Section 11

Quality Assurance

11.1 WHI Extension Study QA Program Overview

For the Women's Health Initiative (WHI) Extension Study, Quality Assurance (QA) responsibilities include activities performed at the Field Centers (FCs) as well as activities initiated and coordinated by the Clinical Coordinating Center (CCC). These responsibilities and activities are based on a QA plan that establishes priorities for high quality data and conduct while preserving efficient and cost-effective operations. The basis of the QA program is to:

- Establish and monitor performance goals
- Document procedures (see description in *Section 4.2 – Study Documentation*)
- Train staff
- Monitor data (completeness, validity, timeliness)
- Provide feedback

11.1.1 Performance Monitoring Plan

The performance of all FCs is reviewed on a regular basis following a 3-step Performance Monitoring Plan. This plan includes CCC and Performance Monitoring Committee (PMC) review of all FC operations and performance based on the performance goals described in *Table 11.1 – Performance Requirements Summary*. The purpose of the three steps is to reinforce good performance, to identify FC-specific performance issues in a timely fashion, and to provide assistance or institute corrective action if performance falls below goals. The three monitoring levels are described below.

Level 1: Routine Performance Monitoring and Follow-up

CCC staff regularly contact the FC staff, review database reports, and perform QA checks for all FCs. They monitor key areas to provide timely and routine feedback on performance to FCs where appropriate. They also provide assistance (e.g., advice, training) where performance needs improvement.

Both the FCs and CCC can run QA reports and each is responsible for reviewing these reports. CCC staff review both the summary and detailed QA reports to identify potential problems and trends at FCs based on the performance goals. Periodically the CCC may request selected documents, such as key-entered *Form 33D – Medical History Update (Detail)*, from FCs for a QA inspection.

The CCC produces an Outcomes Backlog Report monthly and a Mammogram Task Completeness Report quarterly. The performance standards are based on *Form 33 – Medical History Update* collection, outcomes processing, and mammogram report collection. The outcomes processing standard includes the processing from the time a *Form 33* is entered in the database until the time the corresponding outcomes cases are forwarded to the CCC. Thus, processes include collection of *Form 33D*, collection of a Release of Information (ROI), requesting and receiving documents supporting the self-reports on *Form 33D*, and assembly of the cases and forwarding to the CCC. The typical time to carry out all those steps is considered to be three months or less. Any outstanding cases beyond the number typically processed by a FC in a 3-month period are considered backlogged. The outcomes backlog report shows the various components of the outcomes processing, as well as the overall backlog and the *Form 33* collection for each FC.

FCs meeting the performance standards in all categories, for which no other concerns exist, require no action and monthly monitoring continues as usual. Annually the PMC (see below) will send these FCs a note acknowledging that they met Performance Standards in all categories.

FCs performing below the Performance Standard for 1-2 months may receive CCC assistance to improve performance. Taking into account each FC's circumstances and depending on the particular area in which the Performance Standard is not met, the appropriate action for the CCC may include:

- A simple discussion to encourage a better performance, pointing out the performance goals,
- Discussions to help identify problems and investigate ways to improve performance,
- Retraining of the FC staff.

FCs performing below Performance Standards for 3 months are discussed by the PMC.

Level 2: Performance Monitoring Committee

The PMC membership includes two members from the CCC, two FC Principal Investigators (PIs), and two members from the Project Office. The PMC monitors a composite of FC performance measures, reviewing and noting persistent concerns in FC performance.

The PMC meets every 2 to 3 months conference calls. Before each routine call, summaries of performance for each FC to be discussed are circulated to all PMC members. The summaries include information from routine Level 1 monitoring activities by CCC liaisons as well as updated information about the functioning of the FC. During the review of the FC summaries, the PMC determines whether assistance or other action that may be needed, and what those activities should be. The PMC also identifies the person(s) who will, if asked, carry out such activities and identifies any study-wide issues to be brought to the attention of the Extension Study Executive Committee (ESEC). If the PMC determines that assistance or action is needed, a letter summarizing the PMC discussion is sent to the PI of the FCs reviewed, pointing out areas of good performance and areas needing improvement.

During the call, the PMC also completes debriefings on completed outcome visits and calls with FCs and reviews materials received from FCs in response to specific PMC requests from a previous call. Specific or persistent issues and FCs needing improvement are addressed more frequently.

