Section 4

Regional Center Communication, Documentation, and Guidelines Manual

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Regional Center Communication, Documentation, and Guidelines Manual

Introduction

This section describes the methods of communication and documentation used for the Women's Health Initiative (WHI) Extension Study (ES). It also offers guidelines for Regional Center (RC) operations and production of materials RCs may choose to give to participants.

4.1   Lines of Communication

The study organization and committee structure described in the Protocol provides the foundation for communications. Study protocol, policy, or procedural issues or problems identified by any study personnel can be brought to the attention of an appropriate committee member or a designated Clinical Coordinating Center (CCC) representative. Monthly conference calls for RC staff provide an opportunity for all staff to bring concerns and problems up for discussion, resolution and dissemination. These issues may be referred to the Steering Committee (SC) and/or may be referred to one of the Subcommittees for further development and consideration. Issues not clearly falling on a particular subcommittee will be assigned by the SC. It is the responsibility of the subcommittees to evaluate any concerns and make recommendations to the SC for final resolution.

Routine questions of study operations should be directed to the CCC. Contact staff at the CCC for each function are identified on the SharePoint RC Operations site ('Contacts'). Please note the hours and days of coverage, including CCC institutional holidays. There may be additional holidays depending on the day of the week on which the holiday falls, e.g., New Year's Day and Christmas. The CCC will remind all RC staff of upcoming holiday schedules.

CCC (FHCRC) Holidays:

January 1	New Year's Day
	Martin Luther King Jr. Day (3rd Monday)
February	President's Day (3rd Monday)
May	Memorial Day (last Monday)
July 4	Independence Day
September	Labor Day (1st Monday)
November 11	Veteran's Day
	Thanksgiving (4th Thursday)
	Day After Thanksgiving (Friday)
December 25	Christmas Day

The WHI ES will take full advantage of available means of communications: meetings, conference calls, telephone calls, electronic mail (e-mail), regular and express mail, and facsimile transmission (FAX). The availability of a standardized computing environment and e-mail makes e-mail the first choice for all but the most urgent communications.

4.1.1   Conference Calls/Minutes

Routine conference call for each committee and/or staff group are included in the monthly WHI Times. As a body governed by committees, the minutes of each committee meeting or conference call will serve to document the course of the study. All such minutes will be made available to committee members on a regular basis and will consist of the decisions and action items that were discussed on the call.

4.1.2   Electronic Mail

All ES personnel will be given a unique user identifier to access the network. This ID and a user-defined password are required for accessing the database and SharePoint. Groups of ES personnel, as defined by

interests or responsibilities, will be established as an entity distribution list within the e-mail system to facilitate quick and comprehensive distribution.

4.1.3   Mail

Regular and express mail will be used to ship supplies and larger documents. Note that express mail addresses for some institutions, including the Program Office and the CCC, are different from the regular US Mail address. It is recommended that staff not send items to the Program Office by regular mail because of delays in the internal mail system at the National Institutes of Health (NIH).

4.1.4   WHI Directory

A directory of all ES staff, names, addresses, telephone numbers, and e-mail addresses is provided in the directory. See the WHI SharePoint site for listing. The Directory page also includes a listing of the addresses of the various organizations. The directory is only available when logged in to SharePoint.

4.1.5   WHI Times

The CCC distributes the WHI Times by e-mail and posts to the SharePoint RC Operations site once each month. The newsletter includes sections on current activities, messages from the Project Office, procedural reminders, and a timeline of national meetings and conference calls. Past issues of the WHI Times are found on the same SharePoint RC Operations site.

4.2   Study Documentation

For the ES study staff, all current documentation and forms will be available on the SharePoint RC Operations site.

4.2.1   WHI Extension Study Manual

The design and implementation of the ES, as captured in the study protocol, policies, procedures, and data collection instruments, are described in the ES Manuals. The primary function of these manuals is to provide standardized training and reference materials across participating ES organizations as a way of assuring study quality. The ES manuals are posted on the RC Operations page of the SharePoint site.

