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.

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Section 5

Guidelines for Interactions with Participants

Introduction

Interactions with Women's Health Initiative (WHI) Extension Study participants and their proxies occur during follow-up contacts to collect data from non-respondents, update contact information, and collect study outcomes. These contacts provide an opportunity for Field Centers (FCs) to enhance study bonding and retention, as well as become aware of potential problems with study participation. During these contacts, FC staff may become aware of issues troubling the participants (e.g., domestic violence), often beyond the scope of the study itself.

5.1 Interviewer Procedures

This section contains general procedures for research project interviewing of study participants. The guidelines describe the interview function and interviewing techniques, but they are not intended as specific instructions for completing forms. Those instructions are found in *Appendix A - Forms*.

These guidelines are described to assist WHI Extension Study interviewers as they perform their duties in the context of participant contact. They apply to all WHI staff members eliciting information from participants.

In the WHI Extension Study, interviewing to collect data is done by phone, for example with participants who are on no mail follow-up or who have not responded to the mailings.

5.1.1 Overview

As an interviewer, you are the participant's link with the WHI Extension Study. While you do not act alone in establishing a relationship with the participant, an unpleasant interview experience could tip the balance for a participant who is beginning to lose interest or is contemplating withdrawal.

During interactions with participants, FC staff should keep the following general guidelines in mind:

- The WHI Extension Study is a research project, and personnel who staff the FCs are part of a research team.
- Research project interviewers are not caregivers, helpers, or advisors beyond the scope of the protocol.
- Individuals who take part in the study are *participants*, not patients; they join and remain voluntarily.
- Participants contribute to the content of scientific knowledge without gaining much for themselves.

5.1.2 Research Project Interviewing

For successful interviewing, you should have broad knowledge of the research project interview task as well as the forms and their completion. Your knowledge base should include the following:

- *Nature of research interviewing*: An interview is a social interaction designed to exchange information between a questioner and a respondent. The quality of the information exchanged depends upon the skill of the interviewer in handling that relationship.
- *Scope of research interviewing*: The research project interviewer collects data that will answer research questions.

The *research* interview contains elements that separate it from other kinds of interviewing. Strictly speaking, the research interview has the practical, utilitarian goal of data collection. In the WHI Extension Study, research project interviewers must combine the utilitarian objective with a more social objective of participant retention. The retention objective is an important one, and social interaction should be a part of every interview.

- *Significance of research interviewing*: The research project is dependent upon the reliability and validity of the data collected by its interviewers. Bias in interviewing can compromise data.

The interviewer reduces the chance of bias by presenting neutral reactions to all answers and by maintaining a brisk, regular pace of question delivery. Regardless of how carefully worded the questions and how neutrally presented, research interviews are subject to bias from two sources: interviewer delivery and participant responses. It is the interviewer's job to minimize bias from either source.

Interviewers can introduce bias into survey results by interpreting answers, favoring one answer over another, treating some questions as sensitive, reacting to liked or disliked participant characteristics, or using slanted probes or positive or negative filler words. To avoid these potential sources of bias, interviewers must perfect both neutral delivery and neutral response.

Participants can bias their responses by trying to answer questions when they simply don't know the answers. Even when the participant knows the answers, she doesn't always give them truthfully. What's more, she often doesn't realize that she's not being truthful. The participant may bias her response unconsciously by slanting answers to make her self feel better, giving responses she thinks her friends would, or providing answers she thinks the interviewer expects. The interviewer overcomes participants' emotional, unconscious bias tendencies by presenting questions at a regular pace and by maintaining neutrality.

5.1.3 Interviewer Roles

Although the ultimate goal of the research project interview is standardized and reliable data collection, the interviewer also plays an important role as the human conduit of information from participants to the database. The way the interviewer conducts the interviews both facilitates and standardizes the gathering of the data.

The following are some of the important roles of the interviewer:

Manage the Interview

- Control and focus the interview without dominating either the exchange or the participant. Your job is to get information, not to show what you know. The participant's answers to the questions are important. You convey that importance by your professional demeanor, by maintaining control of the situation, and by focusing on the content of the interview.
- Be politely firm and businesslike; timidity signals lack of confidence. If you communicate insecurity or hesitancy to participants, some of them will take advantage and assume a power position, others will feel sympathetic and assume a "mother" position. In either case, the participant's responses could be biased. The participant assuming the power position could distort strong opinions to keep the position; the mothering participant could try to make the interviewer's job easier by answering obligingly.

Collect Data

- Understand the purpose and meaning of the data items on the forms.
- Take no personal stake in the content of the interview. Make sure your opinions and behavior neither add to nor subtract from the research intention of any items in the forms.

Encourage Participation and Adherence

- The goal of any contact is to make the participant's FC encounters pleasant enough to be worth repeating.
- Be friendly but not chummy. Use a manner of speaking that is natural to you. If your usual manner is too casual, then with your supervisor's help, develop a firmness and modularity in this role that is genuine.
- Approach the interview with pleasure and assume the participant will do the same. Most people like being asked about themselves and their well-being; you are giving participants an opportunity to express themselves.
- Keep contact notes on personal conversation for use by the next interviewer. Record participant information that another interviewer might reasonably be expected to know, not gossipy kinds of information.
- Review contact notes before each new contact. Be careful when using comments recorded by another interviewer. There is a difference between "remembering" a participant and "talking about" a participant, which may be interpreted as a breach of confidentiality.

Leave the Door Open for Future Contact with No-Follow-up Participants

- Encourage respondents to remain in the study, but don't oversell or coerce. Many people will agree to participate to end a phone call and then never return materials.
- Leave the door open for participants who are reluctant to continue in the study so that you can make another try at a later time.
- Emphasize the contribution that a participant alone can make if you suspect that other persons in the household are influencing the respondent's decision about staying in the study.

Clarify the Nature of the Research Setting

- Give participants information about your role as an interviewer by making the following points:

  1) That you are a research project interviewer, not a source of primary care.
  2) That you are not in a position to diagnose or refer them to someone other than their primary care provider for further medical care.

Represent the Field Center and the WHI Extension Study

- Always be polite. Remember, you represent the FC and your co-workers.
- Call participants by name to make the experience at the FC more personal. Always use titles (Ms., Mrs.) and last names unless the participant requests otherwise.
- Impart to the participants respect for the confidentiality of the information they provide.
- Positive rapport with the participant influences the quality of the data obtained and the willingness of the participant to remain in the study for the duration. It is important that all interviewers maintain a professional and friendly manner at every contact with the participant.

5.1.4 Interview Guidelines

The research interview is a structured conversation designed to exchange information between a questioner and a respondent. The structure is provided by questions and scripts. The quality of the information exchanged depends upon the skill of the interviewer in handling that relationship. The following are some techniques to keep in mind as you conduct your interviews.

5.1.4.1 Interview Techniques

Prepare for Each Interview

- Review the contact notes in the chart before beginning each contact.
- Make sure you have all the forms and materials necessary to complete the interview.
- Avoid interviewing someone you know. If you see the name of a friend or acquaintance among the participants, tell your supervisor.

Know the Forms Thoroughly

- Follow all instructions and suggested scripts contained on the form itself and in instructions in *Appendix A – Forms*. Following or not following the instructions, scripts, or recommended remarks makes the difference between consistent and inconsistent data.
- Study the questions and data items on the forms so that you understand what they mean. Use the form as a reference at all times.
- Practice parts of the interviews that seem awkward to you until you can ask the questions in a natural manner.
- Review the instructions for each form regularly. Do not rely solely on memory for detailed instructions on form use.
- Use the response categories that are given. Probe for specificity if necessary (see "Probe Carefully" below).
- Avoid as much as possible using the "other" or "don't know" category.
- Never assume you know what the participant means. Probe for clarity if necessary (see "Probe Carefully" below).
- Record open-ended answers verbatim.

- Record your comments in brackets on the form if you have strong impressions about a participant's answer. Indicate the question you are referring to, and make your comments as clear and concise as possible.

Maintain Professional Contact
- Treat every participant with graciousness and respect; treat none as a buddy.
- Do not give personal opinions on any study matters and do not give advice on personal matters even if you are asked.

Set the Appropriate Pace
- Use a brisk, businesslike pace, but don't rush the participant or show impatience.
- Vary from your established pace on cues from the participant. If the participant shows frustration or lack of understanding, then slow down. If the participant shows annoyance or jumps in with answers to anticipated questions, then speed up. But do not skip questions.

Maintain a Neutral Tone
- Speak distinctly, without unusual inflection that could draw undue attention to part of a question.
- Do not place emphasis on specific response alternatives.

Maintain a Neutral Response
- Record information faithfully regardless of whether you think it's good, bad, boring, or exciting.
- Keep your reactions to yourself, no matter what you may think of an individual or the feelings expressed. Practice *not feeling* a reaction; school yourself out of emotional attachment to the information you hear.
- Inspire confidence by your detachment so that participants feel comfortable giving you the unvarnished truth.
- Do not indicate surprise, pleasure, approval, or disapproval of any answer by word or action. Do not gasp, laugh, agree, or disagree. Even a slight intake of breath may indicate to a participant that you are reacting to an answer. Project smooth, gracious acceptance of information, no matter how outrageous the content.
- Repeat the question exactly as it is written if the participant misunderstands a word or a question and asks for clarification. Do not define words, interpret questions, or suggest answers. See "Lack of Understanding or Recall" for how to respond if a participant does not understand a question.

Deliver the Questions Thoughtfully
- Make your delivery smooth, natural, and enthusiastic. Avoid sounding like a robot.
- Sound fresh for everyone. You may ask the same questions a dozen times in a day, but participants hear them only once in their interview.
- Use the questions, scripts, or recommended remarks as they are written, without apology.
- Emphasize that there are no right or wrong answers; the only thing that matters is the truth from the participant.
- Do not try to justify questions or to defend a line of inquiry; you are asking questions that have been asked of many other participants.
- Keep the questions in the order they're written and maintain the flow of the visit.
- Record open-ended answers in the exact words the participant uses.
- Tell your supervisor if you find a problem with the wording of a question.

Probe Carefully

Probing is a critical technique to master, as it is easy to fall prey to directing responses or altering the meaning of a question. Probes must be as uniform as possible within and across FCs.

- Use probes to elicit answers to either closed-ended or open-ended questions.
- If you feel a participant has provided an inappropriate response or doesn't understand the question, first try repeating the question and the response categories verbatim.
- Probe by asking sufficient supplemental questions to get the participant's answers in full but not so many that you don't get the truth.

- Avoid asking leading questions when probing and do not suggest an answer.
- Do not insert your own ideas of what the participant might be saying. Do not agree or disagree with an answer.

Probing for answers to closed-ended questions:

In closed-ended questions, the need for probing arises when the participant gives an answer that is not included in the response categories. In this case repeat the response categories and ask the participant to choose the category that fits best.

Probing for answers to open-ended questions:

In open-ended questions two problems call for probing: the need to *clarify* a response and the need to *get additional information* in a response.

The following are examples of neutral probes to *clarify*:

What do you mean by that?
Why do you say that?
In what way was it a problem?
Could you rephrase that?

The following are some examples of neutral probes to get *additional information*:

Are there other (repeat the phrase from the question)?
How else would you describe (repeat the phrase from the question)?
What else (repeat the phrase from the question)?

Control Silence
Use silence at the right moment to show your patience while waiting for the participant to formulate an answer, but do not leave the silence too long or it will threaten the participant. In role playing with other interviewers, experiment with pauses to discover your own reactions to silences.

5.1.4.2 Special Situations

In conducting interviews on a daily basis with numerous participants, you will encounter special situations. They will be easier to deal with if you have thought about them ahead of time.

The following are some of the special situations you might encounter with WHI Extension Study participants.

Emotion
- Be prepared for unusual circumstances. Talking about cancer or heart disease can arouse emotion in many people. Participants who have recently lost loved ones, especially to one of these illnesses, may become upset with some questions.
- Remain calm but not distant or cold; let the emotion run its course. Often participants who have experienced losses express strong motivation to continue with the project to contribute to the disease prevention effort.
- Stop the interview if a participant is clearly unable to finish. Be sure to arrange to call the participant within a few days — just to make sure everything is all right and to try to reschedule the interview.

Strong Objections to Questions
- Assume the burden of communication; take the blame for misunderstandings. If a participant fails to grasp the meaning of a question, admit that perhaps you didn't deliver it clearly and repeat the question. Do not allow the participant to feel that the questions are too difficult for her to answer.
- If the participant is angry, reluctant or impatient about a single question or a series of related questions, cite "the office" or the "researcher." Blame the project for objectionable material, not the participant for being objectionable.

- Respond in a non-defensive tone as though you have heard the objection before. Don't delay the interview any more than necessary; move on to the next question. If the participant pursues the objection, remind the participant that although the researcher had a purpose in including the question in the interview, the participant doesn't have to answer the question.
- If a participant hesitates or refuses to answer, repeat the question. Say, "Let me go over that again. If you don't want to answer, that's your choice; but my instructions are to ask each of the questions." Add that the participant's feelings or opinions about the question are important. If the participant still refuses, accept the refusal graciously and go on to the next question.

Impatience With the Length of the Interview

- If a participant is anxious to finish the interview, say, "I need only a few more minutes of your time. Your answers are important to us, and we'd like to have all of them."

Curiosity About the Research

- Be ready with standard replies for people who want to know more about the research.
- Do not get involved in long explanations of the project, the forms, the research methods, or the outcomes of the study. Be sure to use standard responses.
- Invite participants to talk to your Principal Investigator (PI) or other appropriate staff person if they wish to carry a discussion further.

Second Guessing Purposes of Questions

- Do not invent your own explanations when participants want you to tell them why certain questions are included in the interview. For participants who persist, tell them that the researcher had a purpose for the question and that you must ask all the questions as they are written.
- Invite participants to talk to your PI or other appropriate staff person if they wish to carry a discussion further.

Advancing Age

- Gauge your pace according to the needs of the participant. Some older participants may require a slower delivery; others may be insulted by it.

Hard of Hearing

- Slow down for participants with hearing problems and speak in lower-pitched (more bass-pitched, not soft-spoken or high-pitched) tones. Female interviewers often increase their pitch when they speak louder which makes hearing more difficult for many participants who hear lower-pitched tones better. .

Lack of Understanding or Recall

- Take responsibility for making questions understandable. Do not make participants feel that it's their fault if they don't understand a question.
- Take away the burden of not remembering: participants shouldn't feel ashamed by lack of recall. If a participant doesn't remember a date, lead a discussion back through some prominent seasons or events, repeating the phrase of the question as you go.
- Repeat the question at least once for the participant who does not understand the question. Repeat it twice if the participant has patience for it. After that, record whatever answer the participant offers and go on. Don't risk annoying the participant for the sake of an answer to a single question.
- If a participant asks what a word means, use only the definitions provided on the forms and in the instructions. If there are none, say "Whatever the word means to you." In some instances, you may also emphasize again that the researchers are interested in the participant's feelings and that you "can't really answer for" the participant or "put words in her mouth."

Wandering, Extra Talking

- Focus the participant's attention on the questions, while always being polite. Respond to attempts at idle conversation, no matter how interesting, with brief answers, then return to the form.

5.2 Guidelines for Participants With Cognitive Decline

These guidelines offer considerations and suggested strategies, not requirements, for working with WHI Extension Study participants who have experienced some level of cognitive decline. These guidelines are meant to assist, not constrain, FC staff that must balance WHI Extension Study procedural requirements with participants' capabilities and needs on a case-by-case basis. The ultimate purpose of these guidelines is to support the appropriate ongoing participation of WHI Extension Study participants.

5.2.1 Identifying Potential Cognitive Decline in WHI Extension Study Participants

Steady, progressive cognitive decline resulting in significant impairment is not a normal aspect of aging. Health and social problems among older persons are dynamic and may vary over time. Thus, cognitive functioning can vary over time. WHI Extension Study participants will experience transient changes in their memory, thinking, and behavior depending on current life events and daily stresses, acute illnesses, or specific medications. Most of the time, these changes are troublesome but not disabling. Rarely, WHI Extension Study participants will have progressive or profound changes in their cognitive status.

Because cognitive deficiencies can vary from minor to severe, your response to them can vary from minimal to substantial. Your response to cognitive decline should be based on a consideration of its severity and significance with respect to functioning. A thoughtful approach to cognitive problems can help staff reduce barriers to WHI Extension Study participation and identify care participants may need.

Procedures and tools for making an accurate evaluation of a participant's cognitive status and capabilities are complex and beyond the scope of these guidelines. Likewise, FC staff is not expected to formally assess a participant's cognitive status. Note that cognitive decline is not necessarily a reason for a participant to discontinue her participation in the WHI Extension Study.

FC staff will become aware of a participant's potential cognitive decline in many ways:

- If the participant seems confused while completing annual data collection forms
- based on information in medical records or health care provider reports provided to FC clinic staff
- based on information provided by the participant, a family member, or friend about a participant's cognitive changes or their consequences in her day-to-day life

FC staff is encouraged to discuss her/his concerns about a participant's cognitive decline with other appropriate FC staff and investigators to determine if additional information or specific accommodations should be considered.

5.2.2 Addressing Cognitive Decline Concerns

When addressing cognitive decline concerns, it is important to be comfortable with and have some skill in carrying out interactions with such participants. Matters will not be made worse by assessing cognitive function with participants, and it may help. FC staff without comfort or skill in this area should refer these participants to other appropriate staff or investigators. It is preferable, however, that FC staff proceeds with a thoughtful assessment and discussion with the participant.

The primary consideration when ***potential*** cognitive decline is identified is the participant's ability to continue to provide appropriate data on WHI Extension Study forms.

5.2.3 Assess Specific Concerns

- With the participant (e.g., *Have you noticed any changes in your memory or thinking lately?*)

  In almost all circumstances, it is appropriate for FC staff to be straightforward with participants and directly confront the issue when it is detected (e.g., *At times today, you seem a little confused or forgetful).* If the participant identifies issues or circumstances that readily explain the confusion, a notation in her chart may be the only action warranted at this point. If the participant describes (or you note): 1) progressive and significant confusion or memory problems; 2) contacts with health care

providers to evaluate her cognitive decline; or 3) tangential or irrelevant responses to your questions, additional steps may be appropriate.

- With a family member, health care provider, or proxy

  Determine if they are aware of the participant's potential cognitive decline and what, if anything has been done to address this issue.

  It is important to obtain the participant's permission to make such a contact. (e.g., *I'm just a little concerned. Would it be okay if I talk with your [*family member, health care provider, or proxy*] to find out more about this?*). Document this discussion in the participant's chart. The person you contact may be knowledgeable about the participant's changes, aware of her participation in the WHI Extension Study, and able to support or suggest accommodations for her ongoing participation.

5.2.4 Changing Level of Participation

If the cognitive decline does not seem to be permanent, or if she still seems able to complete her forms, you may decide to continue her participation as before. If the participant's cognitive decline in WHI Extension Study continues (e.g., a "temporary" cognitive decline does not resolve, the participant continues to be confused when responding to questions), a change in participation status may be warranted. Appropriate changes may include changing to "no follow-up" or "proxy follow-up". Discuss the ongoing situation with appropriate investigators and staff (as above) before completing *Form 9 – Participation Status*. Refer to *Section 9 – Retention* for information on addressing retention challenges and making changes in WHI Extension Study participation levels.

5.2.5 Strategies for Managing a Participant's Cognitive Decline

There are many strategies to consider for managing cognitive decline concerns, depending on the participant's particular situation. These may include:

- Nurture close relationships with the participants, their family members, and their proxies throughout the study, even when no problems exist.
- Provide accommodations (e.g., complete forms over the phone rather than by mail) that will help her continue to participate in the study.
- Provide the participant, her family member, or proxy with a referral to an outside provider, appropriate clinic, or other resource, if they want one. Most FCs already have local resource lists available.
- Actively involve a proxy or caregiver in helping the participant complete study forms. For more information about proxy procedures, refer to *Section 7.2 - Follow-up by Proxy*.
- For participants who have documented or strongly-suspected cognitive decline, FCs will need to ask their local Institutional Review Boards (IRBs) about any requirements for re-consenting participants or reporting this information to an outside provider.
- Document ongoing assessment of the participant's cognitive status, as needed. Such informal assessments may be appropriate over the remainder of the study.