Level 3: Follow Up on Persistent Issues

The CCC is responsible for seeing that the recommended activities identified by the PMC are carried out in a timely fashion. The CCC staff conducts these interactions where appropriate or requests assistance from another person or group with specialized expertise in the area of concern. A Level 3 site visit or conference call may be conducted with one to three members from the CCC, Project Office and/or other individuals identified by the PMC. The PMC holds conference calls with FCs, where possible, rather than delaying a visit due to scheduling difficulties. This is especially effective when the FC has a specific issue that can be discussed on a call; for example, strategies for *Form 33D* collection.

11.2 Training

11.2.1 Field Center Staff

The CCC conducted training for WHI Extension Study lead Outcomes Coordinators (OCs) in June 2005. Training for Outcomes Coordinator (OC) replacement lead staff will be held in October 2005 at the CCC. Other FC OCs may attend as space allows. Additional lead OC trainings will be held every 6-12 months as needed by conference call. CC OCs are responsible for training CC non-lead staff.

In general, staff are required to read the protocol, sections relevant to the performance of their jobs, and to read relevant Bulletins issued since the WHI Extension Study Manual was last updated. See *Appendix C* for a list of the bulletins.

11.2.2 Physician Adjudicators (Required)

The first training for the WHI Extension Study adjudicators will take place September 6, 2005. The CCC and the WHI Morbidity and Mortality Advisory Committee (M&M) developed sessions for a physician training plan in event adjudication for WHI, and this system will continue in WHI Extension Study. Physician adjudicators are trained by reading the appropriate sections of *Section 8 – Outcomes*, and participating in CCC activities for ensuring standardization of adjudication, for example, review of mock packets, conference calls, and case review meetings at regional CC meetings.

11.3 Study Monitoring

Progress Report

The CCC produces an Annual Progress Report from the August 31st database. The report summarizes study progress in all areas to date, including enrollment; follow-up and retention; and outcomes. Many of the reports included in the Annual Progress Report are the same as the routine activity reports and other reports the CCC routinely circulates to the FCs.

Observational Study Monitoring Board (OSMB) Report

The CCC also produces the OSMB Report every year from the August 31st database. It includes all the information in the Annual Progress Report and also displays data by treatment assignment. As a result, it is a confidential report that the CCC distributes only to the OSMB. The OSMB uses this report to monitor study progress and make decisions about notifying participants about health issues.

11.4 Data Monitoring

11.4.1 Activity Reports

Monitoring data is done by both the CCC and FCs to monitor FC performance, from meeting goals in recruitment and retention to appraising the quality of data collected. The primary method used to monitor data quality is the production and review of general and specific reports. FCs can produce many specific reports to evaluate aspects of their operations, compare their performance to study wide-goals (as shown in Table 9.1), and identify issues and procedures that need review. The reports allow the CCs to take corrective action without needing to wait for reports from the CCC. *Section 10 – Data Management* provides a list of reports CCs can run, giving the report name and number and a description of intended use. A second list sorted by WHIX/WHIP number and topic combines all WHIX and CCC reports. The report menus in WHIX are organized by report topic and provide a complete list of reports available at the FCs.

On a regular basis, the CCC prepares the routine monitoring reports and distributes them to the Project Office, Contracts Office, and FC PIs. FCs with good performance are encouraged to share their strategies for achieving this with other FCs on routine staff group conference calls. FCs performing below the performance goals are encouraged to discuss strategies for improving their performance with other FCs and with the CCC.

11.4.2 Completeness of Data Collection

Task Reminder Reports: Task reminder reports list participants due to complete a specific task within a date range and/or for a specific visit and year, including reports listing participants selected to be in different subsamples. A Visit Plan report lists tasks to be completed for a specific participant at a specific visit. FCs are encouraged to run and use the reports on a regular basis to help ensure contacts are made as needed, and to perform the appropriate tasks at the contacts.

Task completeness reports help identify tasks that have not been completed when due, reports for overdue contacts are available for many different contacts and tasks. FCs are encouraged to run these reports on a regular basis to identify tasks that still need to be completed. Note that tasks will be included on the overdue reports only if they were completed and data entered. Tasks may be included in the overdue reports if there is

a delay in data entry. A delay in data entry may be due to normal processing time or to filing the form in the participant file before data entry is done.

Task completeness reports list participants who are missing one or more tasks for a specific contact and include summary reports indicating the percentage of participants who have completed all tasks. FCs are encouraged to use these reports regularly to help identify the following types of problems:

- Particular tasks that were omitted on specific participants
- Consistent omissions in performing procedures due to misunderstandings of when the procedures need to be completed (e.g., mammogram every year for HRT participants and every other year for DM participants)
- Forms that have not yet been data entered

Form Completion and Review: FC staff are responsible for completing all applicable items on clinic-administered forms. *Appendix A – Forms* includes all ES forms and instructions for completing forms at the FCs. The Appendix also includes general instructions for completing forms, including how to record "unknown" responses on both key-entered and mark-sense forms. FC staff are also responsible for reviewing participant self-administered forms for completeness by briefly reviewing the forms to assure the participant has not skipped entire pages. No other review of the self-administered forms is required. For example, FCs do not need to review each question on the form for completion, skip patterns, and consistency of responses between questions and other forms.

