DOCUMENTATION

INTRODUCTION

Maintaining formal written documents that communicate procedures is an important quality assurance strategy. The Women's Health Initiative (WHI) Manuals document study-wide policies and procedures developed and approved by the WHI committee structure. The Clinical Coordinating Center (CCC) and Clinical Centers (CCs) share responsibility for maintaining the WHI Manuals. The CCC is responsible for keeping the content current and the CCs are responsible for ensuring their manuals are updated with the appropriate Bulletins and materials. The CCs are also responsible for documenting their local Quality Assurance (QA) policies and procedures.

This section includes a description of:

- The WHI Manuals
- Bulletins used to update the WHI Manuals
- WHILMA upgrade documentation
- Inquiries used to document procedural questions and answers
- Clinical Center Internal Procedures Manual
- Other methods of documenting decisions
- Available electronic documents

2.1 WHI Manuals

The WHI Manuals serve as the study-wide reference for the study protocol, procedures, data collection activities, and data forms. In addition, the WHI Manuals document all changes that may occur over the course of the study, and in this way reflect the current activities of the WHI.

The WHI Manuals are composed of the following volumes:

- **Vol. 1 - Protocol and Policies:** Contains the WHI protocol and policies for the Clinical Trial (CT) and the Observational Study (OS).
- **Vol. 2 - Procedures:** Contains specific information about WHI operations and task-related procedures for CCs.
- **Vol. 3 - Forms:** Contains most WHI forms (except outcomes and QA-related forms) and corresponding instructions for completing the forms.
- **Vol. 4: Dietary Modification Intervention Manual:** Consists of two parts: the Group Nutritionist Manual and the Participant Manual. Refer to *Vol. 2 - Procedures, Section 6.6.1. - Group Nutritionist and Participant Manuals*, for details.
- **Vol. 5 - Data System Manual:** Contains detailed procedures for using all WHI data systems, such as Personal Computers (PCs), scanners, local area network (LAN), wide area network (WAN), e-mail and the WHI database, WHILMA.
- **Vol. 6 - DXA Quality Assurance:** Contains detailed procedures for performing bone mineral densitometry at the three Bone Density CCs.
- **Vol. 7 - Quality Assurance:** Contains a description of the WHI QA program and gives detailed procedures and resource materials for carrying out local quality assurance procedures.
- **Vol. 8 - Outcomes:** Contains a description of the WHI outcomes documentation process and gives detailed procedures and forms for ascertaining and adjudicating WHI outcomes.
- **Consulting Gynecologists Handbook:** Contains a compilation of materials from the manuals to address the functions of WHI consulting gynecologists, many of whom are off-site and thus have less access to the manuals.

The CCC is responsible for maintaining and documenting changes to the WHI Protocol and for writing, distributing, and updating the WHI Manuals. The CCC distributes 4 copies of each volume of the Manuals (5 of Vol. 4) to each CC without a satellite site and 6 copies (7 of Vol. 4) to each CC with a satellite. Only the three Bone Density CCs receive *Vol. 6 - DXA Quality Assurance*. The CCC also distributes one copy of the WHI Manuals to the CCC subcontractors (McKesson, Bone Density Center at UCSF, EPICARE, Univ. of Minnesota, UW), the Data and Safety Monitoring Board (DSMB), National Institutes of Health (NIH) Project Office, and other organizations as needed. (See *Table 2.3 - Distribution of Materials*).

At least 2 copies of the Consulting Gynecologists Handbook have been provided to each CC, one for the consulting gynecologists and one for the Clinic Practitioner. Clinical Centers can make additional copies as needed.

2.1.1 Bulletins

The CCC uses Bulletins to communicate changes and updates to WHI policies and procedures documented in the WHI Manuals. The changes represent approved revisions by the WHI Committees and clarifications to existing procedures as described in responses to inquiries. A full list of Bulletins that have been released is included in *Vol. 2 - Procedures, Appendix D*, and each volume of the manuals contains a list of Bulletins pertaining to that volume.

2.1.1.1 Schedule

The CCC releases Bulletins on a quarterly basis, as needed, with the schedule corresponding to planned WHILMA upgrades. Procedure changes requiring immediate implementation are sent out as needed.

2.1.1.2 Method of Distribution

The CCC prepares and distributes the appropriate number of Bulletins (one for each WHI Manual) to all CCs and WHI organizations with WHI Manuals.