5.3 Guidelines for Suicidal Ideation

Since distress can vary in severity, so the response by the WHI Extension Study staff must vary. Below you will find suggestions on how to handle three different levels of severity. As state laws governing how to respond to suicidal individuals may vary, each WHI Extension Study PI should consult with a mental health professional to determine the best actions to take when severe distress or suicidality is detected.

It is recommended that each site determine those staff who have the level of comfort and sufficient experience to proceed with the assessment described in Level 1 below. Those staff who feel a participant may be seriously distressed but do not feel comfortable with addressing this with the participant, should ask the designated staff who can comfortably proceed to complete the interaction with the participant. The PI at the site should be made aware immediately of any participant with serious emotional distress symptoms, especially suicidal thoughts.

Level l: Significant symptoms of distress (e.g., depression)

FC staff who identify significant distress should:

1. Seek further information through paraphrasing to clarify the significance of her distress (I hear you saying . . . Did you say . . . etc.). If in doing so the participant does not express suicidal thoughts, proceed with the steps 2-5 below. If she does express suicidal thoughts proceed to Level 2.
2. Recommend to the participant that she consult with her primary care physician who can evaluate and treat her or refer her for specialty care.
3. Request and document in writing (i.e., put in participant's file) permission from participant to follow-up with her within a few days.
4. Notify the responsible WHI clinician or the lead practitioner at the site.
5. Call participant within a couple of days for follow-up.

Level 2: Significant symptoms of distress (e.g., depression) with statement such as "life is not worth living, I wish I were dead."

Clinic staff should refer participant to the responsible WHI Extension Study clinician (e.g., PI) for further evaluation. The responsible WHI Extension Study clinician should assess suicidal intent through direct questioning.

1. If the participant's distress is so bad that she is planning to hurt her self then go to Level 3. If the participant denies that she is planning to hurt or kill herself, proceed through steps 2-6 below.
2. Encourage her to consult her personal physician immediately and offer assistance with that communication (e.g., let her use clinic phone).
3. Request and document in writing her permission to contact a family member. Call family member and inform him/her of the situation. Repeat your recommendation to contact her personal physician as soon as possible.
4. Request and document in writing her permission to contact her personal physician. Call her physician and inform him/her of participant's status.
5. Request permission from participant to follow-up with her within a few days.
6. Call participant within a couple of days for follow-up and notify PI.

Level 3: Significant symptoms of depression with statements indicating suicidal intent

State laws vary regarding the responsibility a staff person has if a participant were suicidal. Therefore, each site should develop a set of guidelines that are consistent with state law. It is recommended that each PI consult with a mental health professional to develop them.

Generally, clinic staff should:

Inform the participant of the importance of preventing her from hurting herself. Request and document in writing her permission to contact a family member, friend or family physician. If the participant refuses to tell her family/doctor, inform her that you are obligated to do so.

1. Call family member and/or physician and inform him/her fully.
2. Develop a policy consistent with state and local laws regarding the FC's responsibility to treat suicide intent. Clinics should consult with a mental health professional (i.e., psychiatrist, psychologist).

5.4 Guidelines for Domestic Violence (DV)

In the course of interacting with WHI Extension Study participants, staff will encounter women who disclose or have evidence that they are in a situation involving domestic violence (DV). Since the level of risk may vary, the response by WHI Extension Study staff can be flexible. State laws may have mandatory requirements governing how to respond to DV. Each FC therefore needs to ascertain any such jurisdictional reporting requirements and apply these within the suggested guidelines that follow. Each FC will also need

to identify the staff member, best suited by experience and comfort level, who should interact with the participant regarding DV, and determine how the staff member receiving the original report should respond.

While many staff members may know information about DV, it is frequently difficult to know what words can be used. For this reason specific scripts for assessing the participant's status are included within the algorithm below. The purpose is to provide timely, emotionally sensitive support to women who reveal that they are currently or were recently in an unsafe, abusive relationship.

There are many factors that contribute to the difficulty staff have in discussing issues related to DV with study participants. Some of these factors may be:

a. the issue of DV is stigmatized in our society and therefore an uncomfortable subject;
b. staff members may have personal experiences with DV by having witnessed violence in their family or personally being a survivor of DV;
c. the WHI study does not have DV as an outcome, and staff may not have been trained in appropriate assessment and brief intervention for women in situations involving DV.

Always discuss issues of DV in a private setting. Self-disclosure of domestic violence may involve a lot of risk-taking for the woman. This is especially true if the woman has never previously shared this information.

While some women may voluntarily self-disclose currently being in a relationship involving DV, many women will not self-disclose information due to various reasons, including fear of retaliation, low self-esteem, shame/embarrassment, isolation, a perception that the staff is not supportive of issues of DV, and lack of trust in the staff (fear that they will be reported).

Assure confidentiality of her answers.
"Your answers to the questions on these forms are confidential. We will not share this information with anyone," (add "within limits of the law" where there are mandatory state or local laws regarding reporting of DV).

General Preparation for DV

- Compile a list of DV resources for your clinic.
- Perform in-service training for clinic staff.
- Establish liaison with community resources.

Algorithm for Assessment and Resource/Referral Support:
WHI participants may disclose that they are in relationships involving DV through their responses to questions on WHI forms or by mentioning this during a phone contact. If staff learn of a possible DV situation, conduct a brief assessment of:

a. The safety of the woman's current situation. "Was the abuse that you mentioned something that is happening in your relationship or your home right now?" "Do you feel safe being home tonight, or do you have a friend's house or would you like the name of a shelter that you might go to?"

   If there is current danger and the woman does not want to go to a friend's house or a shelter, ask "Are there guns, weapons, or knives in your house?" If yes, "Where could you take these so you would be safer?"

b. Her readiness to seek help, "You don't deserve to be in a situation where you are afraid of being hurt. Here is a list of community resources, supportive counselors, and of safe places for you to stay. Do you think that you might be interested in talking to one of these resource people now or in the future?" If the participant does not want the list, then mention, "If at any time you need the phone numbers, please contact me right away."

<u>Resources:</u>

K. Furniss. "Domestic Violence: What Nurses Need to Know."
Kaiser Permanente NW. "Domestic Violence Diagnosis & Assessment."

C.P. Mouton, S. Rovi, K. Furniss, N.L. Lasser. "The Associations between Health Status and Domestic Violence in Older Women: Results of a Pilot Study."

5.5 Guidelines for Contacts with Participants' Survivors

These guidelines offer considerations, scripts, and activities for contacts with WHI Extension Study participants' survivors (e.g., next-of-kin, spouses, or proxies) after a participant has died. These contacts may occur when you:

- try to contact the participant about routine activities (e.g., to collect annual data) and learn that she is deceased
- contact a participant's survivor to provide final medical history information (i.e., *Form 33/33D – Medical History Update*)—this usually occurs because FC staff have previously learned about the participant's death, either from survivors, notification by another participant, reading an obituary, or other sources (e.g., online databases, National Death Index)
- are contacted by a survivor to inform staff of the participant's death
- are contacted by a survivor in response to a routine communication (e.g., *WHI Matters* mailing)
- are contacted by a survivor in response to a written or voice mail expression of sympathy and/or request for final medical history information

5.5.1 WHI Extension Study Expectations for Staff Contacts with a Participant's Survivor

Except within the scope of one's professional licensure, you are <u>not</u> expected to (nor should you) screen for the severity of a survivor's emotional response (e.g., depression, suicidal ideation) nor are you expected to treat that response. However, all staff should maintain a professional demeanor, convey understanding, and offer to end or postpone the interaction for an appropriate period of time. Refer to *Section 5.3 – Guidelines for Suicidal Ideation* for guidelines should you have concerns about a survivor's distress.

5.5.2 General Considerations for <u>All FC Staff</u>

Initial contacts with a participant's survivor. As outlined above, the initial contact with a participant's survivor may occur unexpectedly. If a FC learns of a participant's death via a written source (e.g., obituary, written notification), FC staff should exercise appropriate clinical judgment and consider waiting at least one month after the participant's death before initiating a contact for medical history information.

Generally, all FC staff who routinely make or respond to outside phone calls (e.g., receptionists) should be prepared for possible contacts with participants' survivors. The initial contact, whether initiated by a survivor or a FC staff person, at minimum, should begin with an expression of sympathy and gratitude for the participant's contribution to the WHI Extension Study. It may then be appropriate to refer the caller to a staff person who can begin the process of obtaining final medical history information. Below is a sample script to use for these initial contacts:

Thank you so much for letting me know. I'm sorry to hear about _____ and offer my deepest sympathy. When did this happen? [Pause and document the date, as needed, for completing *Form 120 – Initial Notification of Death*.] *She was an important part of the Women's Health Initiative study over the years and we will miss her. You can be proud of the valuable contribution she has made to women's health care through her participation in this study.*

We would like to get some information to help complete her health records for the study. Is this a good time to talk with you or someone else about her health history or should I have someone call you at another time?

Refer the caller to an appropriate staff person to begin an interview for *Form 33 – Medical History Update* (and/or *Form 33D – Medical History Update (Detail)*, as appropriate) or take down contact information and best time to call. Note that the caller may identify another person to give medical history information, ask the FC to wait for a period of time, express concern about providing such information, or refuse to provide this information. You should be prepared to respond to any of these scenarios.

Form 120 – Initial Notification of Death. Regardless of how the initial information about a participant's death is received, FC staff should initiate a *Form 120* and key-enter the available information in WHILMA so that future participant mailings will be stopped. Depending on the circumstances of the initial notification, it may be appropriate to just enter an approximate date of death and the person providing the information.

Sympathy note. Upon hearing of a participant's death, mail out a sympathy note or card to the next-of-kin or proxy. This note can contain hand-written text similar to the script above (e.g., expression of sympathy, recognition of participant's contribution to the study, setting the stage for future contact about participant's medical history).

Local resource list. The FC should be sure there is a short local resource list available that staff can offer to a survivor. Rather than trying to determine if a particular resource is needed or appropriate, FC staff should consider just generally offering it to each survivor (e.g., at the end of the contact—"*We have a list of resources that I can mail you."*). The resource list may include:

- a basic counseling resource that is relatively low cost or sliding scale
- health information resources (e.g., American Heart Association, American Cancer Society)
- crisis line (contact this resource first to make sure it is appropriate)
- additional resources, such as local/regional treatment sites (e.g., emergency rooms), bereavement/counseling services provided by religious organizations or a hospice group (which often offer services even if the participant did not use the hospice organization), web sites (e.g., http://www.aarp.com/griefandloss/, see "Understanding the grieving process" below)

Review and update this resource list at least every 6 months to confirm that it is still current.

Understanding the grieving process. There are many excellent resources (books, articles, web sites, professionals at your institution and in the community) available for learning more about bereavement and grieving. The most important point to remember is that there is no one "normal" response to loss and a person's response may have very little to do with the current interaction. Manifestations of grieving can take many different forms based on one's previous experience with loss, relationship with the participant, personality, and current life circumstances. A normal affect, anger, crying, withdrawal, denial, and a desire to talk things through are all possible responses. You are not expected to manage these responses beyond maintaining a professional demeanor, conveying understanding, and offering to end or postpone the interaction for an appropriate period of time. Some excellent resources related to grief and bereavement may be found on the World Wide Web, including:

- http://www.aarp.com/griefandloss/: The "Grief and Loss" website for the American Association of Retired Persons. Includes information about common reactions to loss and many other practical resources.
- http://www.centerforloss.com/library/centerforloss/contents.asp: From the Center for Loss and Life Transition in Colorado. This library of brief articles covers information for surviving family and friends as well as those who would like to help or understand the grief process.

5.5.3 Considerations for Staff Who Collect Medical History Information from Survivors

FC staff who contact survivors for medical history information should have good interaction skills and a very basic understanding of the grieving process. Sometimes these contacts can extend longer than expected or just be emotionally draining. If you are the most appropriate person to make the contact, be sure that the call is made when you are not rushed, in a space where you will not be interrupted, and you are prepared operationally and emotionally.

Considerations for making the contact. When you are contacting a participant's survivor to obtain a participant's final medical history information, consider:

- Delay contact for at least one month after the participant's death (use clinical judgment), but avoid contacting survivors around the participant's birthday or on the same day of the death in subsequent months).

- Consider sending out a letter letting the survivor know you will be calling about the participant (so they can gather information) and then follow-up with the actual medical history update call a week or so later.
- Convey professionalism and understanding, particularly if the survivor wishes to delay or postpone the interview or becomes emotional (in which case, you should offer to postpone the interview; see *Section 5.1.4.2 – Special Situations*).
- Ensure that the person you are talking with is the appropriate person from whom to obtain this information (*"Are you able to provide this information or is there someone else we should talk to?"*).
- Follow the basic interview script for *Form 33* (and *Form 33D – Medical History Update (Detail)*; see *Form 33* forms instructions in *Appendix A – Forms).*
- Make use of good interviewing skills (see *Section 5.1 – Interview Procedures*).
- If the survivor is angry, very reluctant to talk, or emotional, do not "blame" the person for his or her feelings or engage in debates about possible objections. You might say, *"It sounds like this is not the best time to talk. Thanks for your time today and I am sorry about your loss."* You will need to judge whether or not it is truly appropriate to offer to call back or whether such an offer might be met with an immediate refusal. In the latter case, instead of making the offer to call back, you might want to just end the call and postpone further contact for an appropriate amount of time. When you follow-up again, you may find some reluctant next-of-kin are now willing to talk.
- If encounters turn difficult, always keep in mind that you are doing the best you can and have all good intentions, even if sometimes you feel like you're not saying the "perfect" thing.
- Offer options for obtaining this information if there is ongoing resistance to doing the interview (e.g., mail or fax medical records or death certificate).
- If the participant is angry, reluctant or impatient about a single question or a series of related questions, cite "the office" or the "researcher." Blame the project for objectionable material, not the participant for being objectionable.

Some survivors may be willing to complete *Form 33/33D* by mail, but not over the phone. In this case, mail the *Form 33/33D* to the survivor. Follow-up for non-response to this mailing should be sensitive to the survivor's possible emotional needs to delay. If a participant's next-of-kin refuses to provide this information or will not sign a medical release, note this information in the participant's progress notes. Your local Institutional Review Board (IRB) may have additional guidelines to consider. Refer to *Section 8.2.7 - Reports of Death* and *8.5 – Fatal Events – Special Considerations* for additional information on procedures related to documenting and investigating a participant's death. *Section 7.2 – Follow-Up by Proxy* also provides some guidelines on identifying and contacting proxies.

5.5.4 Family or Proxy Requests for Information*

Family members, friends, or designated proxies may ask for specific information about the participant who has died. Here is a possible script for responding to such requests:

We are committed to protecting our participants' confidentiality, so I hope you understand that we must follow careful guidelines and procedures before releasing information to people.

After offering this introductory explanation, provide the survivor with the specific guideline below based on the information requested.

- **WHI records**: A participant's WHI records, including consent forms (not medical records obtained outside those generated by WHI) may be made available to the legal next-of-kin upon written request.
- **Results of blood analyses**: Only those analyses that were done at local laboratories during the original WHI (e.g., complete blood count at baseline and Observational Study [OS] Year 3) may be made available to legal next-of-kin upon written request. Analyses done at central labs are not contained in the local databases and are logged centrally by an ID number only, so are not available to study participants or their next-of-kin.

- **Study information and findings:** Findings from the WHI are being published on an ongoing basis. Final results of the main study questions will be published around 2006. The National Institutes of Health (NIH) maintains a web page of study information and updates a list of selected publications at http://www.nhlbi.nih.gov/whi/index.html.

***** Participant rights (even after death) dictate that information or records about her death may only be released to the legal next-of-kin. Although state laws may vary slightly, in general, legal next-of-kin is defined as:

- husband, if the participant was married
- children, if the participant was single and has children (unless the children are all minors)
- mother and father, if the participant was single (if mother and father are deceased, then her sisters and brothers are considered legal next of kin)
- other (if none of the above apply)

5.6 Special Populations Considerations

An important goal of WHI Extension Study is to recruit and retain a representative sample of postmenopausal women of various ethnic, racial, and socioeconomic backgrounds. This includes women with low literacy levels, visual problems, or other conditions that may challenge their ability to participate. Regardless of whether a FC has been designated as a minority site, it is expected that the sample from each FC will include women from a variety of backgrounds. This section on special populations considerations is written as a guide to facilitate CC staff to optimally address the needs of women with a variety of experiences and backgrounds. It recognizes that women will be included in the study who have differences that must be considered as they are recruited and participate in the study.

This section begins with a general discussion of special considerations in cross-cultural counseling and interactions. Information is provided regarding cultural values, beliefs, and behaviors that need to be considered when counseling and interviewing participants as well as suggested approaches for maximizing successful cross-cultural interactions. The special needs of older women are presented, followed by those of women of ethnic minorities. General issues that need to be considered with all minority group women are presented as well as special considerations for women from specific minority groups. The reader is cautioned that these general characterizations may not apply to all minority women. These guidelines are simply meant to offer perspectives that will aid in dealing with these subgroups of women more sensitively, thereby encouraging participation. It should also be noted that some of these issues may be relevant as well for women who are not minorities. This section also considers approaches that should be used with women with special needs.

The final part of this section includes the "Guidelines for Translating Documents into Spanish." Several FCs have been identified to recruit Hispanic participants and require the Spanish version of WHI Extension Study documents. This information is included as a matter of record of how WHI Extension Study documents were translated into Spanish and for reference by FCs in the translation of FC-specific documents.

5.6.1 Special Considerations in Cross-Cultural Counseling and Interaction

One key to cross-cultural counseling is an understanding of value systems in other cultures and their influence on health and nutrition. Every culture has a value system that directs behavior by setting norms.

Cultural Values

A value is a standard that people use to assess themselves and others. It is a widely held belief about what is important and desirable for well-being. Working with participants from diverse backgrounds requires understanding your own values as well as the values of other groups. Too often we interpret the behavior of others as negative because we don't understand the underlying value system of their culture.

There is a natural tendency for people to be "culture bound," to assume that their values or customs are more sensible and right. Cross-cultural counseling and interaction presents special challenges because they require you to work with participants without making judgments as to the superiority of one set of values over another.

To enhance your understanding of cultural differences in values the following list provides a general comparison of Traditional American values with values commonly found in some other countries.

Traditional American Values	**Other Cultures' Values**
Personal control over environment	Fate
Change and variety	Tradition
Competition	Cooperation
Individualism	Group welfare
Future orientation	Past orientation
Directness	Indirectness/"Face"
Informality	Formality
Time Importance	Human interaction importance
Duration of life	Quality of life

Examples of Potential Differences in Values

- Participants and health-care staff may differ on the value of time. Most of us are ruled by time schedules. If "being on time" and "not wasting time" are not familiar concepts to the participant, a 9 o'clock appointment may not be kept until 10 or 11 o'clock. This may be considered entirely appropriate behavior.
- Decisions regarding medical screening or food intake might not be decided by the individual, but by group or family agreement. Thus, a woman may not follow the practices suggested because of extended family values and traditions.
- A woman may not believe that her health habits are related to well-being, but rather attribute them to "fate." Thus prevention will be viewed as a "waste of one's time."

Health Beliefs

Cultures vary in their beliefs of the cause, prevention, and treatment of illness. These beliefs dictate the practices used to maintain health. The value of "good health" is also variable. The traditional American culture emphasizes duration of life, whereas some other cultures place greater emphasis on the quality of life.

A woman may follow a specific process in seeking health care. Family is much more important in some cultures. The family supports and is frequently involved in the treatment, unlike Western medicine where the person is dealt with as a separate individual (not a part of a larger family).

5.6.2 Non-Verbal Communication

Your personality and communicating style affect the counseling process. The women may easily detect attitudes you think you are concealing. Genuine interest and concern for the woman are essential qualities for CC staff members during cross-cultural counseling and interaction.

