
Stadiometer ; Harpenden at Bone Density sites (See <i>Sec. 2.3.2.3</i> and <i>9.3.3</i>)	Calibrate.		X			
Scale reading in kgs; Recommend Detecto Balance Beam (See <i>Sec. 2.3.2.3</i> and <i>9.4.4</i>)	Balance to zero before each participant steps on scale.	X				
	Calibrate with two 25 kg or one 50 kg wt (semi-annually & when moved).				X	
	Certify by independent scale technician.					X
Scale that is not a balance beam	Calibrate weekly and when moved.	X				X
Measuring Tapes ; supplied by CCC (See <i>Sec. 9.5.4</i>)	Visually inspect for wear and tear.			X		
Hand Grip Dynamometer ; Jamar-hydraulic (See <i>Sec. 2.3.2.3</i> and <i>9.6.3.3</i>)	Check for correct zero.	X				
	Check posts, hydraulics, handle, and peakhold, needle; calibrate with weights.				X	
	Certify by manufacturer.					As needed
Freezer (-70° C) (See <i>Sec. 11.3.5.1</i>)	Monitor temperature.		X			
	Check alarm and back-up system, e.g., CO ₂ tank, temp recorder (if present) with certified thermometer.			X		
	Defrost as needed; inspection by service representative.					X
Refrigerated Centrifuge with Swinging Buckets (See <i>Sec. 11.3.5.1</i>)	Monitor temp. 0° to 10° C range with certified thermometer.			X		
	Check speed with tachometer.					X
ECG; MACPC (See <i>Sec. 13.5.2</i>)	Drain battery.			X		
Bone Densitometer (BD sites only)	See <i>Vol. 6, Section 7 - Monitoring Machine Performance</i> for specifications.		X			
OHAUS Pill Weighing Scale (CT1200) (See <i>Sec. 15.6.2.2</i>)	Calibrate with 500 gm and 1,000 gm weights and do span check.		X			
	Do linearity check (and as needed when moved, dropped).			X		

Timed Walk (See <i>Sec. 9.6.5</i>)	Check for correct measurement of 6 meters (and when moved).					X
--	---	--	--	--	--	---

4.3 QA Visits by CCC

Clinical Coordinating Center QA staff conduct routine QA visits to each Women's Health Initiative (WHI) CC starting in the first year of operation. The QA Visit offers an opportunity for the CCC QA staff to learn more about the CCs, share information with CC staff, observe the individual functioning of a CC, and provide feedback.

A minimum of one three-day visit to each CC will be conducted within the first year of CC operations. In subsequent years, a two-day visit will be conducted. The frequency of QA visits is one every two years after Year 1 for those CCs with good or excellent performance as assessed at the most recent QA visit and subsequent performance indicators. In general, a team of two CCC QA staff members, one clinical and one nutritional, conduct QA Visits to each CC. Occasionally a CCC Data Coordinator or other QA staff member will accompany the regular CCC QA staff.

For CCs with satellite sites, a QA visit usually includes a visit to both the primary and satellite CC sites, and the visits may be extended to allow enough time for observations at both sites. The amount of time spent at the satellite site depends on the operations performed at each site and how far the satellite site is from the primary CC. QA visitors may also observe operations conducted at remote sites where the CC conducts visits with participants but has no access to WHILMA.

4.3.1 Preparation for QA Visits

Preparations for the visit includes:

- Setting the dates for the visit.

Timing, dates, and proposed agendas for routine annual visits are based on CC performance on the initial QA visit, date of the most recent visit, and availability of staff. The dates and agenda items for the QA visits come from a collaborative effort between the CCC and CC that begins approximately two months before the visit. Initial QA visits are scheduled after the first DM Intervention group at the CC completes at least Session 3. Dates depend on the availability of appropriate CC and CCC QA staff.

Once dates have been negotiated, the CCC QA staff send the Clinic Manager a proposed list of observations and meetings with lead staff (and discussion guidelines for meeting with lead staff). The Clinic Manager creates an agenda to accommodate the CC schedule. After the agenda is finalized, the CCC QA staff send a copy of the final agenda to the Clinic Manager.

- Completion of selected Training/QA Checklists (DM).

The Lead Nutritionist sends copies of the most recently completed *Form 560 - DM Intervention* and *Form 564 - Dietary Assessment* to the CCC before the visit. The CCC nutritional QA visitors use the completed checklists as a guide for discussion during the visit.

- Submission of participant files to the CCC for the off-site participant file audit.

4.3.2 Content

Quality Assurance visits include a variety of activities, including meetings with lead staff, review of reports, observations using the Training/QA Checklists, and training sessions as appropriate. There may be additional topics added to the agenda based on CC performance issues that require observation or discussion. The additional topics may originate from the CCC or the CC. The CCC may request to meet with specific staff in addition to the lead staff to review activities and provide feedback. The CC staff may request that certain topics be reviewed based on staff members' own observations.