Hard Copy Bulletins: In general, the CCC prepares a Bulletin and sends it to the Government Printing Office (GPO) for copying and distribution to the CCs. The turn-around time at the GPO is usually 3-4 weeks.

E-Mail Bulletins: Occasionally, protocol or procedure changes must be implemented quickly and/or changes may benefit the CCs if implementation occurs quickly. In these cases, the CCC prepares the Bulletin text for immediate implementation and sends it to the CCs via e-mail without manual update pages. A printed version of the Bulletin and any updated manual pages follow in the next quarterly Bulletin.

2.1.1.3 Content

Each Bulletin contains the following information:

- Bulletin number
- Date of Bulletin
- Date to implement procedure changes
- Description of changes
- Update page to the list of Bulletins released
- Bulletin filing checklist
- Manual update pages (with hard copy bulletins)

Manual update pages attached to the Bulletin show the revision date in the footer of each page. On the updated pages, a horizontal line in the left margin indicates the updated text.

Updated forms are also distributed through Bulletins. When a form is updated, a new version number and date are assigned to the form and its corresponding instructions. A copy of the form and the corresponding instructions are attached to a Bulletin for distribution and insertion into the appropriate WHI Manual. Printed copies of the forms are included in the next quarterly forms printing order. The CCC makes every attempt to implement needed form revisions to correspond with the forms delivery date and routine WHILMA upgrades.

2.1.1.4 Filing

Clinic Managers are responsible for communicating changes to CC staff and for implementing the changes described in Bulletins. To assist in informing CC staff of the Bulletins, the CCC includes notices of Bulletin distribution in the “Have You Seen” section of the *WHI Times*.

The CC Clinic Managers are also responsible for ensuring that Bulletins and any attached WHI Manual update pages are promptly and correctly inserted into the WHI Manuals. CCs should designate a specific person to be responsible for updating all CC Manuals. To assist staff with inserting the Bulletins, the Bulletin summary contains a listing of all WHI Manual update pages and detailed instructions for replacing and/or inserting the new pages into the manuals.

Clinical Centers are also responsible for updating the Handbooks when Bulletins are issued that update pertinent materials in the WHI Manuals.

2.1.2 WHILMA Upgrade Documentation (Required)

The CCC sends WHILMA upgrade documentation to the CCs when it releases WHILMA version upgrades. The CCC data staff send the WHILMA upgrade documentation to the CC Clinic Managers and Data Coordinators via e-mail at least one week before the WHILMA upgrade release. Each CC Data Coordinator is responsible for ensuring that the documentation is disseminated to appropriate CC staff and for overseeing the implementation of any new procedures. Updated pages to the WHI Manuals incorporating the upgrade documentation are included in the next quarterly Bulletin.

2.1.3 Inquiry Reporting System

The Inquiry Reporting System (IRS) was developed as a way for WHI staff to ask non-urgent questions about study policies and procedures and receive responses from the CCC. The IRS also provides a means for documenting and distributing the questions and answers to all CCs. An inquiry can include questions about WHI policies and procedures, clarifications of Bulletins or other Inquiries, or topics not covered in the WHI Manuals. Before submitting an inquiry, CC staff are encouraged to search for the answer locally, referring to the WHI Manuals, to CC lead staff and Investigators, and to previously answered Inquiries. (See *Vol. 2 - Section 1.4.2 - Methods of Communication*.)

2.1.3.1 Submitting Questions

To submit an Inquiry to the CCC, CCs send the question to the Inquiry Reporting System (IRS) e-mail address in Microsoft Outlook. (See *Table 2.1 - Instructions for Submitting an E-Mail Inquiry*). Clinical Centers can also use *Form 171 - Inquiry Form* if documents are attached that cannot be sent via e-mail.

2.1.3.2 Responses

Upon receipt, each Inquiry is routed among appropriate CCC staff for review and resolution. The CCC Project Directors routinely monitor the responses and clarify information as necessary. The CCC's goal is to answer all Inquiries within two calendar weeks. The response time may be extended if Inquiries require referral to the WHI committee structure or NIH for response, particularly if there is no current policy regarding the issue adressed in the Inquiry. In these cases, the CCC sends an initial response to the CC that submitted the question to indicate the status of the Inquiry.

When a response is completed, the CCC categorizes the Inquiry by topic using the corresponding WHI Manual volume and section or form number and includes this information in the subject heading of the completed Inquiry. The Inquiry is sent via e-mail to the person originating the Inquiry and to Clinic Managers and appropriate lead staff at all CCs (based on the Inquiry topic), or, rarely, to the originating CC only. Inquiries resulting in a change or clarification of a procedure are incorporated into the WHI Manuals when the applicable sections are revised.

