Section 4

Field Center Communication, Documentation, and Guidelines

Introduction

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

4.1   Lines of Communication

The success of any multi-center study depends heavily on the quality of communications. As the number of participating individuals and institutions increase, so does the need for formal channels and efficient, reliable means of communication. The study organization and committee structure described in the WHI Extension Study Handbook in *Section 3 – Study Policies* 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. Staff groups have been identified for the clinic managers and outcome coordinators. Regular conference calls for these staff groups, as well as the principal investigators, provide an opportunity for all staff to bring concerns and problems up for discussion, resolution and dissemination. These issues are initially brought to the Study Oversight Committee (SOC) for consideration and/or may be referred to one of the Subcommittees of the SOC for further development and consideration. Issues not clearly falling on a particular subcommittee will be assigned by the SOC. It is the responsibility of the subcommittees to evaluate any concerns and make recommendations to the SOC for final approval.

Routine questions of study operations should be directed to the CCC. Contact staff for each function will be identified on an ongoing basis. Please note the hours and days of coverage, including CCC institutional holidays.

CCC (FHCRC) Holidays:
January	1	New Year's Day
		Martin Luther King Day (Monday)
February		President's Day (Monday)
May		Memorial Day (Monday)
July	4	Independence Day
September		Labor Day (Monday)
November	11	Veteran's Day
		Thanksgiving (Thursday)
		Day After Thanksgiving (Friday)
December	25	Christmas Day

The WHI Extension Study will take full advantage of available means of communications: meetings, conference calls, telephone calls, facsimile transmission (fax), regular and express mail, and electronic mail (e-mail). The availability of a standardized computing environment and e-mail makes e-mail the first choice for all but the most urgent communications. The advantages of e-mail are speed, accuracy, reliability of communications, simplification of documentation, and cost, given the existence of the WHI Extension Study network.

4.1.1   Minutes

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 through a computer bulletin board. However, to limit the flood of paper, routine distribution will be limited.

4.1.2   Electronic Mail

All WHI Extension Study personnel will be required to have a WHI Extension Study e-mail address and will be given a unique user identifier to access to the WHI Extension Study network. This ID and a user-defined password will be required for accessing the database and participating in the electronic messaging system. Each user will be able to send and receive messages, and store and retrieve them electronically, and access messages for general dissemination (e.g., minutes from meetings). Groups of WHI Extension Study personnel, as defined by interests or responsibilities will be established as an entity within the e-mail system to facilitate quick and comprehensive addressing and 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 you do not send items to the Program Office by regular mail because of delays in the internal mail system at the National Institute of Health (NIH).

4.1.4   WHI Directory

A directory of all WHI Extension Study investigators and staff addresses, telephone and fax numbers are provided through the CCC. The directory is updated and distributed to all WHI Extension Study personnel on a regular basis.

4.1.5   WHI Times

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

4.2   Study Documentation

4.2.1   WHI Extension Study Manual

The design and implementation of the WHI Extension Study, as captured in the study protocol, policies, procedures, and data collection instruments, are described in the WHI Extension Study Manual. The primary function of this manual is to provide common training and reference materials across all participating WHI Extension Study organizations as a way of assuring the quality of the study. Each FC will receive one manual and FCs with a satellite will receive one additional manual for the satellite site.

The WHI Extension Study Manual includes the following main sections:

Study Protocol and Policies: Sections 1-3 contain the Protocol, the WHI Extension Study 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 FC procedures and guidelines for operations, and serve as the standard by which FC 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 contains all standardized study forms completed by FC 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 should happen to the form when completed. Outcomes forms completed by Physician Adjudicators are included in *Section 8 – Outcomes.*

4.2.2   Bulletins

The CCC uses Bulletins to communicate changes and updates to WHI Extension Study policies and procedures documented in the WHI Extension Study Manual. The changes represent approved revisions by the WHI Extension Study Committees and clarifications to existing procedures as described in responses to inquiries. A full list of Bulletins that have been released is included in *Appendix B*.

4.2.2.1   Bulletin Schedule

The CCC releases Bulletins on an annual basis, as needed, with the schedule corresponding to planned WHI Extension Study database (WHIX) upgrades.