- Silence. You may view silence as awkward, however, other cultures are quite comfortable with periods of silence.
- Verbal Communication. How you speak is as important as what you say in cross-cultural interactions. Your tone of voice should be positive, avoiding condescending, disinterested, or unpleasant tone. The volume should be audible, but not so loud as to make the woman feel uncomfortable. Often we mistakenly assume that a louder voice is clearer and therefore more easily understood by the participant. Articulate each word and adjust your rate of speech, if necessary. Speech that is too rapid might not be understood, while speech that is too slow might actually bore the woman.

  Don't try to imitate an ethnic communication style which is not naturally your own. For example, using Black American language and communication style, when you are not Black American, may be interpreted as ridicule.
- Formality. Anglo-Americans tend to be informal in their verbal communication, but some other cultures prefer to keep a relationship more formal. Don't assume a first-name basis is appropriate for client

relationships. Many Black Americans may view being addressed by their first name as too familiar and may infer disrespect. With any participant, terms of endearment such as "honey," etc. should be avoided. Asking the woman how she prefers to be addressed is the easiest solution, or assume formality when in doubt.

- Rapport. It is important to establish rapport with the participant when beginning the conversation. Use "small talk" to reflect genuine concern for the woman. However, too much chatting, too many questions, or being "too nice" may cause uneasiness or raise suspicion.

5.6.3 Getting Accurate Information

All staff are concerned with getting accurate information from participants, and this is multiplied when the interaction is cross-cultural. Finding approaches that get better information is easier once you are aware of some additional barriers to communication.

Possible Barriers

There are several reasons why a participant of a different culture may not provide a staff member or counselor with good information.

- Lack of trust;
- Participant feels the information you want is inappropriate;
- Participant is uncomfortable with age, sex, education level, or race of the counselor or staff member; and
- Participant will make an effort to "please" the counselor or staff member.

Suggested Approaches

- Establish rapport and show genuine concern.
- Ask questions in several different ways to double-check information.
- Adjust style of interaction to complement differences in age between you and participant.
- Use open-ended questions.

5.6.4 Preparing for Cross-Cultural Counseling or Interaction

- Understand your own cultural values and biases.
- Acquire basic knowledge of cultural values, health beliefs, and nutrition practices for participant groups you routinely serve.
- Be respectful of, interested in, and understanding of other cultures without being judgmental.

Enhancing Communication

- Ask how the participant prefers to be addressed.
- Avoid language that may be offensive or misunderstood.
- Choose a speech rate and style that promotes understanding and demonstrates respect for the participant.
- Avoid slang, technical jargon, and complex sentences.
- Use open-ended questions or questions phrased in several ways to obtain information.

Promoting Positive Change

- Build on cultural practices, reinforcing those which are positive, and promoting change only in those which are harmful.
- Check for participant understanding and acceptance of recommendations.
- Remember that not all seeds of knowledge fall into a fertile environment to produce change. Of those that do, some will take years to germinate. Be patient and provide counseling in a culturally appropriate environment to promote positive health behavior.

Information adapted from: "Cross Cultural Counseling: A Guide for Nutrition and Health Counselors." USDA, US Department of HHS, FHN 250, September 1986.

5.6.5 Working with Ethnic Minorities

5.6.5.1 Ethnic/Racial Sensitivity

Problems:

- May have a preference for interacting with individuals who are representative of own minority group.
- May not have a personal physician or system of regular medical care.
- May perceive members of own minority group to be more aware of and sensitive to life circumstances, perspectives and concerns.
- May perceive lack of employment of individuals from minority groups on clinic staff as an indication of prejudice.
- May become offended if it appears that they or others from ethnic/racial minority groups are treated differently or are not respected.
- Published statistics and information on minority community may not be accurate.
- There may be varying perspectives and experiences in ethnic subgroups within African-American, Hispanic, Native American, and Asian minority groups.

Solutions:

- Make sure staff, particularly receptionist, is pleasant, respectful, and positive.
- Stress that participation in WHI Extension Study does not replace the need for regular medical care.
- Select a staff that is representative of the community and that reflects a balance of ethnic/racial groups.
- Have a staff member of the same ethnic/racial background of the women available to explain study protocols, consent forms, and questionnaires.
- Appoint a local advisory committee; include reputable minority community representatives. Ensure that members are clear about their role and level of involvement.
- Become thoroughly familiar with minority community characteristics, information channels, and power structure.
- Recognize the diversity of ethnic viewpoints within minority subgroups that can influence responses to the study protocols.

5.6.5.2 Personality Motivational Factors

Problems:

- May perceive research as a form of exploitation in which non-minority individuals reap the benefits.
- May be concerned about being used as a "guinea pig" in research.
- May believe that only minority scientists should study minority populations.
- May have past history of being exploited by sales people under the guise of a survey or research study.
- May be less prone to self-disclosure in research, particularly to someone from another ethnic or racial group.

Solutions:

- Explain that the study will provide important information for all women of all ethnic and racial backgrounds.
- Note that women from all ethnic and racial groups are included in the study.
- Inform the woman that researchers from all ethnic and racial groups from across the country are involved in conducting the study.
- Have a staff person of the same ethnic and racial background of the woman available to explain information and to assist in completing questionnaires as needed.
- Present study through public forums, such as churches, community associations, fraternal groups, and in ethnically-focus newspapers.
- Obtain sponsorship of various individuals or organizations that have a reputation of showing concern for the welfare of the minority community.
- Use the media to inform and motivate the community about the study.
- Send letter about project on official agency stationery before initial contact. If initial contact is in person, have identification available from official agency.

5.6.5.3 African-American (Black)

Problems:

- May be quite religious. May not readily accept interventions or actions that are perceived to be against God's will or God's plan in nature.
- More likely to believe in destiny.
- May put a high degree of trust in personal physician regarding all health matters.
- May not participate in health research without the perceived support of physician or regular health care provider.

Solutions:

- Explain carefully and simply the procedures to be used and the reasons for using them.
- Inform local health care providers about the study and that some of their patients may be involved.

5.6.5.4 Hispanic

Problems:

- May not feel comfortable speaking English.
- May seek informal approval from husband or older son for decision making.
- May be concerned that personal information (for example, income or immigration information) will place family at risk.
- May be suspicious of government involvement in a research project if family members have lived in oppressive societies with government informers.

Solutions:

- A staff person bilingual in Spanish and English should make initial contacts with potential participants in minority Hispanic FCs.
- If the person answers the telephone in Spanish, the staff person calling should continue the conversation in Spanish.
- Use the formal and respectful form of the pronoun "you" in Spanish, that is, "usted," when talking to Spanish women.
- The husband or older son, if a husband is not available, should be informed about the study to encourage their informal permission.
- Carefully explain the confidentiality of information obtained in the study.
- Assure the woman that personal information will not be provided to other government agencies.
- Explain that personal data will not be reported at the individual level; only group data will be reported.

5.6.5.5 Native American

Problems:

- May not be comfortable speaking English.
- May associate certain health problem as “normal” part of aging which do not require medical intervention.
- May de-emphasize personal health problems or complaints.

Solutions:

- Provide a trained interpreter or interviewer who speaks the language.
- Work with local Indian Health Service or Native American health care providers to develop referrals and follow-ups.
- Explain that not all symptoms are caused by aging.
- Explain why it is important to maintain health for the benefit of self and especially for the family unit.

5.6.5.6 Asian

Problems:
- May be highly concerned about personal social status issues.
- May not readily provide information that could be perceived to shame or reflect poorly on self, or family members.
- May hesitate to respond to questions about income, educational level, living arrangements, and household composition.

Solutions:
- Assure the woman that all information is confidential and that personal information will only be reported as group data.
- Explain why information on income, education, and family background are important to the study.

5.6.6 Working with Women with Special Needs

Problems:
- May not be able to read or write English or Spanish well.
- May not be able to see well enough to read or complete study forms alone.
- Mobility may be compromised.
- May not be able to complete study forms without assistance.
- May require additional time for completion of study forms.
- May become frustrated and discontinue participation.
- May have child care responsibilities for grandchildren or other young children that may interfere with participation.

Solutions:
- Let women know that assistance can be provided in completing forms if they require it, at FC discretion.
- Provide assistance if possible in completing study forms for women who have a low literacy level, visual problems, or physical mobility problems. Ensure that answers recorded are those of the woman, not of the person providing assistance.
- Women who are illiterate are excluded from the study at FC option.
- Exclude volunteers who can not speak in local FC languages or dialect. Only use translators who are part of the bilingual FC staff or volunteer translators for which levels of fluency in both languages are known to be satisfactory.
- Identify women who require assistance in completing study forms. Incomplete forms or inappropriate responses indicate that a woman is likely to need assistance.
- Designate a family member or person in the household to aid women who require assistance in completing study forms at home if one is available. Clearly identify designated person, note on FC forms, and train in approach to providing assistance. Training should emphasize having the designee focus on obtaining and recording the woman's response and not their own. Items on questionnaires that are sensitive or may be embarrassing to provide answers to family member should be completed with the assistance of FC staff rather than with assistance of family member.
- If FCs cannot provide assistance for women with inadequate literacy skills and if the woman cannot designate a helper to assist, she is ineligible.

5.6.7 Working with Older Women

Recognize the diversity and heterogeneity of older women: They will vary widely on dimensions of health and functional status, educational background, standard of living, and cultural background. The potential for certain health problems increase with advancing age.

5.6.7.1 Health and Functional Impairments

Problems:

- Vision and hearing may be impaired.
- Cognitive impairments such as memory, performance and certain dimensions of intelligence may decline with age. The speed at which information is processed may also be slower. The woman may have difficulty retrieving relevant information.
- May easily fatigue, sometimes become confused.
- May become emotionally distressed (cry) because questions asked evoke sad memories.

Solutions:

- Appeal to the woman's altruism. Tell her that participation is important for future generations.
- Speak slowly, clearly, provide redundant cues (position yourself so that they can both see and hear you speak). Use the low frequency range of your voice; do not yell.
- Be alert for signs of fatigue. If possible, give the woman a brief rest period. Reschedule, if necessary.
- Strike a balance between compassion and objectivity.
- Repeat questions and response categories.
- Do not overload the woman with information.

5.6.7.2 Personality and Motivational Factors

Problems:

- May be less interested in general in topics of the study and may object to the relevance of certain types of data for the study.
- May be more readily influenced by interviewers and more susceptible to interview bias.
- Ethnic/cultural group differences may be more extreme.

Solutions:

- Clearly identify yourself.
- Emphasize the importance of the study and the need for questions and procedures.
- Be sensitive to bias and try not to express opinions.
- Recognize differences in communication styles (language) among different ethnic groups.

5.6.7.3 Cohort Differences (Life Experience Effects)

Problems:

- On average, today's older women have fewer years of formal education than younger women and have encountered fewer tests and standardized interviews.
- May disregard standardized scale formats.
- May sidestep questions and converse "on the side." Information that older women have to report is inherently more complex because they have a lifetime to summarize.
- May misunderstand questions or response options.
- May have different standards about the appropriateness of being asked for certain types of information (e.g., income data; functional status data).
- May be more easily insulted at being asked particular questions (e.g., ability to stand from a chair when answer seems obvious).

Solutions:

- Explain carefully the procedures to be used and the reasons for using them.
- Give the woman a road map of what will happen, how long it will take.
- Anticipate and address participant fears and anxieties about questions being asked, procedures being used.
- Clarify questions and response options using language more familiar to the woman as needed.
- Explain that sensitive information will not be reported at the individual level; only group data will be reported.

- Emphasize the importance and value of the data to be collected and how it will help current and future generations, etc.
- Emphasize that while some questions may not be appropriate to them, they have to be asked of everyone.
- Promise to provide (and follow through) general information about the study as a whole as it becomes available.

5.7 Guidelines for Translating Documents into Spanish

These guidelines for Spanish language translation address:

- Translation of documents for which there is no previous Spanish translation;
- Materials used in health promotion projects, with particular focus on multi-center trials; and
- Checking the acceptability of previously translated documents.

1. Document is translated by a Native Spanish-language translator, who is skilled in grammatical rules and localized regionalisms. The translation will be entered on a computer with Spanish-language capabilities, including spell-check and thesaurus. All target audiences and their particular regional Spanish will be taken into account, including U.S. Border, Mexican, Central and South American, Caribbean (Cuban, Puerto Rican, Dominican) and Peninsular (Spain). A low literacy audience must be taken into account.
2. The first draft is proofread and reviewed by the translator. The document is to be read word by word, line by line to insure accuracy. During this review, the translator scans for errors, general syntax, and readability.
3. The first draft of the translated document is edited by a fully bilingual English/Spanish editor, who was not involved with the original translation of the document. They will have complete command of Spanish and be skilled in grammatical rules and localized regionalisms. All target audiences, and their particular regional Spanish, will be taken into account, including U.S. Border, Mexican, Central and South American, Caribbean (Cuban, Puerto Rican, Dominican) and Peninsular (Spain).
4. All changes by the editor are incorporated, and a second draft is completed. Closely scrutinized proofreading is now performed to correct any remaining grammatical/typographical errors.
5. The second draft is reviewed by designated Spanish-speaking reviewers who are involved in the use of the translated document and who are expert in the content of the original document. Ideally, these reviewers shall: (a) be expert in representing all of the affected subgroups in the target area; (b) keep in mind the goals of the intended message and the target audience; and (c) avoid re-translating the document, by merely changing the style of the piece or by replacing one correct word with another equally correct word. These reviewers will be provided brief summaries of the target population, including Hispanic subgroups, education, language preference and standards.
6. Only the appropriate reviewers comments are incorporated into the document. Although reviewers are sometimes expert on the content, they may or may not be capable of effectively representing all Hispanic subgroups. In addition, these reviewers, capable experts in their own fields, may not be "communications" experts. What might be appropriate by the reviewers standards may not be appropriate for the target audience.
7. A pilot test with the target audience is done if time and money permit.
8. When differences in opinion occur among the reviewers, broadcast-standards in the Spanish language will prevail. It is recommended that the input of Broadcast experts be considered in settling all differences.
9. A third and final draft is created, incorporating Broadcast input. This draft is submitted to the editor(s) for final proofreading and editing.
5. Another draft is prepared on a compatible computer diskette to produce galleys to reduce typesetting errors.

11. Galleys are carefully proofread by the editor(s).
12. Local Hispanic FCs should determine items or sections on forms with which Hispanic women voice confusion or difficulty.
13. Items or sections of forms with which difficulty is noted should be carefully documented, and specific written recommendations for changes should be sent to the Clinical Coordinating Center (CCC).
14. If applicable, incorporate suggested changes from local FCs into a final draft. The final draft should be reviewed by bilingual editor(s) before typesetting.
15. Final galleys are carefully proofread.

Section 5
Guidelines for Interactions with Participants

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Section 6

Enrollment

Introduction

This section describes **guidelines and recommendations** for enrolling participants in the Women's Health Initiative (WHI) Extension Study. WHI participants are invited to join the Extension Study at either the WHI close-out clinic visit or through an invitational mailing. Procedures for enrolling women by mail and in-person are described in this section. Procedures for enrolling women at the close out visit are described in more detail in the *Women's Health Initiative Manuals, Volume 2 – Procedures, Section 16.13 – WHI Closeout* and *Section 16.14 – WHI Extension Study and Supplemental Use Consents.*

At the time they are invited to join the Extension Study, participants are also asked to sign the Supplemental Consent for use of stored specimens by non-WHI researchers at private or non-profit organizations. Procedures for obtaining this consent are also described in this section.

6.1 Overview

Enrollment into the WHI Extension Study is done by inviting women already enrolled in the WHI to extend their participation by joining the Extension Study. Introducing the Extension Study and obtaining consent is done in one of two ways: 1) in person, at the close-out visit for CT participants, or 2) by mail, for Observational Study (OS) participants and Clinical Trial (CT) participants who do not attend the close-out visit. This section discusses procedures for participants enrolled by mail or in-person. This section also provides procedures for obtaining the Supplemental Use consent. Procedures for consenting participants during the close-out visit are provided in more detail in the *Women's Health Initiative Manuals, Volume 2 – Procedures, Section 16.13 – WHI Closeout* and *Section 16.14 – WHI Extension Study and Supplemental Use Consents.*

6.1.1 Clinical Coordinating Center (CCC) Role in Enrollment

The CCC is responsible for monitoring, fostering, and encouraging the enrollment effort, and for providing accurate and timely information on the number of participants enrolled at each Field Center (FC). The CCC distributes weekly enrollment activity reports to all participating FCs and the National Heart, Lung, and Blood Institute (NHLBI). The CCC also supports enrollment efforts by creating enrollment materials, reviewing FC materials and methods for procedural effectiveness and scientific integrity, and providing support in the use of the WHILMA and WHIX databases.

6.1.2 Field Center Role in Enrollment

FCs are responsible for inviting WHI participants to join the Extension Study and obtaining a signed consent form from each participant who agrees to join. This may be done in-person or by mail. Study-wide materials for use by FC staff are listed in *Table 6.1 – Consent Packet Materials*. FCs are also welcome to develop additional materials that can enhance the process, such as a personalized invitation letter signed by the principal investigator.

6.2 Procedures for Obtaining the Extension Study and Supplemental Use Consents

Obtaining a participant's signed consent for enrollment in the WHI Extension Study and for the Supplemental Consent may be done by mail or in-person at a clinic visit, as per local Institutional Review Board (IRB) requirements. Ideally, consents are obtained from participants after their WHI close-out tasks are completed. Each FC is responsible for obtaining consent from its own participants. The two consent forms are presented to all participants, with the exception of those with an "absolutely no contact" or deceased follow-up status. To obtain consent from participants on "proxy" follow-up, see *Section 6.2.4 – Obtaining Consent Forms from Participants on Proxy Follow-up*. Participants may choose to participate in the extension study and choose not to sign the supplemental consent. It is also acceptable for the participant to sign the supplemental consent and not participate in the extension study.

It is up to each FC to decide which staff members are in the best position to participate in the informed consent process. There is no training certification required of staff who will be consenting participants. However, it is expected that any staff involved in providing the consents will be fully knowledgeable of the consents' content, as well as the consenting requirements at their institution. See *Section 2 - Consents* for copies of all consent forms.

WHI Extension Study Consent

In the spring of 2004 the NHLBI approved a five-year extension study of all WHI participants to collect health information through 2010. The WHI Extension Study will help investigators learn more about long-term changes in women's health. All women who participated in WHI will be invited to join the WHI Extension Study.

Two different informed consent forms have been developed for the WHI Extension Study, depending on which component of the WHI the participant was in.

- The Extension Study (Non-HT) Consent is for women who participated in any WHI component other than the Hormone Trial (including OS).
- The Extension Study (HT) Consent is for women in the Hormone Trial, even if they also participated in other components of WHI.

Supplemental Consent (for use of stored specimens by non-WHI researchers at private or non-profit organizations)

When WHI began, participants consented to provide samples of their blood for future research by WHI investigators. These on-going studies have included genetics research to learn how differences in blood, blood proteins, and DNA might be associated with disease risk or health outcomes. The use of participants' blood samples for these studies by WHI investigators can continue under the existing WHI consent. However, we are now asking participants to sign a new, "Supplemental" consent so that WHI stored specimens can be made available to non-WHI researchers at private or non-profit organizations.

Since participants consented to join WHI, huge technological advances have been made in the ways scientists can analyze blood, proteins in the blood, and DNA. Scientists in settings outside of WHI and even outside of traditional academic and medical settings have been involved in making these scientific advances. In some cases, scientists at private and for-profit organizations and companies have the best access to the experience and state-of-the-art technology needed to conduct these newer types of studies. The WHI would like to collaborate with these scientists so that further advances in science can be made and important public health questions can be answered. This collaboration is consistent with our promise to participants that we are using their health information and specimens to answer many important questions about women's health.

The Supplemental Consent, which discusses the sharing of WHI participant blood samples with scientists at for-profit and non-profit organizations outside of the WHI, must be obtained before the samples can be shared. All participants should be approached to sign the Supplemental Consent Form regardless of which study arm they participated in.