2.1.3.3 Filing

Clinic Managers are responsible for ensuring that the Inquiries are distributed and reviewed by all appropriate CC staff members in a timely manner, and for filing the Inquiries for future reference as needed. Various categorization schemes are available for filing IRSs. Clinical Centers may choose one or several of these schemes or develop their own indexing system. Inquiries and responses are referenced by:

- Number (e.g., 95-0078 where 95 refers to the year and 78 refers to a sequence number beginning at 1 in each year.)
- Content area (i.e., Clinic Management, Clinic Practitioner, Dietary Modification, Dietary Assessment, Data Management, Network, Recruitment, Outcomes, or Other)

- Women's Health Initiative Manual volume and section or form number (contained in the subject line of the e-mail and the CCC Summary information at the end of the response)

2.1.3.4 Tracking Answered Inquiries

Every two weeks, the CCC publishes a list of Inquiries that have not been incorporated into a WHI Manual section or form. This list can be found in the Manual Information subfolder under the Public Folders in Microsoft Outlook. The Adobe Portable Document Format file, IRS.pdf, contains the Inquiry number, date, a short description of the Inquiry question and response, and WHI Manual volume and section or form number.

Clinical Centers can search the file for previous Inquiry responses, using the Inquiry number, key-words, or WHI Manual section or form number. See *Table 2.2 – IRS Log Description* for a description of the file. The full text of the inquiry can then be found in the year files that track the original question and response.

Only current Inquiries are included in this log. An Inquiry is current as long as it is the most up-to-date source of information about a topic. When an Inquiry is "closed," that is, used to revise the WHI Manual, it is removed from the log since the Manual is then the most up-to-date source of information on that topic.

Only Inquiries that have been distributed to all WHI CCs are included in this log. If an Inquiry was routed to only one CC, it is not included in this log.

The files in this system are Adobe Portable Document Format (.pdf) files and can only be opened with an Acrobat Reader. CC computers have Readers already installed. If you are accessing these files from a computer outside the CC, you can download the Reader using the link located on the WHI website at www.whi.org/mail.

To find a previously answered inquiry in the Microsoft Outlook Public Folders:

1. Click on the IRS Log.pdf icon contained within the message. This will open the file in your Acrobat Reader (If a window pops up and asks whether to Open or Save the document, click Open).

2. To search: Click on the binocular button (located on the toolbar above the document). Enter the Inquiry number, key-words, or WHI Manual section or form number into the Find Box and Click the Find button.

3. If the Question--Short Description looks as if it may address your question, read the Response--Short Description; and if you would like to read the full Inquiry, record the year and ID number (for example, 99-0044). These numbers will be used below to retrieve the detailed correspondence.

Once you know the year and the ID number:

1. Click on the file that is titled with the year of interest (1999, 1998, or 1997; if an inquiry date is before 1997, then only the short entry is available.). This will open the file in your Acrobat Reader (a window may pop up and ask whether to Open or Save the document. Click open.).

2. Click on the binocular button. Enter the Inquiry number into the Find box (for example, 99-0044) and click the Find button.

3. Following the number you will find the original e-mail that generated the inquiry and the response.

Table 2.1

Instructions for Submitting an E-Mail Inquiry

1. Using Microsoft Outlook, select "New Message."
2. Address your message to "Inquiry Reporting System," located in the Outlook Address book.
3. If possible, categorize your Inquiry. There are eight general Inquiry categories: Management, Practitioner, Dietary Modification, Diet Assessment, Data Management, Network, Recruitment, Outcome and Other. Don't be concerned if your Inquiry seems to fit in more than one, or none of these categories.
4. Write your question(s), giving as much detail as possible. Do not include participant names or ID numbers in your Inquiry. Try to limit your inquiry to one topic or subject; doing so decreases the CCC response time and makes it easier to categorize the Inquiry and find the Inquiry in the IRS log.
5. Send your Inquiry.

Table 2.2

IRS Log Description

Column Heading	**Description**
Year	Each IRS number begins with the last two digits of the year. The Inquiry Reporting System began in 1993.
Inquiry Number	The sequence of Inquiry numbers starts over again each year at 0001.
Question--Short Description	A brief summary of the question. If a multiple-part question, this may read "Questions about. . ."
Response--Short Description	A brief summary of this response. If the actual response is lengthy, or the issue complex, this may read "See IRS for complete response."
Response Date	The date on which the Inquiry was answered and the answer distributed.