11.4.3 Data Entry and Verification

Various features are built into WHIX to help ensure the entered data are valid. These checks serve to prevent the data entry errors made by data entry staff and also to catch errors made by staff recording incorrect data on the forms. Key-entry staff can make corrections to key-entry errors at the time of key-entry. If there is an error in how the data is recorded on the form, data entry staff must return the form to the appropriate CC staff person completing the form for review and correction. (See *Section 10 – Data Management* for procedures for making corrections to forms.)

FCs are required to run and use the following reports to identify existing data entry errors and inconsistencies in existing WHIX data.

- *Encounters without data (WHIX0749)*: Use this report to identify encounters without data. Key-enter the data as needed or delete encounters with no data.
- *Duplicate encounters (WHIX1949)*: Use this report to identify encounters that are entered more than once. Duplicate data entry may occur when the data entry staff are interrupted during key-entry of forms. To avoid duplicate data entry, review key-entry procedures with data entry staff and establish procedures for ensuring forms are not key-entered more than once. For example, indicate on the form when only the encounter data has been key-entered and when the entire form has been key-entered.

FCs are not required to verify any data entry. All outcomes forms key-entered at the CCC are verified. The CCC may request the FC to verify other selected participant forms.

11.4.4 Data Corrections

Investigating and correcting data errors can be time consuming and difficult. The large number of data items in the WHI Extension Study makes it impractical to identify and correct all possible data errors. Many of the steps described above, particularly the data entry features in WHIX, were developed to reduce the chance of data errors at the point of data entry.

FC activities for identifying data errors include:

- Review forms before data entry (see *Section 10 - Data Management*).
- Identify data problems at the time of data entry by responding to error messages in WHIX.
- Review various reports to identify problem areas and review the issues with FC staff to help prevent future errors. For example, recording incorrect dates can lead to inaccurate reporting of timeliness and completeness of data collection.

FC activities for monitoring appropriate data corrections includes:

- Follow standard procedures for documenting data corrections. (See *Section 10 – Data Management.)*
- Review forms for correct documentation of data corrections, as part of the participant file audit. (See *Section 11.4.5 – Participant File Audit below*.)

Data requiring regular review and corrections have been identified based on study priorities, and include:

- Discrepancies between the date the participant signed the informed consent forms and the date recorded on *Form 111 – Consent Status* (including *Forms 111*, *112*, and *113*) and data entered into WHIX.
- Errors in transcription of mammogram results found during participant file audits
- Incorrect or incomplete participant addresses or names

11.4.5 Participant File Audit Content

The CCC performs a file audit of selected participant files to evaluate the quality of FC data collection and documentation. In general, files are selected at random, although files may also be selected based on particular problem areas. Action items identified in both the participant file audit are documented in a report to the FC. See *Table 11.2* 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 11.1*).

To initiate the audit, the CCC sends the FC a list of the participant ID numbers selected for the file audit. In general, the CCC identifies 20 participants with contacts within the previous 12 months. Additional criteria may be added as needed.

Upon receipt of the participant ID numbers for the off-site file audit, the FC 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 file audit that are not included in the on-site audit include the following items:

11.5 Feedback Mechanisms

In addition to the regular PMC monitoring plan, feedback of study-wide performance is provided to specific WHI Extenstion Study Committees. Feedback of summary performance results is provided to each related FC PI the PMC summary report as an electronic copy; Outcomes QA to the Extension Study Outcomes Adjudications Committee, and consent, enrollment, and retention reports to the ESEC.