To initiate the consenting process, FCs will mail the Extension Consent and the Supplemental Consent Forms to participants, either in the packet mailed to CT participants prior to the close-out visit, or in a packet mailed to those who do not attend close-out visits (i.e., OS participants and CT participants with a follow-up status of no visit, proxy follow-up, or no follow-up, or who do not do not attend their close-out visit). If the consent is collected by mail, refer to *Section 6.2.3 – Collecting the Consents by Mail* and refer to *Table 6.1 – Consent Packet Materials* for items to include in the mailings. Make sure that participant barcode labels are affixed to any consent forms that are mailed out. For consents obtained at the close-out visit, see *Women's Health Initiative Manuals, Volume 2 – Procedures, Section 16.13 – WHI Closeout* and *Section 16.14 – WHI Extension Study and Supplemental Use Consents* for details and materials designed specifically for close-out visit mailings.

6.2.1 WHI Extension Study Consent Collected in the FC or by Telephone

6.2.1.1 WHI Extension Study Talking Points

Background:

The NHLBI has approved a five-year extension study of all WHI participants so that important health information can be collected through 2010. The WHI Extension Study will help investigators learn more about long-term changes in women's health. Women in the WHI Hormone Trials (even if they participated in other WHI CT components) will be asked to sign a "WHI Hormone Program Extension Study Consent." All other participants (including OS women) will be asked to sign the "WHI Extension Study Consent."

These talking points are intended for staff who will be discussing the WHI Extension Study with participants for the purpose of obtaining informed consent. This document can also serve as a resource for other WHI staff who may be asked about the Extension Study. Staff should read both the WHI Extension Study Consent and the WHI HT Extension Study Consent in addition to this document. More detailed procedures on carrying out the informed consent process with WHI participants can be found in the *Women's Health Initiative Manuals, Volume 2 – Procedures, Section 16.13 – WHI Closeout* and *Section 16.14 – WHI Extension Study and Supplemental Use Consents* and from your local IRB.

Key Points:

Regardless of whether your clinic chooses an individual or group format to properly inform and educate women about the Extension Study, the following points should be covered:

- The purpose of the WHI Extension Study is to continue to learn about the health of postmenopausal women for an additional 5 years. Thousands of WHI participants are expected to participate in this study.
- You will **not** be asked to come into the WHI Field Center for visits. Each year you will be sent an annual health update (Medical History Update for all participants; an additional Hormone Questionnaire for HT participants) to complete and send back through the mail.
- FOR HT PARTICIPANTS ONLY: You will also be asked to have a mammogram each year for the first two years and to give us permission to obtain copies of the mammogram report.
- You might be asked to sign a medical release form to get more detailed information about health changes you have experienced.
- Any information you provide will be kept confidential. Only WHI Extension Study staff will have access to this information. For safety reasons, Food and Drug Administration (FDA) staff may also examine these records.
- No identifying information will be included in study reports; your health information will be grouped with information from other participants.
- There is no promise or guarantee that you will receive any personal benefit from the study. You should contact your own health care provider about any personal health issues or questions you may have.
- There are no risks to completing the health update forms.
- The study is completely voluntary and you may withdraw at any time.

Additional Points:

The following additional points are appropriate to incorporate into your discussions with participants about why the WHI Extension Study is important.

For HT Participants:

- Women, health care providers, and scientists throughout the world are asking how women's risk for certain diseases change after they stop hormones. We need long-term data from WHI Hormone Program participants like you--women from the Estrogen-Plus-Progestin (E+P) and the Estrogen-Alone (E-Alone)

studies and those who were the active and placebo groups of both studies--to get answers to these questions.

- Many women and their health care providers are evaluating and re-evaluating their hormone choices since they heard about the WHI Hormone Program findings. Just as you contributed to those important findings, your future choices about hormones--what types of medications, if any, you take--can help us learn more about the health effects of these choices.
- We have tried to make participation in the Extension Study as easy as possible—you will not need to come in for clinic visits or exams. The data for this study will come from forms that we send in the mail.
- To ensure your safety and learn more about breast health after women stop hormones, we will ask your permission to obtain your mammogram reports during the first two years of the study. We may also check in with you by phone to get information about where these mammogram reports or other health records are located. However, you do not need to come in to the clinical center anymore.

For Dietary Modification (DM) Participants:

- The health effects of your past dietary choices may continue for years after the WHI Dietary Study has ended. This is true whether you were in the Comparison group and may not have changed the way you eat, or you were in the Dietary Change group and were asked to eat less fat and more fruits, vegetables, and grains.
- We invite you to continue with the WHI by joining the WHI Extension Study so we can answer questions about these longer term effects of diet.
- Your participation in this new phase of the WHI will help advance knowledge about the effect of diet on health in women.
- We recognize that the choice is yours and invite your questions.

For CaD Participants:

- The WHI Extension Study will allow us to answer additional important questions about the health effects of taking calcium and vitamin D. For example:
    - How long do women need to take calcium and vitamin D to prevent diseases like colon cancer and osteoporosis?
    - Does calcium and vitamin D prevent breast cancer?
    - If there are benefits or risks to taking calcium and vitamin D, how long do they last after women stop taking these supplements?

6.2.1.2 Review of Extension Study Consent

After reviewing the talking points, have the participant read (if she did not receive it ahead of time) or review the Extension Study (Non-HT) Consent or the Extension Study (HT) Consent. Following the reading of the consent form, allow ample time to answer any questions she may have. Refer to the "Extension Study FAQ" (Public Folders) to help answer her questions. If questions come up that are not in the FAQ, refer the participant to the appropriate staff (i.e., Clinic Practitioner [CP] or Principal Investigator [PI]) for further clarification.

If the consent process is being done in a group setting, smaller groups are advised to stimulate discussion. It is also recommended that women have the opportunity to ask their questions privately.

If the participant needs more time to consider if she wants to sign the consent, provide her with a postage-paid return envelope to return the consent at a later time.

6.2.1.3 Signing of the Extension Study Consent

Ask the participant to sign and date two copies of the consent form in the appropriate places. Sign and date one or two copies of the form as a WHI representative and witness, as required by your CC's IRB. Ensure

participant barcode labels are on each copy of the consent form. Give one copy of the consent form to the participant to take home with her and keep one copy for her clinic file.

After the participant signs the form, thank her for her time. Let her know that she will be receiving a WHI Extension Study newsletter in the mail about once a year. Remind her that she will start receiving her annual data collection packet within a year. Provide her with a number to call or postage-paid postcard to use for notification of a change of address.

After the participant signs the consent form (or declines), thank her for her years of dedication to WHI. Then initiate discussion of the Supplemental consent (see *Section 6.2.2 – Supplemental Consent*).

Complete and data enter *Form 111 – Extension (Non-HT) Consent Status*, or *Form 112 – Extension (HT) Consent Status*.

6.2.2 Supplemental Consent (for use of stored specimens) Collected in the FC or by Telephone

6.2.2.1 Supplemental Consent Talking Points

Background:

When WHI began, participants consented to provide samples of their blood for future research by WHI investigators. These on-going studies have included genetics research to learn how differences in blood, blood proteins, and DNA might be associated with disease risk or health outcomes. The use of participants' blood samples for these studies by WHI investigators can continue under the existing consent. However, we are now asking participants to sign a new, "Supplemental" consent so that WHI stored specimens can be made available to non-WHI scientists.

Since participants consented to join WHI, huge technological advances have been made in the ways scientists can analyze blood, proteins in the blood, and DNA. Scientists in settings outside of WHI and even outside of traditional academic and medical settings have been involved in making these scientific advances. In some cases, scientists at private and for-profit organizations and companies have the best access to the experience and state-of-the-art technology needed to conduct these newer types of studies. The WHI would like to collaborate with these scientists so that further advances in science can be made and important public health questions can be answered. This collaboration is consistent with our promise to participants that we are using their health information and specimens to answer many important questions about women's health.

It is well understood that the field of DNA and genetic research is growing quickly and can be very complicated to understand. Even those who have significant health and/or science backgrounds can find themselves perplexed at times when answering specific questions related to DNA and genetics. It is recommended that staff review the basics so that they can feel as comfortable with the material as possible. A useful website to serve as a resource to staff is www.nlm.nih.gov/medlineplus/cloning/html.

An in-person discussion about the Supplemental Consent can be done individually or in groups, depending on the CC's specific needs and resources. These talking points are intended for staff who will be having discussions with participants for the purpose of obtaining informed consent. The talking points can also serve as a resource for other WHI staff who may be asked about the Supplemental Consent, how their samples are used, or genetics research in WHI. An optional participant video, introducing the concept of sharing WHI blood and DNA samples with outside scientists, has also been developed for CC use. It is recommended that women view the video to help them better understand the Supplemental Consent form and to generate some enthusiasm for this opportunity to advance our knowledge of this growing field. The video will help answer potential questions and may cut down on staff time. The video may be shown individually or in a group setting.

In addition to these talking points, staff should read the Supplemental Consent and refer to the Supplemental Consent FAQ for suggested responses to participant questions that may come up. More detailed procedures and guidelines on carrying out the informed consent process with WHI participants (including any HIPAA considerations) can be found in the "WHI Close-out Procedures" document and from your local IRB.

Regardless of whether an individual or group format is used to inform and educate women about the Supplemental Consent, the following points must be covered (see "Supplemental Consent Talking Points" [Public Folders] for more details):

Key Points to Cover in Discussions with Participants about the Supplemental Consent:

- The use of blood samples by the WHI scientists can continue under the original existing consent. This new "Supplemental Consent" is specifically asking for permission to share blood and DNA samples with non-WHI scientists at private or non-profit organizations, starting in 2006.
- Collaboration with these non-WHI scientists may lead to even more ways of analyzing samples and to faster development of new tests to diagnose and/or predict diseases.
- The NHLBI and our IRB will carefully review all research proposed by scientists from outside organizations according to high standards and ethical principles. No samples will be made available until these proposals are approved.
- Only those blood and DNA samples that have already been collected and are already stored will be made available to these non-WHI scientists. No additional blood or DNA will be needed, and you will not be asked to give more blood samples.
- All individual data in the WHI is kept confidential. No results of blood or DNA (genetic) studies done using your samples will be provided to you, or your family, doctor, or insurance company.
- The results of this type of research are reported on and applied to groups as a whole. We will not know what the DNA research shows for an individual person's health.
- Consenting to this supplemental use of blood does not mean that you are consenting to or will have genetic testing. You must speak with your own health provider if you are interested in having genetic testing.
- There will be no direct benefit from these studies to your own personal health, but this research will hopefully result in new tests and treatments to prevent or cure diseases.
- At any time, you may withdraw consent for any use of your blood or just for this supplemental use, without affecting your participation in other parts of the WHI.
- There are no costs to you or your insurance for any blood or DNA research using your WHI samples.
- Your blood and DNA samples will be stored at a central site listed under a code number only. No personal identifying information will be included on your samples.
- WHI has been granted a Certificate of Confidentiality from the US Federal Government to make sure that your confidentiality is protected.

6.2.2.2 Review of Supplemental Consent

Following the video, have the participant read the Supplemental Consent (*Section 2 - Consents*) (or review it, if she received it ahead of time). Following the reading of the Supplemental Consent form, allow ample time to answer any questions she may have. Refer to the "Supplemental Consent FAQ" (Public folder) to help answer her questions. If questions come up that are not in the FAQ, refer the participant to the PI for further clarification.

If the consent process is being done in a group setting, smaller groups are advised, to stimulate discussion. It is also recommended that women have the opportunity to ask their questions privately, if possible.

If the participant needs more time to consider the consent, provide her with a postage-paid envelope to return the consent at a later time. Make sure that the consent form copies that she takes with her have participant barcode labels affixed to them.

The field of DNA and genetic research is growing quickly and can be very complicated to understand. Even those who have significant health and/or science backgrounds can find themselves perplexed at times when answering specific questions related to DNA and genetics. It is recommended that staff review the basics so that they can feel as comfortable with the material as possible. A useful website to serve as a resource to staff is www.nlm.nih.gov/medlineplus/cloning/html.

As fields emerge and grow and technology advances, new situations and questions can arise. Not every question will have a clear answer at this point, since we don't know exactly how the field will evolve. It is important to understand that all WHI Extension Study researchers and future collaborators will make every reasonable effort to uphold the toughest ethical standards for research with human subjects, including blood and DNA research.

6.2.2.3 Signing of the Supplemental Consent

Ask the participant to sign and date two copies of the consent form in the appropriate places. Sign and date one or two copies of the form as a WHI Extension Study representative and witness as required by your CC's IRB. Place a participant barcode label on each copy of the consent form. Give one copy of the consent form to the participant to take home with her and keep one copy for her participant file.

If the participant declines to sign the form, thank her for her time.

Complete and data enter *Form 113 – Supplemental Consent Status* indicating the consent status.

6.2.3 Collecting the Consents by Mail

Use *WHIX0870 – OS Extension Consent Batches Screen* and *WHIX0148 – Follow-up Visit Information* to identify OS and CT participants, respectively, who are due for consenting. *WHIX9762 – Close-out and Extension Consent Tracking* can be used for tracking both CT and OS participants who have not completed the consents. See WHILMA upgrade notes Ver. 5.5 for detailed instructions on using WHILMA to identify these participants and for tracking consents.

Once participants are identified as needing a consent mailing, mail the first consent packet, (see *Table 6.1 – Consent Packet Material* and *Figures 6.2 - 6.5* for required mailing packet contents and *Figures 6.6 - 6.10* for optional mailing materials). A second packet, identical to the first, can be re-sent to non-responders 2 months after the first two. FCs have the option of sending a third mailing, two months after the second mailing to non-responders. If there is still no response, the FC may try to contact these participants by telephone to discuss the possibility of then signing one or both consents. The amount of effort that goes into locating and obtaining consents from non-responders is at the FC's discretion.

Complete and data enter *Form 111 – Extension (Non-HT) Consent Status* and *Form 113 – Supplemental Consent Status* for all participants indicating the consent status.

6.2.3.1 Strategies to Boost Extension Enrollment in Women Enrolled by Mail

The optional strategies and model materials described below were created to help CCs increase enrollment in the WHI Extension Study, particularly for minority and older women. These materials are designed to help "personalize" the invitation for women enrolled by mail by:

- boosting the level of "personal" contact with mailed participants;
- helping participants understand the mailed packet, particularly older women who may be overwhelmed by the amount of information;
- encourage participants to call their clinics with questions;
- emphasizing their unique importance, especially those who are members of a minority group or in the oldest age group.

The ideal strategy is to personally contact participants by phone right after the packets have been mailed out, to answer questions and emphasize the importance of their participation. However, given that this may not be feasible, FCs may choose to use materials and procedures designed to supplement the mailed packets. Use any or all of these strategies, according to what local resources will accommodate. These are meant to be suggestions only, and the attached materials are models to be modified according to clinic needs.

Before mailing the enrollment packet:

- A few weeks **before** the packet is mailed, mail a pre-enrollment packet letter (*Figure 6.6*) to let participants know that the packet is coming and to encourage them to call with questions when it arrives.
- In addition, you may want to include one or more of the items described below (i.e., personalized PI letter or some of the other flyers) in the pre-enrollment packet mailing.

Suggestions for the mailed enrollment packet:

- Include a cover sheet that helps simplify the packet (*Figure 6.7*). To make it stand out, consider printing it on colored paper.
- Include a flyer that discusses the unique contribution that each woman makes (*Figure 6.8*). This flyer highlights the importance of older women and minority women to the success of WHI.
- Include a flyer with photos and quotes, like *Figure 6.9*. This flyer was created using clip art from the web. You do not need permission to use these photos or quotes.
- Include a personalized letter, or letter signed by the clinical manager or PI. The letter could highlight the importance of their participation, encourage them to call with questions, and briefly explain what's in the packet.

After the packet is mailed:

- A few days **after** the enrollment packet is mailed, call the participant to see if she has any questions. This may be especially important for older women and for members of minority groups. Refer to the talking points provided in *Sections 6.2.1 – Extension Study Consent Collected in the CC or By Telephone* and *6.2.2 – Supplemental Consent Collected in the CC or by Telephone.*
- If a phone call is not possible, consider sending a reminder letter a few weeks after the packet is mailed (*Figure 6.10*). The letter could reiterate the importance of the packet, remind them to respond, and confirm that they received the packet. By sending a reminder, you may end up with fewer non-responders, saving yourself the time and cost of sending out a second full mailed enrollment packet.

6.2.4 Obtaining Consent Forms from Participants on Proxy Follow-up

A proxy cannot sign either the Supplemental Consent Form or the WHI Extension Consent Form, unless he or she is the participant's power of attorney. Your local IRB may provide additional guidance on obtaining consent from participants on "proxy" follow-up.

To obtain either consent from participants on "proxy" follow-up, start first with a contact with the designated proxy. Confirm with the proxy that the participant is competent to consider and sign the Supplemental Consent Form. Discuss also her ability to consider and sign the Extension Study Consent Form, and confirm with the proxy that he/she would be willing to continue completing annual health forms for the participant. If the proxy agrees that you can proceed with one or both consents, contact the participant and initiate the consent process.

6.2.5 Use of *Form 114 – WHI Genetic Studies Consent Status*

The *Form 114 – WHI Genetic Studies Consent Status* is completed only when a participant requests one of the following changes in her WHI genetic studies consent status.

- The participant requests that her blood not be used for WHI genetic studies; or
- The participant who previously asked that her blood not be used for WHI genetic studies on *Form 11 – Consent Status* now agrees to allow her blood to be used in WHI genetic studies.

This is not a routine task and the participant should not be prompted or asked about her previous WHI genetic studies consent status.

Figure 6.1.
WHI Logo and Catch Phrase

WHI Logo

WHI Catch Phrase

"Be Part of the Answer"

Table 6.1 – Consent Packet Materials

	Documents	Purpose	Source Location	Title in Public Folders	Manual
1	Cover letter for mailed consent packet (required)	A cover letter that introduces the Extension Study and Supplemental Use consents and Summary Worksheet	CC Prints Close-out/Packets/OS Consent mailing packet	Cover letter – OS Mail Consent Packet.doc	*Figure 6.2*
2	WHI Consent Summary Worksheet (required)	Participant records her intention to either sign or decline signing of the Extension Study and Supplemental Use consents	CC Prints Close-out/Packets/OS Consent mailing packet	Consent Summary Worksheet.doc	*Figure 6.3*
3	Cover letter - Extension Study Consent (non-HT) (required)	A cover letter to attach to the Extension Study consent mailed to participants	CC Prints Close-out/Packets/OS Consent mailing packet	Cover letter – OS Mail Extension Study Consent.doc	*Figure 6.4*
4	Extension Study Consent (non-HT) (required)	Used to obtain informed consent for Extension Study (place a participant barcode label on both copies)	CC Prints Close-out/Packets/OS Consent mailing packet	Extension Study Consent (non HT).doc	*Section 2*
5	Cover letter – Supplemental Consent (required)	A cover letter to attach to the Supplemental Use consent mailed to participants	CC Prints Close-out/Packets/OS Consent mailing packet	Cover letter – OS Mail Supplemental Consent.doc	*Figure 6.5*
6	Supplemental Consent	Used to obtain informed consent for the Supplemental Consent (place a participant barcode label on both copies)	CC Prints Close-out/Packets/OS Consent mailing packet	Supplemental Consent.doc	*Section 2*
7	Business reply return envelope with CC address (required)	For participant to return her signed consent forms to the CC	CC prepares	-	-
8	Pre enrollment packet letter *(preflyer.doc)*	Used in pre-packet mailing to explain the study and let participant know the packet is coming	CC Prints Close-out /Packets/ Optional Materials for Consent Mailing		*Figure 6.6*
9	Cover letter flyer *(coverflyer.doc)*	A cover sheet that briefly summarizes the Extension Study	CC Prints Close-out /Packets/ Optional Materials for Consent Mailing		*Figure 6.7*
10	Contribution flyer *(minfly.doc)*	A flyer that discusses the importance contribution of each woman, especially minority and older women	CC Prints Close-out /Packets/ Optional Materials for Consent Mailing		*Figure 6.8*
11	Photo and quote flyer *(electfly.doc)*	An optional flyer with photos and quotes that highlights the reasons women joined WHI	CC Prints Close-out /Packets/ Optional Materials for Consent Mailing		*Figure 6.9*
12	Post-packet flyer *(postflyer.doc)*	An optional flyer used in as a reminder to return the packet a few weeks after the mailing	CC Prints Close-out /Packets/ Optional Materials for Consent Mailing		*Figure 6.10*

Figure 6.2
Cover Letter for Mailed Consent Packet (Required)

Dear Valued WHI Participant,

Thank you for being part of the Women's Health Initiative (WHI)! The WHI was created to learn more about women's health and the causes of disease in women. The information provided by WHI participants like you over the years has already changed medical practice and will continue to help women for generations to come.