The WHI Extension Study Manuals include the following main sections:

Study Protocol and Policies: *Sections 1-3* contain the Protocol, the ES committee and management structure, and the policies governing the scientific conduct of the study.

Procedures, Forms, Data System, and Quality Assurance: *Sections 4-11* describe all RC procedures and guidelines for operations, and serve as the standard by which RC operations are assessed. Procedures that are designated as required in the section heading must be followed to adhere to the protocol.

Study Forms: *Appendix A – Forms* contains the the non-outcomes study forms completed by RC staff and participants, along with a set of instructions describing who completes the form, when and how each data item should be coded, and what happens to the form when completed. Outcomes forms completed by Physician Adjudicators along with the forms instructions are included in *Section 8 – Outcomes*.

4.2.2   Submitting an E-Mail Question

Before submitting a question to the CCC, RC staff are encouraged to search for the answer locally, referring to the ES Manuals, to RC staff and investigators, and to previously answered questions. To submit a question to the CCC, RCs send the question to the RC mailbox at rc@whi.org. Write the question(s), giving as much detail as possible. Do not include participant names. Try to limit the question to one topic or subject.

4.2.2.1   Responses to E-Mail Questions

Upon receipt, each question is routed among appropriate CCC staff for review and resolution. The goal is to answer all questions as soon as possible, though the response time may be extended if questions require referral to a Committee for response, particularly if there is no current policy regarding the issue addressed. In these cases, the CCC sends an initial response to the initiator of the question to indicate its status.

4.3   Regional Center Guidelines

The current ES RCs were previously Clinical Centers (CCs) in the Clinical Trial (CT) and Observational Study (OS) of WHI and Field Centers (FCs) in the ES 2005-2010. Participants who participated in the ES 2005-2010 and have consented again in 2010 are now being followed by the RCs. The following guidelines are offered to help RCs manage their operations. This section can be used as a checklist to ensure that at least the essential elements are in place. It may also be helpful for staff training.

4.3.1   Regional Center Required Areas

- **Participant file area:** This must be a secure area. Any material that is identified with a participant's name, personal information or next of kin information must be locked or in a secure area when not in use to maintain confidentiality of records.
- **Staff work space**: Desk space, computer, phone, printer access, and other typical office supplies and equipment sufficient for staff to complete study duties. The RC must arrange for appropriate computer setup and internet access from their institution's IT support, if needed.

RCs must arrange for appropriate computer and internet access cabling of their facilities.   Access to WHIX, email and other study resources can be found on the WHI Sharepoint site at www.whi.org. After you sign in to Sharepoint with your WHI network ID, click "FC Operations" at the top of the main page.

4.3.2   Guidelines for Computer Work Area

- **Data entry space:** The computer area should be well-lit and well-ventilated.
- **Work space:** The computer table or desk should be large enough to accommodate a generous workspace (for forms, a copyholder, etc.).
- **Workstation:** The keyboard and monitor should be at the proper height. An operator's arms should be bent at a 90° angle when typing. If the table is too high, there are many products available that lower the keyboard. In addition, the monitor should be at eye level. If the table is too low, a stand can be used to raise the monitor to an appropriate height. Some of these aids come with copyholders that may make data entry work easier and faster.
- **Ergonomic chair:** Data entry staff should have a comfortable chair. Back fatigue is a major complaint of computer users. The height should be adjustable, and the back should tilt.

See *Section 10 – Data Management* for additional guidelines.

4.3.3   Equipment and Supplies

Equipment and supplies <u>provided by the CCC</u>

The CCC will provide each RC with one or more computer station and scanner for scanning outcomes cases.