Standard QA visit agenda items include:

- Staff introductions and tour of facility.
- Meetings with lead staff: Meetings are held separately with each of the lead staff (Clinic Manager, Recruitment Coordinator, Clinic Practitioner, Lead Nutritionist, Data Coordinator, and Outcomes Specialist to discuss specific CC issues related to the staff position, including local QA operations and reports. Outlines of the topics discussed during the meetings are distributed before each visit. (See current copies of the discussion guidelines located in the Public Folders of Outlook. Refer to *Section 2.3 Public Folders* for more information.) Other topics are covered based on CC need and request.
 - Review of activity reports with appropriate staff: This includes review of routine CCC monthly activity and subcontractor reports as well as reports the CC can generate in WHILMA, with a focus on areas in which the CC may need assistance.
 - Review of local QA program: This includes review of certification and recertification records, equipment logs, and other local QA activities.
- Observation of clinical operations, dietary modification intervention, dietary assessment, and data management operations, as appropriate: The observations focus on activities that fall under the higher priority levels (see *Section 1.2 - Priorities*). A higher priority may be given to those areas in which the CC requests or needs special attention, and a lower priority may be given to those areas showing good performance at previous QA visits and/or on data monitoring reports.
- Participant file audit. (See description below.)
- Debriefing: The QA staff conduct a debriefing at the end of the visit with the PI, lead staff, and other CC staff, at the CC's discretion, to review and discuss the findings from the observations and meetings. The QA Visitors will hold a separate debriefing with the Clinic Manager and/or PI, if requested, and as time permits. The QA visit report includes items discussed at the debriefing and may include additional items identified after review and discussion at the CCC.

Additional or supplemental training is included as needed: A CC may request CCC QA staff to conduct on-site training sessions by proposing it in the first draft of the QA visit agenda. The appropriate CCC Unit Manager will review the request and determine the feasibility and appropriateness of conducting a training session during the QA visit. If the requested training is not feasible, the QA staff will recommend alternate ways for the CC staff to obtain the training based on the complexity of the activity, availability of expertise for the specified activity, and availability of time and space. Clinical procedure training (e.g., some aspects of ECG, pelvic exam Pap, endometrial aspiration, breast exam, blood draw) is not available on a QA visit. Training done during a QA visit does not replace central training for lead staff.

4.3.3 Participant File Audit Content

The CCC performs a file audit of selected participant files to evaluate the quality of CC data collection and documentation. Files may be reviewed on-site during the QA visit and some may be selected for copying and review at the CCC by clinical, nutritional, and data staff. Additional file audits may also be conducted at other times locally or by the CCC. In general, files are selected at random, although files may also be selected based on particular problem areas. Action items identified in both the on-site and off-site participant file audit are included in the final QA Visit report. See Table 4.2 for list of file audit codes that classify file audit discrepancies into action items. Each file audit is documented using a file audit form (see Figure 4.1)

4.3.3.1 On-Site File Audit

One or more participant files may be reviewed on site during the QA visit. This audit usually includes at least one HRT and one DM participant file with an annual follow-up visit (identified by WHILMA report). Only the contacts for the previous year are reviewed.

During the on-site file audit, the reviewers look for the following:

- Each form is labeled with the participant name and ID number
- Correct name and date on each lab result
- Correct editing procedures.
- Appropriately filed forms
- Copies of lab, pathology, and mammogram reports attached to appropriate WHI forms
- Ink used on non-mark-sense forms
- No outcomes documents (e.g., *Form 120-131*) or other information about outcomes adjudication included in regular participant file
- Hormone Replacement Therapy (HRT) and DM Intervention-specific information separated from routine WHI forms (separated in chart or in a different physical location)
- Forms are used appropriately (used when needed and completed appropriately):
 - question responses clearly marked,
 - results from lab or clinical procedures recorded correctly,
 - edits made appropriately
 - duplicate forms are not completed
- Forms found in the file have been data entered, as needed, and forms are not data entered more than once.
- All forms data entered are filed in the participant file.
- Forms are filed in the correct participant file.
- Other issues or problems as needed.

4.3.3.2 Off-Site File Audit

The CCC requests participant files for the off-site file audit approximately one to two months before the QA visit. This lead time gives the CCC time to complete the audit before the visit and allows the QA visitors to give the CC feedback on the audit during the QA Visit. The CCC sends the CC a list of the participant ID numbers selected for the off-site file audit. In general, the CCC identifies 10 participants for the audit, using the following criteria:

- Participants screened and randomized or enrolled within the last 12 months
- Participants with follow-up contacts within the previous 12 months, including one with an annual visit and with an emphasis on DM and HRT participants.

Once recruitment is completed, all participant files will be selected from those with contacts within the last 12 months. Additional criteria may be added as needed.