Enclosed in this packet are two separate WHI consent forms for you to look over:

1) **The WHI Extension Study** – Because of your contributions to women's health over the years, we are pleased to tell you that WHI scientists have received funding to extend the WHI until 2010 to collect health information by mail. The **WHI Extension Study Consent Form** includes more details about this new opportunity.
2) **The Supplemental Consent for Use of Stored Specimens** – Since you joined the WHI, there have been amazing advances in the ways blood specimens can be studied. More details about the ways we are planning to use WHI samples are in the enclosed Supplemental Consent Form.

Please read through the enclosed consent forms and follow the instructions on the cover sheet for each form. The consent forms should be kept separate when you make your decisions about signing. That is, you may agree to sign one, both, or neither of the forms – the decision is yours.

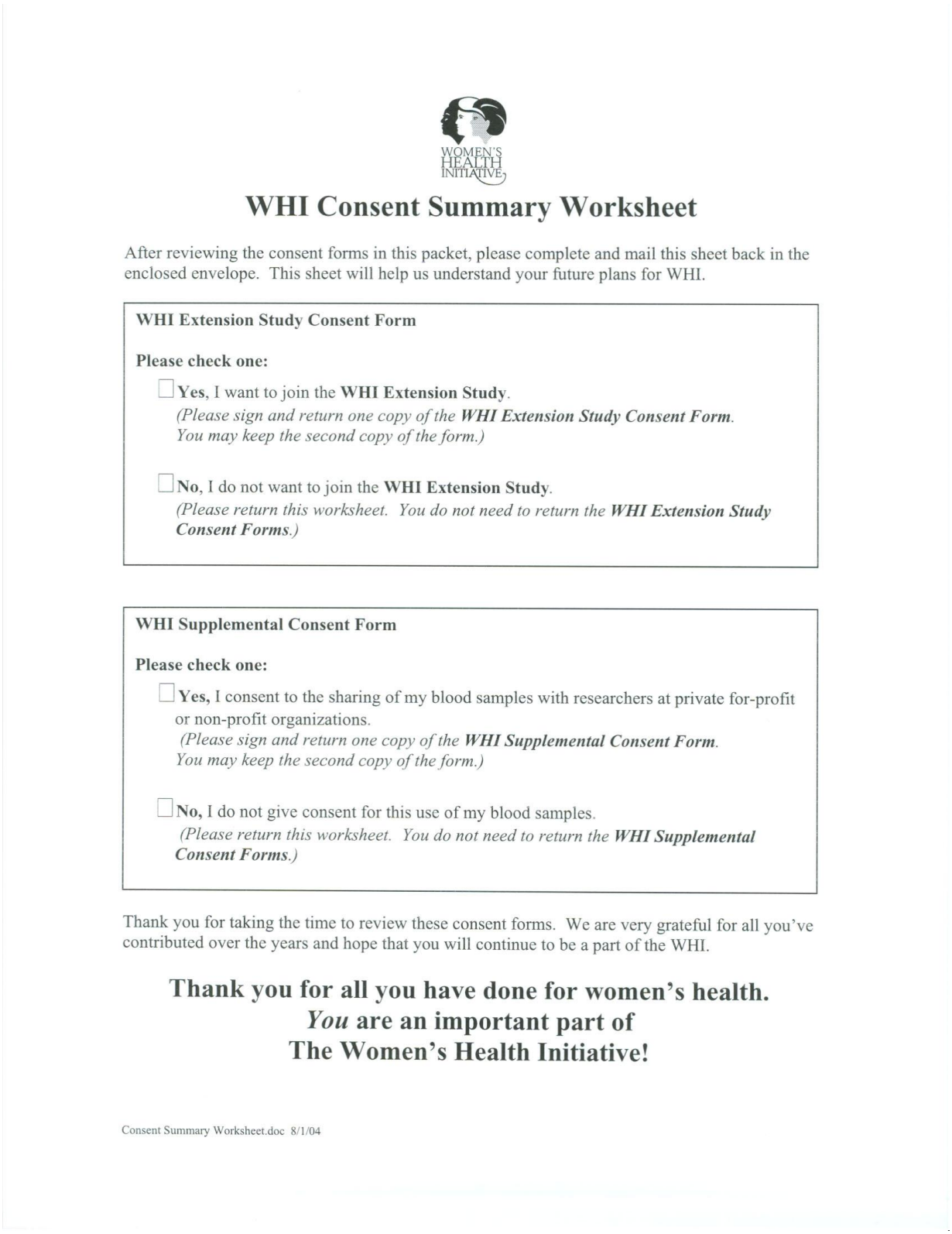
Whether or not you sign the consent forms, we'd like to hear from you. After you read the forms over and decide on your future WHI plans, please fill out the enclosed "WHI Consent Summary Worksheet". We would also like you to review the Personal Information Sheet in this packet and make any corrections right on the sheet. Then, return the Consent Worksheet, Information Sheet, and one copy of each consent form that you sign in the postage-paid reply envelope. The second copy of each consent form is for you to keep.

Thank you in advance for reviewing this information. We are very excited about these new opportunities and hope you will join us for the years ahead. If you have any questions about the WHI Extension Study or the Supplemental Consent, please call the WHI staff at **xxx-xxx-xxxx**.

Warmest regards,

[WHI Staff Name or Investigator]

Figure 6.3
WHI Consent Summary Worksheet (Required)



WOMEN'S HEALTH INITIATIVE

WHI Consent Summary Worksheet

After reviewing the consent forms in this packet, please complete and mail this sheet back in the enclosed envelope. This sheet will help us understand your future plans for WHI.

WHI Extension Study Consent Form

Please check one:

☐ **Yes**, I want to join the **WHI Extension Study**.
*(Please sign and return one copy of the **WHI Extension Study Consent Form**. You may keep the second copy of the form.)*

☐ **No**, I do not want to join the **WHI Extension Study**.
*(Please return this worksheet. You do not need to return the **WHI Extension Study Consent Forms**.)*

WHI Supplemental Consent Form

Please check one:

☐ **Yes,** I consent to the sharing of my blood samples with researchers at private for-profit or non-profit organizations.
*(Please sign and return one copy of the **WHI Supplemental Consent Form**. You may keep the second copy of the form.)*

☐ **No,** I do not give consent for this use of my blood samples.
*(Please return this worksheet. You do not need to return the **WHI Supplemental Consent Forms**.)*

Thank you for taking the time to review these consent forms. We are very grateful for all you've contributed over the years and hope that you will continue to be a part of the WHI.

Thank you for all you have done for women's health.
***You* are an important part of**
The Women's Health Initiative!

Consent Summary Worksheet.doc 8/1/04

Figure 6.4
Cover Letter – Extension Study Consent (non-HT) (Required)

The WHI Extension Study

As a Very Important Participant in the Women's Health Initiative, we are pleased to invite you to join the **WHI Extension Study**. This new study is designed to update WHI participants' health information for five more years after the "close-out" contact. The WHI Extension Study will help us learn more about how women's health changes as they get older. Health care providers and women alike need this information for the important health decisions they will make in the future.

Women from all the WHI programs – Hormone, Dietary, Calcium/Vitamin D, and the Observational Study – are being invited to join the WHI Extension Study. We expect over 100,000 current WHI participants from across the United States to continue in the WHI.

If you decide to join the WHI Extension Study:

- We will ask you to fill out health forms by mail once a year through 2010. The health forms will be like the medical history updates you have completed in the past. They will be sent to you with a postage-paid reply envelope.
- We may ask you to sign a Medical Release form to get more medical details about health changes that you report on the forms.
- We will not ask you to come into the WHI clinic for extension study activities. If we have questions after receiving your forms, we will contact you by telephone.

Attached are two copies of the WHI Extension Study consent form. Please read the form carefully. If you decide to join this new study, sign one copy of the form and return it in the postage-paid reply envelope. The second copy is for you to keep.

Please also complete and return the "Consent Form Summary Worksheet," so that we can be clear about your future plans for WHI. If you do not want to sign the consent, we would still like you to return the completed Worksheet, but you do not need to return the consent form.

If you have any questions about the WHI Extension Study, please contact the WHI staff at the telephone number listed in the cover letter.

We appreciate all of the time and effort you have shared over the years and hope you decide to continue with the Women's Health Initiative. You have given so much to the cause of women's health, and we hope you will be a part of finding these new answers as well.

Thank you for participating in the Women's Health Initiative.

You are making a difference in women's health!

Figure 6.5
Cover Letter – Supplemental Consent (Required)

The WHI Supplemental Consent for Use of Stored Specimens

Recently, there have been important breakthroughs in health care because women like you have been a part of the WHI and provided valuable information for answering questions about women's health. The blood samples you have provided are also precious resources for women's health research. For example, WHI scientists are learning how proteins and DNA (the genetic building block of life) affect certain health conditions.

Since you joined the WHI, medical science and technology have grown in ways we never thought possible. Some of the new techniques for analyzing blood are so specialized or expensive that they can only be done by scientists at a select few private non-profit or for-profit research centers or companies. We would like to partner with these non-WHI scientists in the hopes that there will be even more breakthroughs in women's health. The blood samples and DNA you have provided in the past are an important link in that partnership, and we are asking your permission to share them with other scientists. Your gifts to women's health research can then go even further.

The attached consent form explains the ways we are planning to use WHI blood samples and DNA. Please keep the following in mind as you read the form:

- Your blood samples will be shared with non-WHI scientists only if you sign the consent.
- We are not asking for more blood, only to share stored samples you have already given.
- Your personal identity will always be kept confidential, away from the samples, and it will never be shared with other scientists, private companies, your doctor, or your insurance company.
- Neither you nor the WHI will profit from studies that use your blood samples.
- There are no costs to you or your insurance for any of the blood or DNA studies.
- You may withdraw your consent to share these samples at any time, and it will not affect your participation in other parts of the WHI.
- You will not be given individual results of any blood or DNA studies.

Please read the consent form carefully. If you agree to this supplemental use of your stored blood samples, sign one copy of the form and return it in the postage-paid reply envelope. The second copy is for you to keep.

Please also complete and return the "Consent Form Summary Worksheet", so we can be clear about your future plans for your blood samples. If you do not want us to share your samples, we would still like you to complete the Worksheet, but you do not need to return the consent form.

If you have any questions about the Supplemental Consent Form, please contact your WHI Clinical Center at the telephone number listed in the cover letter.

Thank you for being a part of the Women's Health Initiative and its legacy of health for generations of women to come!

Figure 6.6
Pre-enrollment Packet Letter

An Invitation to Our WHI Participants

Good News!

The Women's Health Initiative (WHI) Extension Study has been funded through the year 2010.

WHI is one of the most important women's health studies ever done and is now part of medical history. People around the world are talking about this landmark study. This means that you have already made a valuable contribution to women's health care. Generations of women will benefit because of your selfless participation in the WHI.

We invite you to join with us as we continue to study ways to improve women's health. The WHI Extension Study will help us learn even more about how to prevent major causes of health problems in women.

There are no clinic visits in the WHI Extension Study. If you agree to join this study, we will ask you to complete yearly forms, similar to those you have already seen. These forms should not take more than 20 minutes to complete each year.

In the next few weeks, you will receive a packet of materials with more details about how to enroll in the Extension Study. The enrollment packet includes a lot of information, so please call us if you are not sure what to do or have any questions about the packet.

Only WHI participants have this exciting opportunity to join the WHI Extension Study. That's why each and every participant is valuable, and no one can take your place in this study.

We hope you will decide to take part in the WHI Extension Study.

Thank you!

Figure 6.7
Cover Letter Flyer

An Invitation to Our WHI Participants

WOMEN'S HEALTH INITIATIVE

Good News!

The Women's Health Initiative (WHI) Extension Study

has been funded through the year 2010.

WHI is one of the most important women's health studies ever done and is now part of medical history. People around the world are talking about this landmark study!

You have already made a valuable contribution to women's health. Generations of women will benefit because of your selfless participation in the WHI. We invite you to join the WHI Extension Study to help us learn even more about how to prevent the major causes of health problems in women.

There are no clinic visits in the WHI Extension Study, only mail and phone contact.
The questionnaires you will receive each year are very short and should take no more than 20 minutes to complete.

Please review the material in this packet for more details.

We hope you will continue to take part in the WHI!

Thank you!

Figure 6.8
Contribution Flyer

WOMEN'S HEALTH INITIATIVE

We Need **You** for the WHI Extension Study!

You may wonder if joining the WHI Extension Study is really that important. Here are a few of the many reasons why your participation is more important than ever:

- Like all WHI participants, you are a unique individual. No one else can provide the information that you can. Each and every participant is valuable!
- Some women may believe that they should not continue because they are no longer as healthy as they were when they first joined the WHI. Nothing could be further from the truth! We need to track your health – good or bad – for our study results to be complete.
- If you are an African American, Latina, Asian American, or American Indian, you are a member of a group that has not always been included in health research. WHI is trying to correct that, so your role in the WHI is especially important. WHI is the largest study to look at the health of women from various racial and ethnic groups in the US, but we can only do that if you join.
- One purpose of the WHI is to learn more about the health issues women face as they age. You should not feel that you are getting too old to participate. Our oldest participants are especially important!
- Finally, keep in mind that only WHI participants have the opportunity to join the WHI Extension Study. If you don't join, no other woman can take your place. The value of the study results depends on the participation of each one of you.

For all that you have already contributed, we thank you. You are an important part of the answer!

Figure 6.9
Photo and Quote Flyer

Why should I join the WHI Extension Study?

Here is what women are saying…

"We have granddaughters. We want them to have the answers to living a long, healthy life."

"If the researchers need more information from me to find out how to prevent diseases, I'm ready to provide it."

"The WHI has already added new information about women's health. Can you just imagine how much more information we'll have after the WHI Extension Study?"

"There is little information about the health of women like me. WHI is our first and best hope to find those answers."

"My spiritual beliefs and my family are very important to me. We need more information about the health issues of women like me so I am joining the WHI Extension Study."

Figure 6.10
Post-packet Flyer

An Invitation to Our WHI Participants

As you are aware, The Women's Health Initiative (WHI) Extension Study has been funded through the year 2010. A few weeks ago we sent you a packet of materials inviting you to enroll in this important study. We have not yet received your reply. If you have already returned your materials, please ignore this reminder.

We hope you decide to join with us as we continue to study ways to improve women's health. The WHI Extension Study will help us learn even more about how to prevent major causes of health problems in older women.

As we said in the earlier packet, there are no clinic visits in the WHI Extension Study. If you agree to join this study, we will ask you to complete yearly forms, similar to those you have already seen. These forms should not take more than 20 minutes to complete each year.

We are happy to mail you another packet, in case the materials were misplaced. The enrollment packet includes a lot of information, so please call us if you are not sure what to do or have any questions about the packet you received. If you did not receive the packet or have misplaced it, we also ask you to give us a call.

We hope you will decide to take part in the WHI Extension Study.

Thank you!

Section 6
Enrollment

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Section 7

Follow-Up Contacts

Introduction

Follow-up contacts with Women's Health Initiative (WHI) Extension Study participants occur to collect follow-up data, maintain current contact information, follow participants for study outcomes, and promote retention. These contacts provide an opportunity for Field Centers (FCs) to continue a professional, caring relationship with the participant throughout the duration of the study. Follow-up contacts include the following:

- Annual mail contacts (CCC).
- Annual phone contacts to participants who do provide data by mail (FC).
- Non-routine contacts (FC).

Required forms for follow-up data collection are identified in *Appendix A – Forms*. All Clinical Trial (CT) participants who were not enrolled in the HT receive the same follow-up data collection forms as Observational Study (OS) participants; participants who were enrolled in the HT receive additional data collection forms. The target dates for the routine annual follow-up contacts (mailings or phone calls for those on "no mail") and newsletter mailings are based on the original WHI randomization or enrollment date. Changes in participation status do not alter these target dates.

This section describes the required and recommended procedures for carrying out routine and non-routine follow-up contacts for all WHI participants. Refer also to *Section 5 – Guidelines for Interactions with Participants* for information on interviewing procedures and dealing with special situations that may be encountered during follow-up contacts (e.g., domestic violence, cognitive decline).

7.1 Annual Mail Contact and Follow-Up of Non-Responders

Follow-up data are collected annually from participants enrolled in the WHI Extension Study. Activities to collect the data consist of a series of mail and telephone contacts during the follow-up period. Data collection attempts by mail (Contacts 1-3) are conducted by the Clinical Coordinating Center (CCC) on an annual basis. For participants who do not respond to Contacts 1-3, data collection attempts by telephone (Contact 4) are conducted by FC staff.

Annual mailings to OS participants began the first week of May, 2005, and to CT participants in October, 2005. The timing of mailings is determined by the participant's original enrollment/randomization date in WHI. For the first year (2005-2006), the mailing schedule is slightly different, and is based on whether the participant's close-out visit was an annual or semi-annual visit. By August 2006, all participant mailings follow the regular mailing schedule as described below.

7.1.1 CCC Responsibilities for Annual Follow-Up

A series of mail contacts to collect follow-up data from WHI Extension Study participants is conducted annually by the Clinical Coordinating Center (CCC). The CCC is responsible for all printing (through the Government Printing Office [GPO]), assembly, and outgoing postage costs for the mail contacts. The three mail contacts include:

- An initial mailing of the entire questionnaire packet (Contact 1), mailed 2 months before randomization/enrollment date.
- A second mailing of the entire questionnaire packet to those who do not respond to Contact 1 (Contact 2), mailed 3 months after the first mailing.
- A third mailing of the entire questionnaire packet to those who do not respond to Contacts 1 or 2 (Contact 3), mailed 2 months after the second mailing.

Spanish-language versions of the contact materials are mailed to participants whose primary language is Spanish, as indicated by the "Preferred Language" flag on the Contact Information Screen in WHIX (see *Section 10 – Data Management*).

CCC staff will mail Personal Information Updates (PIU) to participants when they learn of address changes (via the US Post Office), and will complete a *Form 120 – Initial Notification of Death* when they are notified that a participant is deceased.

7.1.1.1 Mailing of Annual Questionnaire Follow-Up Packet 1 (Contact 1)

A follow-up packet is mailed annually by the CCC to all WHI Extension Study participants (except those with an invalid address or whose participation status in WHIX is set to no CCC mail contact, no follow-up contact, absolutely no contact, or deceased) two months before the participant's enrollment/randomization anniversary month.

If a participant does not meet the criteria at the time of her scheduled mailing, WHIX will continue to check her status each month to see if she is eligible for a mailing. For example, if she has an undeliverable address when she is first due and then the address is corrected, she will receive a mailing the following month. The CCC will try monthly for seven months to send a Contact 1 mailing to a participant. If, after seven months, the participant still does not meet the criteria to receive a mailing, the FC is responsible for attempting to collect the forms that would have been sent in the packet.

If a participant enrolls in the WHI Extension Study after her scheduled mailing would have occurred for that year, she will appear on *MAIL003 – Members Needing FC Follow-Up* for that year, and will resume the normal mailing schedule the next year.

The Contact 1 packet includes:

- A cover letter with the FC telephone numbers listed (see *Figure 7.1 – Cover Letter for Contact 1)*;
- A postage-paid, CCC-addressed return envelope with business reply information;
- A sharpened #2 pencil;
- Data collection forms. All participants receive a *Form 33 – Medical History Update* and a *Form 151 – Activities of Daily Life* annually. In addition, participants who were enrolled in HT receive *Form 150 – Hormone Use Update* annually. All participants receive a one-time form, *Form 134 – Addendum to Medical History Update*, in their first annual packet.