Scanning Equipment includes the following:

- PC (preconfigured with scanning software)
- Monitor
- Printer
- Scanner

Equipment and supplies <u>RCs must purchase</u>

Each RC will provide their own personal computers. The PCs should be configured with:

- Current.release of Microsoft Windows operating system and its latest patches.
- Current release of Microsoft Office Suite.
- Internet Explorer 11 from current release of Microsoft Windows operating system.
- Reliable and continuous access to the internet.
- Current version of Adobe Acrobat (for WHIX reports).
- Anti-virus software and VPN client software.
- Current version of Java SE Runtime Environment for running Java applets under Internet 11.
- Ethernet. -->Category 5E/6 Ethernet cables for the computer(s).
- Rewriteable DVD/USB drives for local backup or network base backup.
- On-site maintenance for PC (from vendor).
- Disk image on DVD or USB thumb drive for system recovery.
- All computer supplies, such as paper and cleaning supplies.
- Laser printer cartridges.
- Phone with voice mail or answering machine.
- #2 pencils for use with mark-sense forms.
- Files for participant charts.

A small network printer and scan guns are also recommended at each site.

4.3.4   Staffing

The staffing required to accomplish the technical requirements, with the exception of the Principal Investigator (PI), shall be contained within the unit prices for outcomes ascertainment. This includes effort for outcomes coordination (follow-up on non-responders to central *Form 33 – Medical History Update* mailings, medical records collection, case packet assembly, and scanning case packets to forward to the CCC for central adjudication) and clerical effort for obtaining and entering the results into the study database. The level of effort for these tasks will vary according to the number of participants followed and the average numbers of outcomes.

RC management and outcomes processing may be performed by the same person. Specific duties of each function follows.

4.3.4.1   Regional Center Management

Responsibilities:

- Manage RC facilities, operations, and administrative details.
- Supervise RC personnel and staffing.
- Oversee RC flow.
- Prepare administrative, budget, and progress reports as well as cost estimates, plans, and projections for future needs.
- Communicate with RC PI and serve as administrative contact person for CCC.
- Interpret and implement protocol policies and procedures.
- Maintain documentation for all RC operations.
- Run routine WHIX reports.
- Interact with the CCC and Performance Monitoring Committee as needed.

4.3.4.2   Staff Contact/Outcomes Coordinator

Responsibilities:

- Collect *Form 33* from participants who do not respond to the CCC mailing or require phone contact (No CCC mail).
- Collect *Form 33 – Medical History Update* from deceased participants' proxy contacts (MRC only) and SRC participants with a new cancer.
- Review *Form 33* for completeness and check with participant to get appropriate details of medical history and health provider contacts.
- Key-enter study forms.
- Review *Form 33* forms to identify events that indicate a possible WHI outcome.
- Ensure participant has a current Release of Information (ROI) signed and dated prior to investigation of any potential outcome.
- Request medical records documentation required for an outcome investigation from external sources such as a hospital, physician's office or laboratory and request additional documentation if needed.
- Monitor and track timeliness and completeness of documents requested from external sources using WHIX generated reports and review of the physical system.
- Evaluate medical records documents to determine if they are appropriate and adequate for adjudication.
- Assemble adjudication case packets.
- Scan participant's outcome files. This involves using electronic scanning system to be provided by the CCC.
- Monitor data quality including review and follow-up on WHIX generated tracking and monitoring reports.
- Maintain list of providers maintained in the WHIX database.
- Run routine WHIX reports.

4.4   Guidelines for Developing Participant Materials

Participant materials are written materials given to women at any time during participation in the ES. RCs may submit locally developed templates to the CCC for study-wide consideration. When submitting materials to the CCC, please indicate when and how the materials are to be used. To submit participant materials to the CCC, send the material to the e-mail address rc@whi.org. Approved documents can be found on SharePoint in Appendix F of the Manual of Operations.

Consider the following guidelines when preparing any participant materials. They include suggestions about content, visual design, writing style, printing and mailing. These guidelines will be used by the CCC and the IRB when reviewing materials developed by individual RCs.

4.4.1   Content

- Be brief. Include only what the reader needs to know.
- Keep language appropriate at about a 6th grade level. The reading level of participant materials is very important. You can use Microsoft Word™ to evaluate a document. Several suggestions for improving a document's readability are listed below.

  o **Use the active voice wherever possible:** State the subject and verb directly instead of describing an object as acted on by an unstated subject. Speak directly to the participant. The passive voice often makes the writing less clear because it often leaves out who will do the action.