The following columns may be completed, as appropriate:

Manual Vol.	A reference to the WHI Manual where more information may be found.
Section	A reference to a section of the referenced manual. More than one section is often referenced.
Form	A reference to a relevant WHI form.

2.2 Clinical Center Internal Procedures Manual (Recommended)

Each CC is encouraged to develop a CC Internal Procedures Manual and to have it available as a resource to all CC staff. Important topics for this manual include:

- CC-specific policies, procedures, and forms
- Emergency procedures
- Procedures for disseminating WHI documentation and updates
- CC QA plan (including training and certification, local standards of performance, and monitoring)

Additional suggested topics for the manual are listed in the *Vol. 2, Section 2.9 - Clinical Center Procedure Manual*.

2.3 Other Documents

The CCC distributes other materials as shown in *Table 2.3- Distribution of Materials.* The table lists the materials and indicates to which groups they are distributed, and frequency of distribution.

2.3.1 WHI Times

The CCC distributes a staff newsletter, the WHI Times, to all WHI staff via e-mail two times each month. The newsletter include sections on current activities, recruitment updates, message from the Project Office, procedural reminders, a list of materials distributed to CCs since the last newsletter, and a timeline of national meetings and conference calls. Clinical Center staff are encouraged to post and share the information in the newsletter with CC staff who do not have e-mail access.

2.3.2 Minutes

The CCC is responsible for preparing and distributing minutes for national committee meetings and conference calls, including the Council, Steering, and CC National Staff Group committees and the Annual General Meeting. The CCC distributes the minutes to all CC PIs and Clinic Managers and the Project Office, as appropriate. The Chairs of other committees are responsible for preparing and distributing minutes as needed to members and to the CCC for archiving. Regional staff groups are not required to keep minutes but regional leads may choose to do so, in which case the minutes can be distributed as described above. Clinic Managers and lead staff are encouraged to post and share the minutes with CC staff who do not have e-mail access.

2.3.3 Public Folders

Accessed through the web-based WHI Outlook e-mail system, the Public Folders provides access to electronic versions of various reference lists. The CCC updates the Public Folders on an as needed basis. A footer within each file indicates the date it was last revised.

The Public Folders is divided into primary folders that serve to organize the documentation material. Each file within the Public Folders has been saved one of two ways; as a Microsoft Word file or as an Acrobat Document. Microsoft Word allows you to open, read, and print copies of a file, but does not allow edits unless you save the file to another location on your server and give it a new name. An Acrobat file allows you to view and print the document but will not allow you to edit or save it. The printed appearance of each file (that is, page breaks and some formatting) may be affected by the type of printer at your site. The Public Folders are listed below. Files may be added or deleted as appropriate.

Committee Minutes

- Executive Committee Minutes
- Steering Committee Minutes

Directory and Contacts

- Lead Staff List
- Alphabetical List
- Coordinating Center Contact List
- Advisory Committee Roster
- Vendors for Clinical Center Equipment and Supplies

Manual Information

- QA Visit Discussion Guidelines – See *Section 4.3.2 – Content* for a description of their use during QA visits.
- Inquiry Reporting System Log – *See Section 2.1.3 – Inquiry Reporting System* for a description of the IRS Log
- Summary of Bulletins – Outlines changes within each Bulletin
- Bulletins to Review for Annual Certification – See *Section 3.3 – Certificiation* for a description.
- *Form 801 – WHILMA Change Request*

Reports

- Quarterly Performance Monitoring Report – See description in *Section 4.1.1 – Study Progress.*

Scientific Publications

- Status of Approved Publications
- Writing Group Nominations
- Bibliography of Published WHI Papers

WHI Times – **(**Listed by date)

Table 2.3

Distribution of Materials

	Distributed to								
Materials	Project Office	DSMB	CC PIs	Clinic Manager	Lead Staff	All staff	Subcontractors	Frequency	Distributed via:
Bulletins	X	X		X			X	Quarterly, as needed	E-mail/hard copy
Inquires				X	X (as appropriate)			As needed	E-mail
WHI Times	X		X			X	X	2/month	E-mail
Minutes									
• Steering Committee	X		X	X			X	2/month	Attached to e-mail
• Council	X		X	X			X	Quarterly	Attached to e-mail
• National Lead Staff	X		X	X	X		X	Monthly	E-mail
• Regional Staff Group			X	X	X (as appropriate)			Monthly	

Section 2
Documentation

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