The *Form 33* has two labels:

1) **Date Label**: a Date Label with date of the last WHI Medical History Update (finished date of last *Form 33*), contact number (C1, C2, or C3), and participant ID.
2) **Participant ID label:** a Participant Identification Label with participant name, participant ID and barcode, contact number (C1, C2, or C3), and form number.

All other forms have only a Participant Identification Label, with participant name, participant ID and barcode, contact number, and form number.

The packet is sent third-class (bulk) mail in a mailing envelope printed with the CCC's return address, the CCC bulk mailing permit number, and a request for notification of change of address.

7.1.1.2 Second Mailing of Entire Follow-Up Packet (Contact 2)

A second complete follow-up packet is mailed the month after the participant's enrollment/ randomization anniversary month (three months after the mailing of Contact 1) to those participants who did not respond to the first mailing (i.e., those who did not complete and return the forms sent in Contact 1). If a participant does not complete all of the forms originally mailed in Contact 1, the Contact 2 packet includes only those forms not returned in response to the first mailing.

The Contact 2 packet includes:

- A cover letter (different from the Contact 1 cover letter--*see Figure 7.2 – Cover Letter for Contacts 2/3*) with FC telephone number listed;

- A postage-paid, CCC-addressed return envelope with business reply information printed on the envelope*;*
- Any data collection forms that were not completed and returned in response to the first mailing.

The packet is sent third-class (bulk) mail in a mailing envelope printed with the CCC's return address, the CCC bulk mailing permit number, and a request for notification of change of address.

7.1.1.3 Third Mailing of Entire Follow-Up Packet (Contact 3)

A third packet (identical to the Contact 2 packet) is mailed three months after the enrollment/ randomization anniversary month (two months after Contact 2) to non-responders only (i.e., those who have not completed and returned all of the forms sent during earlier contacts). Only those forms that were not completed during earlier contacts are included in the Contact 3 packet.

7.1.1.4 Processing Returned Packets (Contacts 1-3)

CCC staff is responsible for indicating in WHIX that packets have been returned. When a packet of forms is received at the CCC, the forms are scanned immediately, which prevents those forms from being sent to the participant again. Return of a form is indicated by scanning the entire form in WHIX. The scanned form data and image will be available to the FC within two weeks of the form arriving at the CCC.

When possible, the CCC will correct errors, such as light bubbles. Forms with data errors such as multiple marks, missing data, or incorrect skip patterns will be scanned as usual, but FC staff will be responsible for contacting participants by telephone to resolve problems (e.g., missing data) on *Forms 33* and *134*. Problems needing resolution by the FC will be identified at the CCC and will appear on *QA001 – Unresolved Alerts.*

Participant Comments on Forms:

CCC staff will also review the form for any handwritten comments, post-it notes, or letters. When notes are written on the form, they will be scanned along with the form. If there are comments on the form, the CCC will bubble in the FCA (Field Center Alert) bubble on the form. The FC can check for comments on the form by looking at the FCA field on the encounters screen. Forms with the FCA bubbled in will appear on *FCA001 – Forms with Comments to Review*. The CCC flags any health or study-related note written on a form, or any personal note that is a request for FC attention. The CCC does not take action if a participant requests to be taken off the study; in these cases, the FC must follow-up with the participant. Comments are not always written in the "comments" section of the form; sometimes they are written in the margins, so FCs should be sure to review the entire form for comments. Post-its, letters, or other communication enclosed with the forms are sent to the FC in the weekly mailing.

Unscannable Forms:

If a form cannot go through the scanner (e.g., because it's torn or crumpled) the form will be key-entered by the CCC. No images will exist for key-entered forms. The CCC will send the originals to the FC.

Incomplete Packets and/or Non-Response:

If a packet containing only one form is returned, the CCC scans the form to indicate that it has been received. If any of the forms were not returned in the packet or they were returned blank, they will be resent as part of the Contact 2 and possibly Contact 3 packets.

Following the three mailings, if a participant still has a missing form(s) or has not responded to any of the mailings, she will appear on *MAIL003 – Members Needing FC Follow-Up* (see *Section 7.1.2.2 – FC Data Collection for Non-Respondents to Mailings*).

7.1.1.5 Making Address Corrections and Updating Personal Information

Each packet mailed out to WHI Extension Study participants has the CCC's return address in the upper left-hand corner, with the line "Change Service Requested" printed underneath. In the event that the participant's address on the mailing envelope is incorrect, the U.S. Post Office (USPO) will provide the CCC with a photocopy of the envelope and a statement as to why it was not delivered. If the address has been changed, the new address will be provided. If the address has changed and no forwarding address is available, it will be marked "undeliverable". An envelope may also be returned with a "deceased" stamp (See *Section 7.1.1.6 – Completing Form 120 for Deceased Participants*).

For **changed addresses where the new address is provided by the USPO**, the CCC will update the address in the "Contact Information Screen" in WHIX immediately. This will prevent future mailings from being sent to the old address. The CCC will mail a *WHIX0441 – Personal Information Update* (PIU) to the participant and ask her to review and update any incorrect information. The participant will return corrected PIUs to the CCC in a postage-paid envelope.

When a participant has an **undeliverable address and a new address is not available**, the CCC will set the "undeliverable address" flag on the "Contact Information Screen" immediately (see *Section 10 – Data Management*). This will prevent future mailings from being sent to the undeliverable address. The FC should run *WHIX0611 – Address Problems* monthly and obtain correct addresses for participants who are listed on the report.

The CCC does not change address information or mail out a PIU to participants who have sent in an address change as a handwritten note on a form. These notes are sent to the FCs for FC staff to take the appropriate steps to follow up (i.e., contact the participant to confirm the change and send out a PIU for review).

7.1.1.6 Completing *Form 120 – Initial Notification of Death* for Deceased Participants

In the event that the CCC learns that a participant is deceased, the CCC will complete and key enter a *Form 120 – Initial Notification of Death* with the date of death only. This will prevent additional mailings to that participant and will automatically set her participation status to "deceased". The CCC will notify the FC by e-mail and send the *Form 120* and any notes, comments, or letters from family members or the USPO to the FC. FCs will process these participants according to procedures in *Section 8 – Outcomes*.

7.1.2 FC Responsibilities During Annual Follow-Up Mailings (Required)

The FC's responsibilities during the follow-up mailings include:

- Running weekly and monthly follow-up reports in WHIX.
- Following-up with participants who do not respond to the mailed packets.
- Following-up with participants who have missing data or multiple marks on a form.
- Reviewing forms with comments to see if action is needed.
- Collecting a *Form 33D – Medical History Update (Detail)* when indicated by data provided on *Form 33 – Medical History Update*.
- Completing procedures outlined in *Section 8 – Outcomes* when notified that a participant is deceased.
- Sending out Personal Information Updates to participants with address changes, if the FC learns of the address change.
- Conduct participant searches as needed.
- Making address and other contact information corrections as soon as they become available.
- Collecting mammograms and data entering *Form 85 – Mammogram*.

7.1.2.1 Running Monthly Follow-up Reports from WHIX

Several reports are available to help FCs keep track of the status of participant follow-up. Detailed instructions for running these reports in WHIX are given in *Section 10 – Data Management*.

Every month, each FC should run the following reports:

1. *WHIX0611 – Address Problems.* This provides a list of all participants (or their proxies) with undeliverable addresses in the FC's database. It does not include those with follow-up status of no follow-up, deceased, or absolutely no contact. Included on the report are the participant's name and (undeliverable) address; member ID; home phone; work phone; applicable notes; best time to call; telephone numbers for other contacts; follow-up status; and date marked (i.e., the date the undeliverable address flag was set).

   Undeliverable addresses should be updated as soon as possible, since a participant will not receive any mailings until the address is fixed. If the participant does not receive her mailings, the data will eventually need to be collected by FC staff (see *Section 7.1.2.2 – FC Data Collection for Non-Respondents to Mailings*). Also, the sooner you try to get an address correction, the more likely it is that you will be able to locate the participant. Undeliverable addresses should be corrected within one month of appearing on *WHIX0611*. Participants will continue to appear on this report until the "undeliverable address" flag has been removed or follow-up status changes.

   This report also provides a list of participants (or their proxies) with problem addresses (e.g., the address is incomplete or will not fit on a mailing label). Address lines that are too long should be fixed immediately. An address line is too long if it appears on this report as more than one line. To fix the problem, use Address Line 2 for the second line of the address, or abbreviate words in the first line so that they stay within the 30-character width limit of the mailing labels.

   Addresses that are incomplete should be resolved as soon as possible. If the zip code is missing, try calling the USPO or the participant to obtain the complete/correct address. If you cannot fix the address right away, set the undeliverable address flag on the "Contact Information Screen" in WHIX. This will prevent mailings from being sent to an undeliverable address. Incomplete addresses should be fixed within two weeks of appearing on *WHIX0611*. Participants will continue to appear on this report until either the address has been fixed or the "undeliverable address" flag has been set. Once you have made all of the necessary edits indicated on the report, run the report again to confirm that problems have been cleared. Note: You do not need to correct international addresses that appear because they have no zip code, etc.

2. *MAIL003 – Members Needing FC Follow-Up*. The purpose of this report is to provide a list of those participants who have not completed all of the required data collection forms (i.e., *Form 33 – Medical History Update* [collected annually], *Form 150 – Hormone Use Update* [HT only] and *Form 134 – Addendum to Medical History Update* [collected during first year of follow-up only]) following the three CCC mailings. A participant appears on this form two months after the mailing of Contact 3 if no *Form 33* has been data entered since Contact 1 was initiated and if her follow-up status is not any of the following: no follow-up, deceased, or absolutely no contact. Participants also appear on this report if the CCC was unable to mail the data collection packets (i.e., if they are on "no mail" follow-up or if they have an undeliverable address). FCs should not attempt to contact participants to collect annual form data until they appear on the report.

   This report lists participant name, participant ID, home phone number, work number, best time to call, phone numbers of other contacts, and follow-up status. As described below in *Section 7.1.2.2 – FC Data Collection for Non-Respondents to Mailings*, FCs should use this report as a prompt to initiate follow-up contacts to participants who have not completed a *Form 33*.

   Participants remain on this report until one of the following occurs: either a *Form 33* has been completed; follow-up status changes; or the next year's contacts begin.

3. *FCA001 – Forms with Comments to Review*. This report lists the participants with handwritten comments on their forms requiring FC review.

4. *WHIX0621 – Outcomes Screening Action Required.* The purpose of this report is to provide a list of participants who need a phone contact to clarify data received on their outcomes follow-up forms (*Forms 33* and *134)*. This contact may be necessary in the case of missing data, multiple marks on an item, or incorrect skip patterns.

5. *WHIX0622 – Members with Potential Outcomes.* This report identifies participants who need a *Form 33D* (see *Section 8 – Outcomes*).

6. *QA001 – Unresolved Alerts*. This report provides a list of participants who need a phone call to correct forms that have missing or inconsistent data on any of the follow-up forms.

7.1.2.2 FC Data Collection for Non-Respondents to Mailings

FCs are required to attempt to collect *Form 33 – Medical History Update, Form 134 – Addendum to Medical History Update* (collected during first year of follow-up only), and *Form 150 – Hormone Use Update (HT only)* for participants who have not responded to that year's mailings. If a participant has not responded to Contacts 1-3, FC staff should initiate telephone contacts to collect the data. This is done through a series of attempts to reach the participant or her proxy to collect the data. Non-respondents needing follow-up data collection are listed on *MAIL003 – Members Needing FC Follow-Up*.

FC follow-up data collection activities consist of two types of contacts: a phone contact to ascertain correct address and to collect *Form 33 – Medical History Update* from the participant or proxy (Contact 4), and, if needed, mail or phone contacts with the personal contacts to trace participants.

FC attempts to collect *Form 151 – Activities of Daily Life* from non-respondents are optional.

Any data forms collected by FC staff will be data entered at the FC.

7.1.2.3 Telephone Contact to Ascertain Correct Address and to Collect Medical History Update (Contact 4) (Required)

If *Form 33* has not been returned by two months after the third mailing of the follow-up packet (CCC Contact 3), the FC should attempt to reach the participant by telephone. The purpose of this call is to confirm that the correct address is shown in WHIX and to complete *Form 33 – Medical History Update, Form 134 – Addendum to Medical History Update (first annual follow-up only),* and *Form 150 – Hormone Use Update (HT only)*. Use *MAIL003 – Members Needing FC Follow-Up* to determine which participants require follow-up telephone contacts.

Direct contact with the participant or other personal contact is preferable at this point to confirm that we have the correct address and phone number for her (e.g., a message left on an answering machine reminding her to mail in the packet is not sufficient since there is no way to confirm that she has received the packet or the phone call).

When calling, make at least 8 telephone attempts the first month and 4 attempts the second month during the "best times to call" (identified on *Form 20 – Personal Information*). Refer to *Figure 7.4 – Suggested Script for Contact 4 Telephone Contact*. If contact is made with the participant, verify the address and complete *Form 33* over the telephone. *WHIX0441 – Personal Information Update*, can also be completed at this time. Completion of any other forms (i.e., *Form 151*) is optional, depending on the willingness of the participant to complete additional forms by phone.

If you determine that the telephone number and/or address have changed, update WHIX accordingly. If a participant requests a change in her participation status, you may initiate a *Form 24 – Retention Worksheet* (see *Section 9.3 – FC Activities for Retention Challenges*), if appropriate. If you find out that she is deceased,

complete a *Form 120 – Initial Notification of Death* and process according to *Section 8 – Outcomes*. Data entry of *Form 120* will automatically set her participation status to "deceased".

FCs have the option of mailing the forms to participants who, as determined by the phone contact, are willing to complete the forms but are unwilling to complete them over the phone. These forms should be data entered at the FC upon receipt.

If you are unable to make contact with the participant, contact her proxy or one of her personal contacts to determine the location and vital status of the participant. After this contact, continue to try to reach and interview the participant, if appropriate. If you learn during this process that the participant is unable to complete the forms herself, attempt to collect the data from her proxy. Do not interview the proxy unless the participant is deceased, unable to communicate, or has poor cognitive functioning. (See *Section 7.2 – Follow Up by Proxy*.)

7.1.2.4 Making Address Corrections and Collecting Personal Information Updates

For **changed addresses where the new address is provided by the USPO in response to a mailing**, the CCC will update the address in the "Contact Information Screen" in WHIX. The CCC will mail a *Personal Information Update* to the participant at her new address, along with a postage paid return envelope addressed to the CCC. The CCC will enter any changes the participant has written on the returned PIU and send the form to the participant's FC.

When a participant has an **undeliverable address and a new address is not available**, the CCC will set the "undeliverable address" flag on the "Contact Information Screen" immediately. This will prevent future mailings from being sent to the undeliverable address. Participants with an undeliverable address will appear on the *WHIX0611 – Address Problems* the next time it is produced (see *Section 7.1.2.1 – Running Monthly Follow-up Reports from WHIX (Required)*). FC staff should initiate a search to find the correct address by contacting the participant. Refer to *Section 9.4 – Locating "Hard to Find" Participants* for instructions on conducting searches for lost participants. Try to update the address as soon as possible, so as not to lose permanent contact with the participant.

When the FC learns of any change to personal information that comes from a source other than the CCC (e.g., the participant calls the FC directly or they learn of the change during a data collection phone call), the FC needs to either mail out a Personal Information Update for the participant to review, or needs to review the information with the participant by telephone. The CCC will automatically mail PIUs to participants if it learns of an address change through the annual mailings.

7.1.2.5 Processing Information on Deceased Participants

When the FC learns that a participant is deceased (either from the CCC or a family member), FC staff should initiate contact with persons listed her Personal Information Update. If a death is confirmed, complete and data enter a *Form 120 – Initial Notification of Death* and process according to procedures outlined in *Section 8 – Outcomes*. This will automatically change her participation status to "deceased".

7.1.2.6 Handling Mailings to Snowbirds

There are two address options in WHIX for each participant. FCs can change the "current address flag" to indicate which address is to be used for mailing during a particular time period. This is useful for participants who are known to be away for a predictable portion of the year. Dates are included on the screen to help remind the FCs of the participant's location during that time. FCs are responsible for indicating which address is the best one to use by setting the flag next to that address. If the alternate address becomes the better address, FCs can set the flag to indicate that the alternative should be used for mailings. FCs can run the *ADR001 – Addresses for Members with More Than One Address* report to help remind them when the flags should be reset for a particular participant. If FCs don't get a chance or don't wish to change the flags for a participant with more than one address, participants are still likely to eventually receive the packet, since packets are mailed up to 3 times over a period of 7 months.

7.2 Follow-Up by Proxy

Some follow-up contacts, because of a participant's illness, disability, or death, may need to be conducted with a proxy. A proxy "stands in" for the participant and provides information about her health. The proxy should be someone who has frequent contact with the participant and knowledge of her health status. Use *Form 20 – Personal Information* for information on where to locate proxies. When contacting proxies, use the following order of priority: 1) proxy identified on Personal Contact Screen; 2) spouse or partner; 3) nearest relative; 4) friend; 5) physician. Refer to *Figure 7.5 – Suggested Script for Proxy Telephone Contact*.

If the participant is deceased, unable to communicate, or has poor cognitive functioning, *Form 33* data are collected from the proxy by either telephone or mail. If data are to be provided by a proxy, complete *Form 9 – Participation Status* to change the follow-up status to "proxy" (except if the participant is deceased). When a proxy is identified, confirm that the proxy contact information on the "Contact Information Screen" in WHIX is correct and make corrections as needed.

7.2.1 Designating a Proxy

FCs must have Institutional Review Board (IRB) approval to collect participant data from a proxy if the participant's consent form does not include explicit approval for contact of personal contacts.

Approval to conduct follow-up contact(s) by proxy should be a careful decision based on the participant's situation and the individual proposed to serve as her proxy. Obtain approval to conduct contacts by proxy from the participant or her legal next-of-kin, if possible. Proxy contacts must be approved by the FC Principal Investigator (PI) and other FC investigators, consultants, and/or staff, as determined at your FC.

When the proxy is first identified, establish contact with that person(s) and discuss how he/she was identified as the proxy (e.g., listed as a close contact or her personal physician). Determine if s/he has any questions about the study and/or the proxy role. If necessary, initial contact with the proxy can be by mail. When contacting a proxy by mail, include the *Cover Letter for Proxy Contact (Figure 7.6)* to explain the purpose and role of the proxy.

Local IRB approval of the materials and procedures is required before collection of proxy contact information can begin. If the local IRB requires changes to the materials or procedures, FCs may modify them as requested. Revised participant materials should be submitted to the CCC for review before use.

7.2.1.1 For Participants Who Do Not Have a Designated Proxy

If a participant has not designated a proxy, or if the proxy is deceased, cannot be located, refuses contact, or is unable to participate, FCs may (subject to local IRB approval) contact one of the participant's other personal contacts to serve as the proxy.

When using other personal contacts to collect proxy information, in order of data collection preference, contact:

- Spouse or partner
- Other close family member
- Close friend
- Health care provider

7.2.2 Proxy Follow-Up by Mail by CCC (Required)

The CCC will mail the annual data collection forms directly to the designated proxy when a participant is on "proxy follow-up". These forms will be mailed according to the same procedures as those used for non-proxy participants (i.e., three mailed contacts) with a cover letter specifically designed for proxies (see *Figures 7.6 – Cover Letter for Proxy Contact* and *7.7 – Cover Letter for Proxy Contact 2/3)*. A field on the PIU screen allows a proxy's address to be flagged as undeliverable.

If the participant is on proxy follow-up but a proxy has not been identified, the participant will appear on *MAIL003* and FC staff will need to identify a proxy and collect follow-up data for that year. Once contact information has been entered in WHIX, data will be collected from the proxy by mail in subsequent years.