Table 11.1
Performance Requirements Summary – WHI Field Centers

		Oct 2005 – Sept 2006	Oct 2006 – Sept 2007	Oct 2007 – Sept 2008	Oct 2008 – Sept 2009	Oct 2009 – Sept 2010
RETENION	Performance Standard	≥ 95% F33 that are due are collected, OR ≤ 15 not collected (cumulative, 10/05 – 9/06)	≥ 93% F33 that are due are collected (cumulative, 10/05 – 9/07)	≥ 92% F33 that are due are collected (cumulative, 10/05 – 9/08)	≥ 91% F33 that are due are collected (cumulative, 10/05 – 9/09)	≥ 90% F33 that are due are collected (cumulative, 10/05 – 9/10)
	Allowable Deviation from Standard	≥ 92% F33 that are due are collected, OR ≤ 20 not collected (cumulative, 10/05 – 9/06)	≥ 91% F33 that are due are collected (cumulative, 10/05 – 9/07)	≥ 90% F33 that are due are collected (cumulative, 10/05 – 9/08)	≥ 89% F33 that are due are collected (cumulative, 10/05 – 9/09)	≥ 87% F33 that are due are collected (cumulative, 10/05 – 9/10)
	Minimum Technical Requirements	≥ 90% F33 that are due are collected, OR ≤ 25 not collected (cumulative, 10/05 – 9/06)	≥ 89% F33 that are due are collected (cumulative, 10/05 – 9/07)	≥ 88% F33 that are due are collected (cumulative, 10/05 – 9/08)	≥ 87% F33 that are due are collected (cumulative, 10/05 – 9/09)	≥ 85% F33 that are due are collected (cumulative, 10/05 – 9/10)
	Method of Surveillance	Form 33 - Medical History Update Workload report from CCC				
	Points Awarded	Meets Standard: 40 W/in Allowable Deviation: 25 < Allowable Deviation: 0	Meets Standard: 40 W/in Allowable Deviation: 25 < Allowable Deviation: 0	Meets Standard: 50 W/in Allowable Deviation: 25 < Allowable Deviation: 0	Meets Standard: 50 W/in Allowable Deviation: 25 < Allowable Deviation: 0	Meets Standard: 50 W/in Allowable Deviation: 25 < Allowable Deviation: 0
OUTCOMES	Performance Standard	≤ 4.5 month outcomes processing backlog	≤ 4.0 month outcomes processing backlog	≤ 3.5 month outcomes processing backlog	≤ 3.5 month outcomes processing backlog	≤ 3.5 month outcomes processing backlog
	Allowable Deviation from Standard	Up to 5 months outcomes processing backlog	Up to 4.5 months outcomes processing backlog	Up to 4 months outcomes processing backlog	Up to 4 months outcomes processing backlog	Up to 4 months outcomes processing backlog
	Minimum Technical Requirements	≤ 5.5 month outcomes processing backlog	≤ 5.0 month outcomes processing backlog	≤ 4.5 month outcomes processing backlog	≤ 4.5 month outcomes processing backlog	≤ 4.5 month outcomes processing backlog
	Method of Surveillance	Outcomes Processing Workload Report from CCC				
	Points Awarded	Meets Standard: 40 W/in Allowable Deviation: 25 < Allowable Deviation: 0	Meets Standard: 40 W/in Allowable Deviation: 25 < Allowable Deviation: 0	Meets Standard: 50 W/in Allowable Deviation: 25 < Allowable Deviation: 0	Meets Standard: 50 W/in Allowable Deviation: 25 < Allowable Deviation: 0	Meets Standard: 50 W/in Allowable Deviation: 25 < Allowable Deviation: 0
MAMMOGRAMS	Performance Standard	≥ 70% Mammogram reports collected and recorded into database (year 1 mammograms due 4/05 – 9/06)	≥ 80% Mammogram reports collected and recorded into database (cumulative, 4/05 – 3/07)	N/A	N/A	N/A
	Allowable Deviation from Standard	≥ 65% Mammogram reports collected and recorded into database (year 1 mammograms due 4/05 – 9/06)	≥ 75% Mammogram reports collected and recorded into database (cumulative, 4/05 – 3/07)	N/A	N/A	N/A
	Minimum Technical Requirements	≥ 60% Mammogram reports collected and recorded into database (year 1 mammograms	≥ 70% Mammogram reports collected and recorded into database (cumulative, 4/05 –	N/A	N/A	N/A

		due 4/05 – 9/06)	3/07)			
	Method of Surveillance	Mammogram Task Completion reports from CCC		N/A	N/A	N/A
	Points Awarded	Meets Standard: 20 W/in Allowable Deviation: 10 < Allowable Deviation: 0	Meets Standard: 20 W/in Allowable Deviation: 10 < Allowable Deviation: 0	N/A	N/A	N/A

Table 11.2
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 *Form 11 (12, 13, 14, 15)* 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.
12	Use of the correct version of the form.
R	Other required action item.

Figure 11.1
Chart Audit Form

CC:_____

ID: __ __ - __ __ __ __ __ __ - __ Enrolled: _ _ - _ _ - _ _ On-Site ___ Reviewer: _____

Off-Site ___ Reviewers: Clinical____ Data_____

Form #	Form Date		Qx # - description	Form response – description	WHILMA data – description	Comments	Code

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