Upon receipt of the participant ID numbers for the off-site file audit, the CC copies the chart for each participant and sends the copies to the CCC within one day. The forms and time period of forms to be copied may change, depending on the issues to be addressed in the audit. The initial notice to the CC about the file audit will include the specifics of which parts of the file to copy for the CCC.

Specified items reviewed in the off-site file audit that are not included in the on-site audit include the following items:

- Correct interpretation and recording of results on the appropriate form, specifically,
 - Form 82 – Endometrial Aspiration*
 - Form 83 – Transvaginal Uterine Ultrasound*
 - Form 85 – Mammogram*
 - Form 86 – ECG*
 - Form 89 – Breast Follow-up, as needed*
 - Form 92 - Pap Smear*
- Clinical contact notes are present and used to enhance communication and ensure participant safety
- Presence of DM Progress Notes on regular basis, (e.g., after every other session, after Individual Session), and with enough information to give the reader some knowledge of the participant
- System for tracking DM Intervention participants through use of Member Task Status Report (*WHIP165*)
- Completion of all expected tasks using Group Session Schedule (*WHIP0431*)
- Use of current version of the forms

Table 4.2

Codes for Standard Action Items

Code	Description
1	Question on form is blank while corresponding question in WHILMA has a response (this includes no participant ID on a form).
2	Question response in WHILMA does not match corresponding question response marked on the form, or question response in WHILMA is blank while corresponding question response is marked on the form.
3	Edits to items on the forms are incompletely documented, missing staff initials and/or date.
4	An item on a clinic-administered form requiring a response is not answered.
5	A form found in the participant file has not been data entered.
6	A form entered into WHILMA was not found in the participant file or in the copy of the participant file.
7	The contact date on <i>Form 11 (12, 13, 14, 15)</i> does not match the date the participant signed the corresponding consent form.
8	Questions on a form were not marked correctly or results from lab or clinical procedures were not recorded correctly onto the corresponding form.
9	A duplicate form was completed and entered into WHILMA for the same task.
10	Forms or other participant materials for a different participant were found in the file or copy of participant file.
11	Clinic-administered form was completed in pencil rather than pen.
R	Other required action item.

Figure 4.1
Chart Audit Form

CC: _____

ID: _____-_____-_____

HRT____

DM____

DM___ Randomized Date: __ - __ - __

On-Site ____ Reviewer: _____

CaD_

Randomized Date: ____ - ____ - ____

Off-Site _____ Reviewers: Clinical _____ Nutrition _____ Data _____

[illegible]

4.3.4 Documentation of QA Visit

4.3.4.1 QA Visit Report

The CCC QA staff prepare a written report of the findings from the QA visit, and sends the report to the CC and the WHI Project office within one month after completing the visit. The report includes the following sections:

- Introduction: The dates of the QA visit, a list of QA staff conducting the visit, the general purpose of the visit, observations or topics added to the standard agenda based on clinic performance, and an outline of the report format.
- Summary: A brief description of the CC's overall performance.
- Summary Table: A list of QA checklists indicating those that were completed for the QA visit and those that resulted in action items.
- Action Items: A list of the required and recommended action items for the CC and a list of action items for the CCC generated from the QA visit. This includes a list of all the findings of the on and off-site file audit.
- QA Checklists: All QA Checklists completed during the visit and for the off-site participant file audit. These completed Checklists form a detailed explanation of the required and recommended action items.
- Lead Staff Discussion Guidelines: Notes taken during meetings with lead staff
- Other Related Materials: Includes CC-specific materials such as CC organizational chart, clinic flow, clinic procedures, or participant materials.
- Copy of QA visit agenda.
- Copy of Chart Audit forms.

Required CC action items are indicated as such in the WHI Manuals and immediate implementation is required. Recommended CC action items are suggestions to improve the efficiency and consistency of the CC and can be implemented at the CC's discretion.

4.3.4.2 CC Response and Final Report (Required)

The CC is required to provide a written response to the QA Visit. The CC response is due at the CCC within two weeks of receipt of the report. The CCC forwards the report to the WHI Project Office

This page left blank intentionally

Section 4

Observations

Table of Contents

Contents	Page
INTRODUCTION	4-1
4.1 CC Observations.....	4-2
4.1.1 Observations for Certification	4-2
4.1.2 Observations for Quality Assurance	4-2
4.2 Equipment Checks.....	4-3
4.3 QA Visits by CCC.....	4-5
4.3.1 Preparation for QA Visits	4-5
4.3.2 Content.....	4-6
4.3.3 Participant File Audit Content.....	4-6
On-Site File Audit.....	4-6
Off-Site File Audit.....	4-7
4.3.4 Documentation of QA Visit	4-10
QA Visit Report..... 4-10	
CC Response and Final Report (Required).....	4-10
Tables	
4.1 CC Equipment Maintenance.....	4-4
4.2 Codes for Standard Action Items	4-8
Figures	
4.1 Chart Audit Form.....	4-9