7.2.3 Proxy Follow-Up by Phone by FC

If a proxy fails to reply to the mailed attempts, he/she will appear on *MAIL003 – Members Needing FC Follow-up* to collect *Form 33* (and *Form 134*, if not collected previously). (See *Figure 7.5 – Suggested Script for Proxy Telephone Contact*). Phone contact with the proxy may also be necessary if repeated attempts to reach the participant have failed, or if the participant is recently deceased. When the proxy is first contacted by the FC, discuss how that person was identified as the proxy (e.g., designated by the participant, listed as a personal contact). Determine if s/he has any questions about the study and/or the proxy role. Provide the proxy with relevant information about the study (e.g., Proxy Update, consent forms, study information sheets), as needed. Any ongoing efforts used to promote rapport and retention with the participant should also extend to your contacts with the proxy.

If the participant is alive, each proxy contact should be preceded by a discussion of the participant's ability to resume her own follow-up contacts, depending on her particular situation. If it has not been done, complete a *Form 9 – Participation Status*, to reflect that she is on "Proxy follow-up" and complete the proxy's contact information.

If the participant is deceased, details on proxy follow-up outcomes information are described in *Section 8 – Outcomes*.

For participants on "proxy follow-up", all relevant forms will be collected by mail annually. These may include:

- *Form 33 – Medical History Update* and, if appropriate, *Form 33D – Medical History Update (Detail).*
- *Form 134 – Addendum to Medical History Update* (collected during first annual data collection only).
- *Form 151 – Activities of Daily Life*
- *Form 150 – Hormone Use Update* (for HT participants only)
- *WHIX0441 – Personal Information Update.*

For participants whose proxies do not respond to the mailed forms, collect only *Form 33 – Medical History Update, Form 134 – Addendum to Medical History Update,* and *Form 33D – Medical History Update (Detail)* by phone. The other forms should not be collected by phone from the proxy.

For women who are deceased (see *Section 8 – Outcomes*), collect the following from the proxy:

- *Form 120 – Initial Notification of Death*
- *Form 33 – Medical History Update* and, if appropriate, *Form 33D – Medical History Update (Detail).*

7.2.4 Using Proxies to Obtain Medical Records

The role of the proxy in obtaining medical records is determined by local state and institutional laws and policies. The designated proxy, especially if she/he is a family member or has medical power of attorney, may be able to sign medical releases. FCs will need to contact their local IRB and medical institutions for information and policies on this issue.

7.3 Follow-up of Participants with Less than Full Participation Status (Required)

For women with less than full participation status, collect annual forms to the extent possible, given her status. Specific situations are given below as examples.

7.3.1 Participants on No Mail Follow-Up

Annual follow-up mailings will not be sent to participants who have requested "partial follow-up with no mail". For a woman who refuses mail contact but allows phone contact, the FC will collect the forms by telephone annually. These women will appear on *MAIL003 – Members Needing FC Follow-up*, along with non-responders.

7.3.2 Participants Who Are Lost-to-Follow-Up

Continue to search periodically for participants who are lost to follow-up. For procedures, see *Section 9.4 – Locating "Hard to Find" Participants*. Annual mailings will continue to be sent to women who are "lost-to-follow-up", in the hopes that they will complete a *Form 33* and no longer be "lost", as long as they have a deliverable address in WHIX. Mailings are not sent to "lost to follow-up" women who have an undeliverable address.

7.3.3 Participants on No Follow-Up

A letter or postcard (see model in *Figure 7.8 – Postcard for Participants on No Follow-Up*) should be sent or phone call made yearly to inquire if the participant would be willing to "rejoin" the WHI Extension Study or if she would, at a minimum, complete *Form 33 – Medical History Update*. See *Section 9.5.3 – Reactivation of Participants with Changes in Participation Status*.

7.3.4 Participants on Absolutely No Contact (Required)

Do not mail, phone, or attempt to collect data from participants who have requested absolutely no contact.

7.4 Non-Routine Contacts

Non-routine contacts may occur for any WHI Extension Study participant. These contacts give the FC the opportunity to continue efforts to build rapport and promote retention. Reasons why a participant may contact the FC non-routinely in person or by phone are detailed below along with brief information and references on how to manage such contacts:

- **Questions about the WHI study (perhaps in response to a recent news item):** The nature of the participant questions will determine the approach you take. Refer the participant to a FC staff person or investigator who has understanding of the issues involved with the news item or specific skill in responding to concerned participants (see *Section 9 – Retention*).
- **Report an outcome or other major event:** If the participant reports an outcome at a **non-routine** contact, remind her to record this information on her next routine medical history update. Interim reports of outcomes are not processed.
- **Provide new address or phone information:** Update the most recent *WHIX0441 – Personal Information Update* report in the participant's file and provide this information to the appropriate data entry staff person to update the information in WHIX.

Each of these non-routine contacts should be documented in contact notes contained in the participant's file along with any referrals or actions taken.

7.5 Mammography

All HT participants in the WHI Extension Study are required to have an annual mammogram during the first two years of the study. The two mammograms are counted as Extension Study mammograms if done between January 1, 2005 – March 31, 2007 and they are more than nine months (270 days) apart. FCs do not actively pursue mammograms after March 31, 2007. It is not required that FCs data enter a *Form 85 – Mammogram* for a mammogram that is done after March 31, 2007 but FCs may do so at their own discretion.

The mammogram is to be performed by a standard low dose radiation technique. It is recommended, but not required, that the mammogram occurs at an American College of Radiology (ACR) or Food and Drug Administration (FDA)-accredited facility and read by a qualified radiologist.

FCs will collect mammogram reports that are ordered by the participant's usual Primary Care Provider (PCP). Unlike the WHI, FCs in the WHI Extension Study will not be responsible for following up with participants for incomplete or abnormal mammogram findings. FCs are responsible for the following tasks:

- obtaining the mammogram report
- reviewing the results of the mammogram
- recording the results of the mammogram report onto the *Form 85 – Mammogram*
- data entering the *Form 85 – Mammogram*

FCs will classify and code mammograms on the *Form 85 – Mammogram* using the ACR classification system as negative, benign, probably benign, suspicious, or highly suggestive of malignancy. Breast ultrasounds, MRIs, or other newer medical procedures are not acceptable substitutes for mammograms.

The participant's PCP should order the mammogram and provide any follow-up or direction following the mammogram.

Participants are reimbursed by the FC for any screening mammogram not covered by Medicare, Medicaid, or other third party insurance, as well as partial payments, and/or co pays. The Extension Study does not cover the cost of any follow-up mammogram or diagnostic test the participant's PCP orders as the result of an abnormal mammogram. FCs should have a list of resources available for referring participants who are uninsured or have no PCP.

7.5.1 Timing of Mammogram

The majority of HT participants will have been on a regular schedule of annual mammograms as part of WHI. Anniversary dates for the mammograms may coincide with the annual mammograms that were done before close-out of WHI. Even though the WHI anniversary date of the participant may not coincide with the date of the Extension Study annual mammogram, the mammogram report is still collected. The due date for the first mammogram for the Extension Study is one year after the participant's last mammogram (if the last mammogram occurred on or after January 1, 2004) otherwise the due date for the first mammogram is January 1, 2005. It is well understood, however, that some participants have been less diligent, for a variety of reasons, and schedule mammograms less frequently. Other participants may be on a more frequent schedule for closer medical observation.

7.5.2 Requesting and Receiving Mammogram Results

FCs will determine individually how to best obtain the mammogram results in a timely manner based on their staffing, organization, requirements of their local IRB and HIPAA, and their contractual budgets.

The most efficient procedure to collect mammogram reports is to request the participant to mail the mammogram report directly to the FC. If this can not happen, a Release of Information (ROI) is obtained from the participant to collect mammogram results from the participant's PCP or the facility where the mammogram was done.

Recommendations for receiving timely follow-up mammograms include:

- Develop a plan with the participant and/or her PCP for obtaining a mammogram report.
- Send reminder letters and make reminder phone contacts to participants and/or the participant's PCP. However, some caution is advised so that the participant and/or the PCP are not over burdened with reminders. Send a stamped, self-addressed envelope to the participant for mailing her mammogram report back to the FC.
- Emphasize to the participant why she needs to have a mammogram rather than telling a participant that "we need a mammogram report,"
- You may use a lay report in lieu of the original report. To use a lay report, the following criteria must be included as part of the lay report:
  - date
  - participant's name
  - institutional letterhead
  - normal or benign findings are documented
  - recommended mammogram follow up is 12 months or more
- Have the participant sign several releases, if permitted by your IRB, to use for requesting future mammogram requests.
- Establish a contact person at the PCP's office.
- Establish a contact person at the mammogram facility.
- Be proactive and persistent.
- Use the WHIX reports to identify and track the participants who are due for a mammogram.
- Refer to Question #9 on the *Form 150 – Hormone Use Update* if you need to know the date and the location of the participant's mammogram in the last year,
- Check with the participant or the PCP one week after the date of the participant's scheduled mammogram to see if a mammogram report has been received.

7.5.3 Recording Results of Mammogram Reports

Mammogram coding is based on the ACR's classification system. Most radiology facilities use this system in their reporting of the mammogram results. The results of the mammogram report should be reviewed and recorded on the *Form 85 – Mammogram* and data entered. If the report does not use the ACR's classification system, the descriptions in the form instructions should help find the appropriate category to complete the form accordingly.

There will be instances when the BI-RADS code will not correspond to the narrative text and best judgment is needed to assign a code that most accurately reflects the results of the mammogram report. Refer to the *Form 85* instructions for guidelines on coding the summary results into the appropriate BI-RADS category.

7.5.4 Actions Based on Mammogram Results

FCs should not take any action based on the results of the mammogram report. All actions or future interventions are the responsibility of the participant and the participant's PCP.

7.5.5. Mammogram Tracking

WHIX reports are available to help track mammogram collection. The FC can track mammograms that are due and mammograms that have been completed by using *MAMM001 – Mammograms Due.* The *MAMM002 – Mammograms Not Completed* will assist the FC to monitor the success of collecting the *Form 85 – Mammogram*.

7.6 WHI-Extension Study Dietary Modification (WHI-ES DM) Program Description

The WHI-ES DM program is the low intensity dietary maintenance and assessment program for WHI-ES participants previously randomized to the WHI Dietary Modification (DM) Trial.

This program has three components: (1) general letter, (2) continuation of the *WHIse Choices* newsletters, and (3) dietary assessment.

7.6.1 General Letter

Women who joined the WHI-ES and who were previously randomized in the WHI DM Trial (intervention and comparison) will receive a letter thanking them for their participation in the WHI-ES, underscoring the importance of following up the dietary intervention effects in light of the uncertain results of the WHI DM Trial, especially for breast cancer (see *Figure 7.9 – WHI-ES DM General Letter*). The letter will direct women to the WHI Extension Study newsletter, *WHI Matters*, for study updates and periodic nutrition news and dietary tips. The letter will also introduce the optional dietary maintenance and assessment components of follow-up. The letter will be provided in Spanish for Spanish-speaking participants.

7.6.2 Continuation of the *WHIse Choices* Newsletter

Following the letter, WHI-ES women who were in the Dietary Change (intervention) arm of the DM Trial (n~1,510) will receive quarterly mailings, a continuation of the *WHIse Choices* newsletter received during the WHI DM Trial, with strategies for maintaining the low-fat dietary pattern should they wish to do so. Because self-monitoring of food intake was found to be a strong correlate of adherence, the mailings will include encouragement for women to continue self-monitoring. The strategies in the newsletters will be behaviorally and nutritionally based, include recipes, and be written in a style following the motivational interviewing principles of self-efficacy, empowerment, and exploration and resolution of ambiguity that began being implemented in the WHI DM intervention program in 1999.

Each *WHIse Choices* newsletter will include a toll-free telephone number that women can call if they have questions or no longer wish to receive the newsletters. The toll-free telephone number will route to the WHI CCC in Seattle, Washington.

The newsletters will be mailed centrally from the WHI Extension Study CCC in Seattle, Washington. Mailings will be provided in Spanish for Spanish speaking participants.

7.6.3 Dietary Assessment

Dietary assessment will be continued among a consenting subset of WHI-ES DM participants. The purpose of the dietary assessment is to estimate mean intake of the intervention and comparison groups during WHI-ES, which will assist in the interpretation of diet-disease effects during WHI-ES. Diet will be assessed by one 24-hour recall conducted by telephone interview. A single 24-hour recall per person is adequate for estimating group means. The subsample will be composed of WHI-ES-consented women who were part of the WHI DM Trial 4.6% subsample cohort. Women in this cohort provided additional data at WHI years 3, 6, and 9, including 24-hour recalls, and thus are familiar with the 24-hour recall format. Approximately half of the women will receive the 24-hour recall during 2007 and half during 2009/2010. In this way we will be able to estimate intake throughout the WHI-ES while minimizing participant burden and dietary assessment costs.

Consenting for this additional recall will be done by approach letter and telephone call. About two weeks before the 24-hour recall, participants will be mailed an approach letter describing the 24-hour recall process and specifying that when called, they may choose not to be interviewed (see *Figure 7.10 – WHI-ES DM Approach Letter* and *Figure 7.11 – 24-Hour Recall Interview Script*). If consent is not granted, the interviewer will thank the participant for her time and end the call. During the WHI DM Trial, 3% of participants declined the 24-hour recall. If consent is granted, the interviewer will proceed with the recall, which takes about 20 minutes.

The Fred Hutchinson Cancer Research Center (FHCRC) Nutrition Assessment Shared Resource (NASR) will conduct the 24-hour recalls using the 5-step multiple-pass method as they used during the WHI DM Trial. In this method, participants first list all foods and beverages consumed followed by interviewers asking about typically forgotten foods, eating occasions, details, and final questions about anything else consumed. To facilitate the interview, participants will receive a serving size booklet with the approach letter. Thirty percent of recalls will be taken for weekend days and 70% for weekdays. Per standard WHI procedure, interviewers will make 12 call attempts per participant and after every fourth attempt they will leave a voice-mail message with contact information. After making contact, receiving consent, and completing the recall, the interviewer will thank the participant for her time. Quality assurance monitoring of the calls will be done on 10% of the recalls with participant's permission. The CCC will mail a thank you letter to participants who complete the 24-hour recall (see *Figure 7.12 – WHI-ES DM Thank You Letter*). Calls and letters will be provided in Spanish for Spanish-speaking participants. The FHCRC NASR uses the Minnesota Nutrient Data System for coding and nutrient analysis of the 24-hour recalls.

7.6.4 WHI-ES DM Timeline

WHI-ES DM maintenance program and dietary assessment timeline				
	WHI-ES Year 1-2 (2006-2007)	WHI-ES Year 2-3 (2007-2008)	WHI-ES Year 3-4 (2008-2009)	WHI-ES Year 4-5 (2009-2010)
Mail general letter	1 mailing to WHI-ES intervention and comparison participants			
Mail *WHIse Choices* newsletter	2 mailings to all WHI-ES DM intervention participants	4 mailings to all WHI-ES DM intervention participants	4 mailings to all WHI-ES DM intervention participants	4 mailings to all WHI-ES DM intervention participants
Implement 24-hour recall	Half of the 4.6% subsample of WHI-ES DM participants			Half of the 4.6% subsample of WHI-ES DM participants

Figure 7.1
Cover Letter for Contact 1

Thank you for being part of the Women's Health Initiative Extension Study! The purpose of the WHI Extension Study is to learn more about women's health and about the causes of disease in women. As a participant in the WHI Extension Study you are asked to fill out forms each year so we can update information on your health. This information will be used to learn more about the relationship between lifestyle habits and women's health. We want the results of this study to represent all women, so your continued participation is very important to us.

The enclosed forms ask several questions about your health, including your recent medical history. Please use the enclosed pencil to complete the forms so our machines can read your answers. When you have completed the forms, return them right away in the postage-paid envelope to the Extension Study Clinical Coordinating Center in Seattle, Washington.

If you have any questions about the forms or need help filling them out, you may call your Clinical Center at the telephone number listed on the attached page. For the next several years, we will need to know where to send your newsletter and health forms. Please notify your Clinical Center if you move to a different address or if your phone number changes.

All information you provide will be kept confidential and your name will not be linked with data given to anyone other than WHI research staff. Participation in this study is voluntary and you may refuse to answer any questions on the forms. However, we do appreciate having complete follow-up information on all participants to make sure the results of the WHI Extension Study are accurate and scientific.

We appreciate your continued participation in the WHI Extension Study. This is an important study that may help us to improve the health of women for generations to come. Every woman counts, so please keep in touch.

You are part of the answer!

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Figure 7.2
Cover Letter for Contact 2 / 3

A few months ago we sent you a packet of health forms to complete for the Women's Health Initiative Extension Study. We have not yet received all of your completed forms. New forms and a postage-paid envelope are enclosed, in case your copies were misplaced or not received. **If you have already completed and mailed your forms, you do not need to fill them out again and can ignore this request.**

The purpose of the WHI Extension Study is to learn more about women's health and about the causes of disease in women. As a participant in the WHI Extension Study you are asked to fill out forms each year so we can update information on your health. This information will be used to learn more about the relationship between lifestyle habits and women's health. We want the results of this study to represent all women, so your continued participation is very important to us.

The enclosed forms ask several questions about your health, including recent medical history. Please use the enclosed pencil to complete the forms so our machines can read your answers. When you have completed the forms, return them right away in the postage-paid envelope to the Extension Study Clinical Coordinating Center in Seattle, Washington.

If you have any questions about the forms or need help filling them out, you may call your Clinical Center at the telephone number listed on the attached page. For the next several years, we will need to know where to send your newsletter and health forms. Please call your Clinical Center if you move to a different address or if your phone number changes.

All information you provide will be kept confidential and your name will not be linked with data given to anyone other than WHI research staff. Participation in this study is voluntary and you may refuse to answer any questions on the forms. However, we appreciate having complete follow-up information on all participants to make sure that the results of the WHI Extension Study are accurate and scientific.

We appreciate your continued participation in the WHI Extension Study. This is an important study that may help us to improve the health of women for generations to come. Every woman counts, so please keep in touch.

You are very important to the WHI, so we hope to hear from you. You are part of the answer!

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Figure 7.3
Personal Information Update Cover Letter

Thank you for being part of the Women's Health Initiative (WHI) Extension Study! The purpose of the WHI is to learn more about women's health and the risk for disease in postmenopausal women. One of our most important goals is to keep track of any major changes in your health through the end of the study. In order to do that, we need to make sure we can contact you throughout the course of the study. We ask that you check and, if necessary, update the contact information we have for you, the other contacts you listed, your doctor or primary care clinic, and your proxy.

To help us continue to collect the study information we need, we are asking you to:

1. Review the enclosed ***Personal Information Sheet***. This sheet has information you have given us about your personal contacts and your doctor or clinic. If you notice that any information is wrong, please cross it out and write in the correction. Also, if any information is blank, we ask that you fill in the missing information.

2. Mail the updated ***Personal Information Sheet*** back to the WHI Clinical Coordinating Center using the postage-paid envelope provided. If you do not have any corrections, we would still like you to mail the sheet back to us. Simply write "no corrections" on the top. That way we will know that you received our request and were able to review the information.

Thank you for taking the time to complete this important task. Remember that all information you provide to us will always be kept confidential. We appreciate your continued participation in the Women's Health Initiative. This study is important for the health of women for generations to come.

Every woman counts, so please keep in touch!

Figure 7.4
Suggested Script for Contact 4 Telephone Contact

The caller should telephone until she/he is able to reach the woman or other personal contact. Actual contact is required to confirm that the FC has the right address and phone number.

"Hello Mrs./Miss/Ms._____, this is _____ from the Women's Health Initiative Extension Study **(name of field center)** ."

"Several weeks ago a form packet was mailed to you from the Women's Health Initiative Extension Study. Did you receive the packet?"

If not received:

"I'm sorry to hear that. Maybe it was sent to the wrong address. Let me check your mailing address so that we can update our files."

(Record correct address, then continue.)

“Because your participation is very important to us and we would like to include your responses in the study results, I would like to go over one of the forms with you over the telephone. Is this a good time for us to complete the form over the phone?”

If no:

"When would you like me to call back?"

(Confirm time, thank participant, terminate call, call back later to conduct interview.)

If yes:

“Great. I will read you the questions over the telephone and record your answers.”