4.2.2.2   Method of Distribution

The CCC prepares and distributes one (or two) copy of Bulletins (one for each WHI Extension Study Manual) to all FCs with WHI Extension Study 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 FCs. The turn-around time at the GPO is usually 3-4 weeks.

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

4.2.2.3   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 Extension Study 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.

4.2.2.4   Filing

Designated FC staff are responsible for communicating changes to other FC staff and for implementing the changes described in Bulletins. To assist in informing FC staff of the Bulletins, the CCC includes notices of Bulletin distribution in the "Have You Seen" section of the *WHI Times*.

The FC staff are also responsible for ensuring that Bulletins and any attached WHI Extension Study Manual update pages are promptly and correctly inserted into the WHI Extension Study Manual. FCs should designate a specific person to be responsible for updating the FC Manual. To assist staff with inserting the

Bulletins, the Bulletin summary contains a listing of all WHI Extension Study Manual update pages and detailed instructions for replacing and/or inserting the new pages into the manual.

4.2.3   Inquiry Reporting System

The Inquiry Reporting System (IRS) was developed as a way for WHI Extension Study 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 FCs. An inquiry can include questions about WHI Extension Study policies and procedures, clarifications of Bulletins or other Inquiries, or topics not covered in the WHI Extension Study Manuals.

4.2.3.1   Submitting Questions

Before submitting an inquiry, FC staff are encouraged to search for the answer locally, referring to the WHI Extension Study Manuals, to FC staff and investigators, and to previously answered Inquiries. To submit an Inquiry to the CCC, FCs send the question to the IRS e-mail address in Microsoft Outlook. (See *Table 4.1 – Instructions for Submitting an E-Mail Inquiry*.)

4.2.3.2   Responses

Upon receipt, each Inquiry is routed among appropriate CCC staff for review and resolution. The CCC's goal is to answer all Inquiries as soon as possible, though the response time may be extended if Inquiries require referral to the WHI Extension Study committee structure or National Heart Lung and Blood Institute (NHLBI) for response, particularly if there is no current policy regarding the issue addressed in the Inquiry. In these cases, the CCC sends an initial response to the FC 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 Extension Study 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 appropriate staff at all FCs (based on the Inquiry topic), or, rarely, to the originating FC only if the Inquiry is relevant only to the initiator of the Inquiry. Inquiries resulting in a change or clarification of a procedure are incorporated into the WHI Extension Study Manual when the applicable section is revised.

4.2.3.3   Filing

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

- Number (e.g., 05-0078 where 05 refers to the year and 78 refers to a sequence number beginning at 1 in each year).
- Content area (i.e., Data Management, Outcomes, or Other), WHI Extension Study Manual section or form number (contained in the subject line of the e-mail and the CCC Summary information at the end of the response).

4.2.3.4   Tracking Answered Inquiries

An IRS Log for viewing past inquiries is included 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 Extension Study Manual volume and section or form number.

FCs can search the file for previous Inquiry responses, using the Inquiry number, key words, or WHI Extension Study Manual section or form number. (See *Table 4.2 – IRS Log Description* for a description of the file.) The full text of the inquiry can then be found in the files by year to track the original question and response.

Only current Inquiries are included in the IRS 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 Extension Study 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 FCs are included in this log. If an Inquiry was routed to only one FC, 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. FC computers have Readers already installed. If you are accessing these files from a computer outside the FC, 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 Extension Study Manual section or form number into the Find Box and Click the Find button. To continue the search, click the Find Again box.

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, 05-044). These numbers will be used below to retrieve the detailed correspondence.

Once you know the year and the ID number:

1. Return to the Main Menu and click on the file that is titled with the year of interest (2005). 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, 05-044) and click the Find button. You may also scroll the inquiries (in descending order), to locate the specific Inquiry.

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

4.3   Field Center Guidelines

The Extension Study FCs have been selected because of their involvement in the Clinical Trial (CT) and Observational Study (OS) of WHI. The following guidelines are offered to help investigators maintain their FC 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   Field Center Required Areas

- **Participant file area:** This must be a secure area. Any material that is identified with a participant's name should be locked or in a secure area when not in use to maintain confidentiality of records.
- **Computer area**: Computer equipment and staff work space: This area must be sufficient for staff to complete the duties of the study.

