

**Section 11  
Quality Assurance**

**Table of Contents**

<b>Contents</b>	<b>Page</b>
<b>11.1 WHI Extension Study QA Program Overview.....</b>	<b>11-1</b>
11.1.1 Performance Monitoring Plan .....	11-1
<b>11.2 Training.....</b>	<b>11-2</b>
11.2.1 Field Center Staff .....	11-2
11.2.2 Physician Adjudicators (Required) .....	11-2
<b>11.3 Study Monitoring .....</b>	<b>11-3</b>
<b>11.4 Data Monitoring .....</b>	<b>11-3</b>
11.4.1 Activity Reports .....	11-3
11.4.2 Data Entry and Verification .....	11-3
11.4.3 Data Corrections.....	11-4
<b>11.5 Feedback Mechanism.....</b>	<b>11-4</b>
 <b>Tables</b>	
11.1 Performance Guidelines Summary – WHI Regional Centers .....	11-3

## Section 11

### Quality Assurance

#### 11.1 WHI Extension Study QA Program Overview

For the Women’s Health Initiative (WHI) 2010-2015 Extension Study, Quality Assurance (QA) responsibilities include activities performed at the Regional Centers (RCs) 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 RCs 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 RC operations and performance. Performance goals are described in *Table 11.1 – Performance Guidelines Summary – WHI Regional Centers*. The purpose of the three steps is to reinforce good performance, to identify RC-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 RC staff, review database reports, and perform QA checks for all RCs. They monitor key areas to provide timely and routine feedback on performance to RCs where appropriate. They also provide assistance where performance needs improvement.

Both the RCs 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 RCs based on the performance goals.

The CCC produces an Outcomes Workload Report monthly. The performance standards are based on *Form 33 – Medical History Update* collection, outcomes processing. 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 33*, collection of a Release of Information (ROI), requesting and receiving documents supporting the self-reports on *Form 33*, and assembly of the cases closing the cases and scanning for 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 RC in a 3-month period are considered backlogged. The outcomes workload report shows the various components of the outcomes processing, as well as the overall backlog and the *Form 33* collection for each RC.

RCs meeting the performance standards in all categories, for which no other concerns exist, require no action and monthly monitoring continues as usual.

RCs performing below the Performance Standard for 1-2 months may receive CCC assistance to improve performance. Taking into account each RC’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,
- Providing phone training to the appropriate RC staff.

RCs 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 RC Principal Investigators (PIs), and two members from the Project Office. The PMC monitors a composite of RC performance measures, reviewing and noting persistent concerns in RC performance. The PMC will establish performance goals in Year 2 of the 2010-2015 ES.

The PMC meets at least quarterly by conference calls. Before each routine call, summaries of performance for each RC 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 RC. During the review of the RC 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 Steering Committee. If the PMC determines that assistance or action is needed, a letter summarizing the PMC discussion is sent to the PI of the RCs reviewed, pointing out areas of good performance and areas needing improvement.

During the call, the PMC also reviews materials received from RCs in response to specific PMC requests from a previous call. Specific or persistent issues and RCs 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 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 33* collection.

**Table 11.1  
Performance Guidelines Summary – WHI Regional Centers**

	<b>Performance Standard</b>
Year 1 Oct 2010-Sept 2011	≥ 95% F33 & F151 that are due are collected (cumulative, 10/10-9/11)
Year 2 Oct 2011-Sept 2012	≥ 94% F33* that are due are collected (cumulative, 10/11-9/12)
Year 3 Oct 2012-Sept 2013	≥ 93% F33 & F151 that are due are collected (cumulative, 10/12- 9/13)
Year 4 Oct 2013-Sept 2014	≥ 92% F33 & F151 that are due are collected (cumulative, 10/13- 9/14)
Year 5 Oct 2014- Sept 2015	≥ 92% F33 & F151 that are due are collected (cumulative, 10/14-9/15)

\* Year 2- Collect F155 instead of F151. RC’s to collect shortened version of F155 from participants with a “no CCC mail” or “undeliverable” status.

	<b>Performance Standard</b>
Year 1 Oct 2010-Sept 2011	≤ 4.5 month outcomes processing backlog
Year 2 Oct 2011-Sept 2012	≤ 4.0 month outcomes processing backlog
Year 3 Oct 2012-Sept 2013	≤ 3.5 month outcomes processing backlog
Year 4 Oct 2013-Sept 2014	≤ 3.5 month outcomes processing backlog
Year 5 Oct 2014- Sept 2015	≤ 3.5 month outcomes processing backlog

## **11.2 Training**

### **11.2.1 Regional Center Staff**

The CCC conducted training for 2010-2015 ES RC staff responsible for overall scanning operations. The training in January 2010 included:

- how to prepare chart for scanning
- overview of scanning (hands-on)
- WHIX updates for 2010-2015 Extension

CC OCs are responsible for training CC non-lead staff.

In general, staff are required to read the protocol and sections relevant to the performance of their jobs.

### **11.2.2 Physician Adjudicators (Required)**

The majority of the 2005-2010 ES Physician Adjudicators (PAs) continue to adjudicate in the 2010-2015 ES. Training will be provided to those PAs where form changes indicate that training should be conducted. Training will be done before formal adjudication begins. The CCC and the WHI Ancillary Study Committee (ASC) 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, conference calls, and case review meetings at regional CC meetings.

## **11.3 Study Monitoring**

### **Progress Report**

The CCC produces an Annual Progress Report. 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 RCs.

### **Observational Study Monitoring Board (OSMB) Report**

The CCC also produces the annual Observational Studies Monitoring Board (OSMB). 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 Workload Reports**

Monitoring data is done by both the CCC and RCs to monitor RC 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. RCs can produce many specific reports to evaluate aspects of their operations, compare their performance to study wide-goals (as shown in *Table 9.1 – Summary of Retention Activities*), 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 RCs.

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

#### **11.4.2 Data Entry and Verification**

Participants return most forms to the CCC, where the forms are reviewed and scanned. The RCs are responsible for collecting forms from participants who do not respond to the mailings and for doing the data entry of those forms. RC staff also data enter several parts of the *Form 33* form that are not scanned.

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.

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.

#### **11.4.3 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 following standard procedures for documenting data corrections. (See *Section 10 – Data Management*.)

#### **11.5 Feedback Mechanisms**

In addition to the regular PMC monitoring plan, feedback of study-wide performance is provided to specific WHI Extension Study Committees. Feedback of summary performance results is provided to each related RC PI and to the Outcomes Adjudications Committee.