    Active voice: We will send you a packet each year.
    Passive voice: The packet will be sent to you each year.

  o **Use shorter sentences and words:** Participant material is made more readable by using shorter sentences and simpler words, less wordy phrases and more positive wording. Many people have a hard time following the key point in a long sentence, particularly if it has a lot of clauses. Ideally,

sentence length will vary so the reader won't find the material monotonous. An average readable sentence length in American English is 17-23 words. If your sentence is over 25 words, your writing may be difficult to read.

o **Use simple phrases:** Use a simple and relaxed conversational style.

Simple phrase: Women can be part of the answer.
Wordy phrase: Women now have the opportunity to be part of the answer.

o **Words:** Some words commonly used in the ES are not familiar to the lay public or have negative connotations. Therefore we suggest using simpler substitute words when preparing participant materials. A list of recommended words is given below.

Commonly Used Words:	Recommended Substitute Words:
approximately	about
assistance	help
cardiovascular disease	heart disease
clarify	make clear
concerning	about
conclusion	end
currently	now
diseases afflicting women	diseases in women
do not hesitate to call	feel free to call
e.g.	for example
exposed/exposure	worked with/lived with
i.e.	that is
immediate	right away
impact	make a difference, effect
in order to	to
in the absence of	without
myself	me
notify you	let you know
participate in	join or take part in
prior to	before
procedures	tests, exams, activities
provided	given
remain	live or stay
require	ask, need
research	study (some ethnic groups think of experiment or exploitation when they hear the word research)
reside	live
select	choose
similar	like

Commonly Used Words:	Recommended Substitute Words:
subjects	participants, women
submitted	given
voicemail	a recording machine

- Do not make false claims or promises.

4.4.2   Formatting

- **Use 14-point Serif fonts:** Participant material is more readable if a $\geq$ 12-point font is used (the font used here is 12 points). The ideal font size for older populations is 13 or 14. Do not use script, or sans serif fonts. Serif type is the most familiar style (this type is Times New Roman) and the easiest to read. Mixing several types styles on the same page may also be confusing.
- **Use upper and lower case:** Use upper and lower case letters even in titles and headings. CAPITAL LETTERS are more difficult to read and recall. Use larger or **bolder** print or underlining instead.
- **Preserve white space:** Do not crowd too much information on a page.

4.4.3   Visual Design

- Make sure that the visuals draw the eye to the two or three key points.
- Include the study logo and catch phrase on all pieces.
- Consider inclusion of your own institutional seal for credibility.
- Include lots of white space in the margins and between blocks of text.
- Use illustrations (simple line drawings are best) to reinforce information and direct the eye to the key points.

4.4.4   Writing Style

- Use a simple and relaxed conversational style.
- Avoid large blocks of text. Break information into bulleted lists whenever possible. Ask yourself, "Can I scan this in a few seconds and find what I need?"
- Use short and simple words ("handouts about" rather than "handouts pertaining to").
- Use short and simple sentences with as few qualifying phrases as possible. The best structure is: subject, verb, object. Limit each sentence to one idea.

4.4.5   Printing

- Prepare electronic copies for the printer.
- Print on at least a 60-pound paper if double sided. Self-mailers are often printed on 65-pound paper.
- Letters must be on your institutional, a referring agency's institutional, or WHI letterhead with an official signature and timely date.
- Color of type print and paper should be consistent with and complement those agreed upon for the study. Black print on white or yellow is the easiest to read.

4.4.6   Mailing

- Print labels or hand write addresses on mailing envelopes. Participants may respond positively to handwritten envelopes but time and cost factors may prohibit this strategy. Postal regulations state that one may hand write the name and address when using bulk mailing, but anything else handwritten on the envelope is considered a message and is prohibited.
- Do not knowingly mail to the same individual more than three times.