Field Centers must arrange for appropriate computer and internet access cabling of their facilities. WHI data management system will migrate from a local instance of WHILMA and private leased lines, to one where WHIX is centralized at the CCC and access is through the Internet. The new system goes into effect October

1, 2005. Access to the CCC is through the staff site. The URL for the staff site will be WWW.WHI.ORG/STAFF. The home page on the staff site will have a link to WHILMA and a link to mail.

4.3.2   Guidelines for Computer Work Area

- **Data entry space:** The computer area should be well-lit and well-ventilated. Since computers generate heat, they should not be in a cramped, windowless cubbyhole.

- **Work space:** The table or desk that the computer is on 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 or a "CRT valet" to lift the monitor totally off the desk and position it at an appropriate height. Some of these aids come with copyholders that may make data entry work easier and faster. Most computer supply companies have free trial periods for these types of equipment.

- **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. Before buying any furniture, if at all possible, ask staff to try it out personally since everyone's needs and preferences are different.

- **Glare-reducing screen:** Another common complaint of computer users is screen glare. There are many glare-reducing screens available that help with this problem. You can also try adjusting room lighting and positioning the screen so that it doesn't face the sun.

- **Printer table:** Laser printer control buttons should be within easy reach. There should be an adequate storage area for paper, labels and toner cartridges.

- **Computer cleaning supplies:** There are numerous cleaning products available, both for the screen and the floppy disc drives. They are a good investment, not only to increase the life of the machine, but to maintain operator comfort.

- **Personal Computer (PC) locking device:** Each PC should have a security device that locks it to the desk or table.

- **Surge protector:** Each PC should have a surge protector.

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

4.3.3   Equipment and Supplies

Equipment and Supplies Provided by the CCC

The CCC will ship a pre-configured PC to each site no later than the last week of September 2005. The PC will be configured with:

- Current version of Windows and Internet Explorer.
- Current version of Microsoft Office.
- Current version of Adobe Acrobat (for WHIX reports).
- Anti-virus software and VPN client software.
- Java Initiator for running Java applets under Internet Explorer.
- Ethernet.
- Read-write CD player for local backup.
- On-site maintenance for PC (from vendor).
- Ghost image on CD for system recovery.
- FCs will receive a new printer directly from the vendor, in the CCC budget.

- WHI Extension Study data collection forms, all of which come from the Government Printing Office (GPO). See *Appendix A* and *B* for a list of printed forms and *Form 170 – Forms Order* for more information about ordering forms.

Equipment and Supplies FCs Must Purchase

- All computer supplies, such as paper and cleaning supplies
- Laser toner cartridges.
- Fax machine.
- Phone with voice mail or answering machine.
- #2 pencils for use with mark-sense forms.
- Files for participant charts.

4.3.4   Staffing

The staffing required to accomplish the technical requirements, with the exception of the Principal Investigator (PI) and Clinic Manager effort, shall be contained within the unit prices for outcomes ascertainment and mammogram tracking. 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 forwarding case packets for central adjudication) and clerical effort for obtaining mammogram reports and selected exposure updates (HT participants only), 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.

4.3.4.1   Field Center Management

- Manage FC facilities, operations, and administrative details.
- Supervise FC personnel and staffing.
- Oversee FC flow.
- Prepare administrative, budget, and progress reports as well as cost estimates, plans, and projections for future needs.
- Communicate with FC PI and serve as administrative contact person for CCC.
- Interpret and implement protocol policies and procedures.
- Maintain documentation for all FC operations.
- Maintain updated IRB records.
- Carry out copying and typing requests.
- Perform word processing and correspondence.

4.3.4.2   Outcomes Coordinator

- Evaluate medical records documents to determine if they are appropriate and adequate for adjudication.
- Assemble adjudication case packets.
- Collect *Form 33/33D – Medical History Update/Detailed* from deceased participants' proxy contacts.
- Collect *Form 33* from participants who do not respond to the CCC mailing.
- Ensure participant has a current Release of Information (ROI) signed and dated prior to investigation of any potential outcome.
- Review *Form 33/33D* forms to identify events that indicate a possible WHI outcome.
- Review *Form 33/33D* for completeness and check with participant to get appropriate details of medical history and health provider contacts.
- 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 WHILMA generated reports and review of the physical system.
- Route requested outcomes adjudication case packets for adjudication.

- Track Mammograms.
- Monitor data quality including review and follow-up on WHILMA generated tracking and monitoring reports.
- Maintain participant's outcome files. This includes creating new outcome charts and filing.
- Review list of providers maintained in the WHIX database.
- Key-enter and scan study forms.
- Run routine WHIX reports.

4.4   Guidelines for Developing Participant Materials

Participant materials are written materials given to women at any time during screening or participation in WHI. FCs should submit participant materials to their local FC's Institutional Review Board (IRB) and the CCC for review and approval. When submitting materials to the CCC, please indicate when and how the materials are to be used. Materials such as print adds or PSAs are not considered participant materials and do not need to be reviewed.

The following guidelines should be considered 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 when reviewing materials developed by individual FCs.

4.4.1   Content

- Be brief. Include only what the reader needs to decide to contact you. Ask yourself, "Would I really read this after a busy day?"
- Put the most important points first and last. Use a logical sequence for the rest.
- Keep language appropriate at about a 6th grade level. The reading level of participant materials is very important. It may not be widely known that to follow the instructions on an aspirin label requires a 10th grade reading level while one if four American adults reads at a 5th grade level or below. Also, the grade level achieved in school is not a measure of an individual's reading skills. You can use Microsoft *Word*™ to evaluate a document using the Tools menu and selecting Grammar. Several suggestions for improving a document's readability are listed below.

    - **Use the active voice where ever 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 your 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.

    - **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. A long word has three or more syllables.

    - **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.

    - **Words:** Some words commonly used in the WHI Extension Study 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
diseased 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
subjects	participants, women
submitted	given
voicemail	a recording machine

- Do not make false claims or promises.
- Pilot test developed materials. Show the materials to age-eligible women not connected with research for only a few seconds, then ask, "What would you say this is all about, in your own words?" Then ask them to read it over more slowly and tell you what it is about. Revise materials if necessary and then retest.

4.4.2   **Formatting**

- **Use 12-point Serif fonts:** Participant material is more readable if a ≥ 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. Sans-serif fonts don't have the squiggles (serif) on the ends of the lines that make the letter recognition easier. 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. During screening, you have three screening visits and several months to convey the complex information regarding the WHI to the potential participant.

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, including posters.
- 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.
- Show the material for a few seconds to some age-eligible women not connected with research and ask them what they notice first, what they remember, what they should do, etc.

4.4.4   **Writing Style**

- Use a simple and relaxed conversational style. Don't be afraid to use the word "you." Ask yourself, "Would I talk like this to my grandmother?"
- 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 camera-ready (not Xerox) 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.
- Type style and size for the text should be consistent and should be 12 point or larger. Do not use script or sans serif fonts. These fonts don't have the squiggles on the ends of the lines and therefore make letter recognition harder.
- Do not use all capital letters, even in titles or headings. Capital letters are more difficult to read and recall. Use larger and bolder print instead.

4.4.6   **Mailing**

- Type or handwrite 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 handwrite 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.

Table 4.1
Instructions for Submitting an E-Mail Inquiry

1. Using Microsoft Outlook, select "New" to create a new e-mail.

2. Address your message to "Inquiry Reporting System," located in the Outlook Address book.

3. If possible, categorize your Inquiry. There are four general Inquiry categories: Management, Data Management, 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 4.2
IRS Log Description

Column Heading	Description
Year	Each IRS number begins with the last two digits of the year.
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 WHI Extension Study the Inquiry was answered and the answer distributed.

The following columns may be completed, as appropriate:

Section	A reference to a section of the referenced manual. More than one section is often referenced.
Form	A reference to a relevant WHI Extension Study form.

Section 4
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