Conduct interview: complete Form 33.

“Thank you very much for spending the time to answer these questions over the telephone. We're very glad to have you as part of the Women’s Health Initiative Extension Study.

(Terminate call.)

Figure 7.4 (continued)

If yes:

"Good. Because your participation is very important to us and we would like to include your responses in the study results, I would like to go over one of the forms with you over the telephone. Is this a good time for us to complete the form over the phone?"

If no:

"When would you like me to call back?"

(Confirm time, thank participant, terminate call, call back later to conduct interview.)

If yes:

"Great. I'll read you the questions over the telephone and record your answers."

Conduct interview: complete Form 33.

"Thank you very much for spending the time to answer these questions over the telephone. We're very glad to have you as part of the Women's Health Initiative Extension Study.

(Terminate call.)

If during a contact you learn that the participant is deceased, is unable to communicate, or has poor cognitive functioning, end call appropriately (e.g., if she is deceased): *"I am so sorry to hear that Mrs./Miss/Ms._____ has passed away. She was an important member of our study."*

If deceased - complete Form 120 – Initial Notification of Death

If poor cognitive function, communication abilities, explore possibility of changing to proxy follow-up.

If at any point during the contact her participation status changes (e.g., she requests no further telephone contact):

Update Form 9 – Participation Status.

Initiate Form 24 – Retention Worksheet (optional).

Figure 7.5
Suggested Script for Proxy Telephone Contact

Ask to speak to (in order of priority for contact):

Proxy (if one has been identified)

If none identified:

spouse or partner

nearest relative

friend

Once contact is established, start at beginning of script.

If none of the above are available, contact the woman's physician.

"Hello, this is _____ from the Women's Health Initiative Extension Study **(name of field center)** . May I speak to ***[proxy name]*****?"**

If proxy is available, continue.

If proxy is not currently available:

"Can you suggest a time when I may be able to call back and speak with him [her]?"

Confirm time, thank person on phone, call back later to talk with proxy.

If identified proxy continues to be unavailable after several calls, try to contact another proxy.

If participant is deceased:

"We were very sorry to hear that Mrs./Miss/Ms._____ has passed away. As you may be aware, she was an important member of our study, the Women's Health Initiative."

(Continue below.)

If participant is unable to communicate or has poor cognitive functioning:

"We were very sorry to hear that Mrs./Miss/Ms._____ has had a recent decline in her health. As you may be aware, she is an important member of our study, the Women's Health Initiative."

(Continue.)

"Because we want the study to represent **all** women, we would still like to include her in the results. In order to do this, I would like to ask you some questions about her health during the past year. Would this be a good time for me to ask the questions?"

If yes:

Complete Form 33 – Medical History Update.

"Thank you very much for your help in the Women's Health Initiative Extension Study. The information you have provided is very important to the results of the study."

If no:

"When would you like me to call back?"

(Confirm time, call back later to conduct interview.)

If husband/partner refuses to participate, thank him/her, terminate the call, and try to contact another proxy.

In order of priority for contact:

spouse or partner

nearest relative

friend

Once contact is established with new proxy, start at beginning of script.

If none of the above are available, contact the woman's physician.

For all participants, Update Form 9 – Participation Status, if it has not already been updated (e.g., regarding the participant's death or poor cognitive functioning).

Figure 7.6
Cover Letter for Proxy Contact

Thank you for your willingness to serve as a proxy (personal health contact) for a participant in the Women's Health Initiative Extension Study. The purpose of the Women's Health Initiative is to learn more about women's health and the risk for disease in postmenopausal women. This important health study includes over 110,000 women across the U.S. One of our most important goals is to keep track of any major changes in the health of our participants through the end of the study. When a participant in the Women's Health Initiative becomes unable to answer questions about her health, we ask for her proxy's help in providing this information.

Enclosed in this packet are the health update questionnaires that we are asking you to complete, to the best of your ability. They include questions about any hospitalizations or serious illnesses the participant may have had in the previous year. This information is collected to help WHI find answers to important questions about women's health. Depending upon your responses, you might be contacted for additional details. If there is something that you do not know, it is okay to leave the answer blank.

Thank you for taking the time to complete these important questionnaires. It is very important for WHI to have complete follow-up information on all participants to ensure that WHI results are accurate and trusted by scientists and physicians. With your generous help, the Women's Health Initiative will have the information that is vital for the study to succeed. If you have any questions or need any help, please call your Clinical Center at the phone number listed on the following pages. Remember that all information you provide to us will always be kept confidential. We appreciate your participation in the Women's Health Initiative. This study is important for the health of women for generations to come.

Thank you for your contribution to the Women's Health Initiative!

Figure 7.7
Cover Letter for Proxy Contact 2 / 3

Thank you for your willingness to serve as a proxy (personal health contact) for a participant in the Women's Health Initiative Extension Study. A few months ago we sent you a packet of health forms to complete for the Extension Study. We have not yet received your completed forms. New forms and a postage-paid envelope are enclosed, in case your copies were misplaced or not received. **If you have already completed and mailed the forms, you do not need to fill them out again and can ignore this request.**

The purpose of the Women's Health Initiative is to learn more about women's health and the risk for disease in postmenopausal women. This important health study includes over 110,000 women across the U.S. One of our most important goals is to keep track of any major changes in the health of our participants through the end of the study. When a participant in the Women's Health Initiative becomes unable to answer questions about her health, we ask for her proxy's help in providing this information.

Enclosed in this packet are the health update questionnaires that we are asking you to complete, to the best of your ability. They include questions about any hospitalizations or serious illnesses the participant may have had in the previous year. This information is collected to help WHI find answers to important questions about women's health. Depending upon your responses, you might be contacted for additional details. If there is something that you do not know, it is okay to leave the answer blank.

Thank you for taking the time to complete these important questionnaires. It is very important for WHI to have complete follow-up information on all participants to ensure that WHI results are accurate and trusted by scientists and physicians. With your generous help, the Women's Health Initiative will have the information that is vital for the study to succeed. If you have any questions or need any help, please call your Clinical Center at the phone number listed on the following pages. Remember that all information you provide to us will always be kept confidential. We appreciate your participation in the Women's Health Initiative. This study is important for the health of women for generations to come.

Thank you for your contribution to the Women's Health Initiative!

Figure 7.8
Postcard for Participants on No Follow-Up

WOMEN'S HEALTH INITIATIVE EXTENSION STUDY

1. Have you had any major health problems since we last saw you?
   ☐ No ☐ Yes → Please describe:_____
   _____
2. Is this address label correct?
   ☐ Yes ☐ No → Change to:_____
   _____
3. May we contact you about joining the Women's Health Initiative Extension Study?
   ☐ No ☐ Yes

   I have questions, please call me at:_____
   Best times to call:_____

Please call [FC phone number] or return this postcard to [FC address].

Figure 7.9
WHI-ES DM General Letter

WOMEN'S HEALTH INITIATIVE

To our valued WHI Extension Study participants who were in the Dietary Study

Thank you for continuing your commitment to the Women's Health Initiative by joining the WHI Extension Study. Recently, we sent you an important issue of the *WHI Matters* newsletter summarizing the results to date about the WHI Dietary Study that had been published in the *Journal of the American Medical Association*. These results showed that breast cancer rates may turn out to be lower in the low-fat Dietary Change (intervention) group compared to the Comparison (usual diet) group. However, the observed 9% difference was not statistically *significant* (a measure used to evaluate study results), meaning that the results remain uncertain.

As a participant in the WHI Extension Study, the health information you provide every year will help scientists determine if the WHI low-fat dietary pattern will eventually result in statistically significant changes over time of breast cancer, colorectal cancer, and heart disease. This is because the effect of diet change may take a long time to develop. To learn more about dietary effects over time, there is a small chance that you will be called and asked about the foods you eat. If you are called, you may choose whether or not to participate in the interview.

We will continue providing you with up-to-date news about the Women's Health Initiative, plus general health and nutrition news, in upcoming issues of *WHI Matters*. If you were in the Dietary Change group of the Dietary Study, we are pleased to let you know that the National Institutes of Health will continue providing quarterly issues of the *WHIse Choices* newsletter. We hope the newsletters will be helpful to those of you who wish to maintain the low-fat eating pattern adopted during the WHI Dietary Study. The first *WHIse Choices* for the Extension Study period, planned for later this year, will give you the option of not receiving future issues, if you prefer.

Thank you for being in the WHI! The Women's Health Initiative is one of the largest and most comprehensive studies ever conducted. Because of your continued cooperation, we will continue to find the answers to important questions concerning women's health. In addition to the updates we send, ongoing news about WHI may be found at www.whi.org, www.nhlbi.nih.gov/whi, and http://orwh.od.nih.gov/WHIConference.htm.

You are part of the answer!

SPONSORED BY THE NATIONAL HEART, LUNG, AND BLOOD INSTITUTE

Figure 7.10
WHI-ES DM Approach Letter

FRED HUTCHINSON
CANCER RESEARCH CENTER
A LIFE OF SCIENCE

WHI Clinical Coordinating Center

DATE

«Title» «FirstName» «LastName»
«Address1»
«City», «State» «PostalCode»

Dear «Title» «LastName»,

In the next few weeks, staff from the Coordinating Center for the Women's Health Initiative Extension Study in Seattle will call you for a short interview. The interviewer will ask about foods you ate on the previous day. The enclosed booklet will help you estimate your serving sizes. Please have it available for the telephone interview. You do not need to do anything special to prepare for the call. The interview will take about 20 minutes.

You were specially selected for this interview, and we hope that you will participate. This information will help us learn more about how diet affects women's health.

If you would like to participate but are busy when we call, we will ask if we can call you at another time. If you would rather not participate, you are welcome to decline when called.

If you have any questions, please ask the interviewer when he or she calls.

Sincerely,

Garnet Anderson, Ph.D.
Women's Health Initiative
Co-Project Director, Clinical Coordinating Center
206/667-2834

Figure 7.11
24-Hour Recall Interview Script

Women's Health Initiative Extension Study (WHI-ES)
Dietary Modification (DM) Trial Cohort

24-HOUR RECALL INTERVIEW SCRIPT

MAKE THE PHONE CALL. PRESS THE PRIVACY RELEASE BUTTON AFTER THE PHONE IS ANSWERED.

Hello, my name is <your name> and I'm calling from the Coordinating Center for the Women's Health Initiative Extension Study in Seattle. May I please speak with_____?

Ql. Is this_____? VERIFY NAME OF PARTICIPANT ON CALL RECORD SHEET.

- IF YES, GO TO Q2.
- IF NO, AND PARTICIPANT IS NOT AVAILABLE,

  When would be a good time for me to call again? Thank you very much. Good-bye.

  WRITE DOWN TIME ON THE CALL RECORD SHEET. DELETE PARTICIPANT INFORMATION FROM THE RECORD HEADER SCREEN.
- IF YOU REACH VOICE MAIL OR AN ANSWERING MACHINE, AND

  This is the fourth, eighth, or 12th call attempt:

  This is <your name> calling from the Coordinating Center of the Women's Health Initiative Extension Study in Seattle. I am calling for _____ to complete a telephone interview about foods you eat. Please call 1-800-704-2804 and leave your name, phone number, and generally the best times to reach you. Also tell us you are calling about the WHI study. Thank you.

Q2. This is <your name> calling for the Coordinating Center of the Women's Health Initiative Extension Study in Seattle. I am calling to complete an interview about what you eat. Is this a good time for you to talk?

- IF YES, GO TO Q3
- IF NO,

  Is there a more convenient time for me to call you today? Thank you. I will call you again at _____.

  NOTE TIME ON CALL RECORD SHEET.
- IF NO CONVENIENT TIME LATER THAT DAY CAN BE ARRANGED,

  Thank you very much, I will call again another day. Good bye.

  NOTE ON THE CALL RECORD SHEET.
- IF FIRM REFUSAL,

  I understand that you don't want to be called again for this part of the study. Thank you.

  NOTE REFUSAL ON THE CALL RECORD SHEET.

Q3. There is a legal requirement that you consent to participate in this interview. So I would like to read you a brief description of the interview process before we begin.

This interview requires answering detailed questions about the foods you ate and the beverages you drank the previous day. The interview will take about 20 minutes.

By taking part in this study, you will help increase scientific knowledge about how diet affects women's health. There are no risks of participating in this interview.

Everything you tell me will be kept strictly confidential as required by law. Your personal identity will not be revealed in any publication or release of results.

Your decision to participate in this interview is voluntary. You may stop at any time and for any reason.

Do you have any questions?

- IF NO, GO TO Q4.
- IF YES, AND YOU DO NOT KNOW THE ANSWER TO A PARTICIPANT'S QUESTION, WRITE DOWN THE QUESTION CAREFULLY**.**

  I am going to refer your question to one of the scientists on this study. We will call you with an answer very soon. GO TO Q5.

Q4. Do you agree to participate in this interview? NOTE ANSWER ON CALL RECORD.

- IF YES, GO TO QUESTION 5.
- IF NO,

  Thank you very much for your time. Have a good day.

Q5. The interview will take about 20 minutes. Is this a convenient time?

- IF A CONVENIENT TIME, GO TO QUESTION 6.
- IF NOT A CONVENIENT TIME,

  What are more convenient times for me to call you today and on other days? (IF APPROPRIATE**, If it is better for me to call you at home, may I have your home phone number?) Thank you, I will call you again.**

  NOTE TIMES ON THE CALL RECORD SHEET.

Q6. There is a 10% chance my supervisor will listen to this interview to monitor my performance.

- IF PARTICIPANT SAYS SHE DOES NOT WANT THE SUPERVISOR TO LISTEN TO THE INTERVIEW, **I will call you back on an unmonitored line**. CALL THE PARTICIPANT BACK ON ANOTHER LINE.

GO TO QUESTION 7.

Q7. This interview has 3 parts. The first part is called the Quick List. You will just list the foods and beverages you ate and drank yesterday. Next, we will describe the foods and beverages in more detail. Then, I will review your intake for any final revisions.

I need just a moment to enter some information into the computer. Please use this time to get your Serving Size booklet and think about what you ate and drank yesterday.

- IF THE SERVING SIZE BOOKLET IS NOT AVAILABLE**, A ruler, measuring cups, and measuring spoons work just as well. I can wait a minute while you get them.**

Complete the NDS-R Record Header Tab:

- The participant's ID number which is listed on the Call Record Sheet.
- The date of intake (previous day, which is the date the food was consumed).
- The participant's name and gender.
- Your interviewer ID.
- Visit number.

Q8. For the Quick List, tell me the time and place you ate and then briefly list everything you had to eat or drink starting from midnight, <day of week>, until midnight last night. Okay? What time was it when you had your first item to eat or drink after midnight <day of the week>?

ENTER EACH FOOD AND BEVERAGE ITEM ON THE NDS-R QUICK LIST WINDOW.

ENTER ENOUGH INFORMATION SO YOU WILL BE ABLE TO RECOGNIZE IT WHEN YOU GET TO THE FOOD SEARCH WINDOW. ITEMS WILL BE GROUPED BY MEALS AS THEY ARE ENTERED: BREAKFAST, LUNCH, DINNER, SNACKS. THIS WILL HELP YOU AND THE PARTICIPANT SPOT OMISSIONS. THINK ABOUT THE FOODS, BEVERAGES AND MEALS THE PARTICIPANT HAS RECALLED. ASK ABOUT POSSIBLE OMITTED FOODS AND BEVERAGES AT EACH MEAL/SNACK AND BETWEEN MEALS AND SNACKS. THE FOLLOWING ARE EXAMPLES OF PROBES:

Did you have:

- **anything to eat or drink in the car?**
- **any snacks in the morning while you were at work?**
- **fruit, chips, or a dessert with your lunch?**
- **anything to eat or drink when you got home from work, for example, while dinner was being prepared or before you ate dinner?**
- **something to drink with dinner?**
- **anything to eat or drink before you went to bed?**

WHEN FINISHED PROBING AFTER THE QUICK LIST, GO TO Q9.

Q9. Now we'll go over the foods we just listed and you can describe them in more detail. When I ask you about amounts, please use the Serving Size Booklet (AND/OR measuring cups and spoons OR ruler), to help you estimate portion sizes. The first thing you said you had yesterday was <name of food/beverage> at <time of day>.

PROBE FOR ADDITIONS AT THE ADD FOOD WINDOW.

PROCEED WITH THE 'FOOD SEARCH', AND 'ITEM DETAIL' WINDOWS TO FURTHER DESCRIBE EACH ITEM. FOLLOW PROBES ON THE SCREEN TO COMPLETE THE DETAILS REQUIRED.

AFTER GETTING THE DETAILS, GO TO Q10.

Q10. Now we will review your day's intake. Feel free to stop me at any time if you recall having any other foods or beverages or if I have stated an incorrect amount or type of food.

USE THE 'FOOD REVIEW' WINDOW TO THOROUGHLY VERBALLY REVIEW THE DAY'S INTAKE WITH THE PARTICIPANT. READ EACH FOOD, PREPARATION METHOD (WHEN NECESSARY) AND SERVING SIZE TO THE PARTICIPANT TO CONFIRM FOOD INTAKE. MAKE CHANGES, IF NECESSARY. WHEN YOU ARE FINISHED REVIEWING THE INTAKE, ASK ONE FINAL TIME IF THE PARTICIPANT RECALLS EATING OR DRINKING ANYTHING ELSE.

AFTER REVIEWING, GO TO END.

END. This concludes the interview. Thank you, <participant's name> , for giving us such detailed information. This information is very important to this research project.

COMPLETE THE RECORD TRAILER TAB:

The INTAKE was USUAL (*default).*

The RELIABILITY OF THE INFORMATION is the subjective opinion of you, the interviewer.

If the participant seemed confident in recalling his or her intake, record RELIABLE.

If the participant was unable to remember meals or snacks, record UNABLE TO RECALL ONE OR MORE MEALS. Make a note to alert the RN.

If the interview seemed unreliable for other reasons, record UNRELIABLE FOR OTHER REASONS. Note why on the Call Record Sheet. Make a note to alert the RN.

AFTER THE INTERVIEW:

1. EDIT THE RECORD.
2. COMPLETE THE CALL RECORD SHEET.
3. PRINT OUT ALL RECORD REPORTS AND ATTACH TO THE CALL RECORD SHEET.
4. IF YOU HAVE A RN QUESTION PRINT OUT A RECORD REPORT, ATTACH IT TO THE CALL RECORD SHEET, NOTE 'RN' ON THE CALL RECORD SHEET.
5. PLACE THE CALL RECORD SHEET IN THE '*COMPLETE RECALL TRAY*'.

Figure 7.12
WHI-ES DM Thank You Letter

FRED HUTCHINSON
CANCER RESEARCH CENTER
A LIFE OF SCIENCE

WHI Clinical Coordinating Center

DATE

«Title» «FirstName» «LastName»
«Address1»
«City», «State» «PostalCode»

Dear «Title» «LastName»,

A few weeks ago, staff from the Coordinating Center for the Women's Health Initiative in Seattle called to talk with you about the foods you ate on the previous day. Thank you for taking the time for this activity. This is an important part of the Women's Health Initiative study that will help us learn more about how diet affects women's health.

We appreciate your continued participation in the Women's Health Initiative. Together we can do a lot to improve the health of women for generations to come.

Sincerely,

Garnet Anderson, Ph.D.
Women's Health Initiative
Co-Project Director, Clinical Coordinating Center
206/667-2834

7.7 Standard Operating Procedures (SOP) for Ancillary Studies of Self-Reported Outcomes in the Women's Health Initiative

This section describes the procedures for obtaining consent for the study of self-reported outcomes (SRO) by ancillary studies (ASs) in the Women's Health Initiative (WHI). These procedures refer specifically to studies using self-reported outcomes where participants from multiple WHI Field Centers (FCs) are needed to obtain a large enough sample.

These procedures are intended to be used to obtain validation data (e.g., medical records) on conditions previously reported to WHI either to confirm all eligible cases or, in the case of more common conditions, to estimate the reliability of self-reported events in a representative sample of eligible cases. The ancillary study (AS) may be a stand-alone validation study to test whether self-report is good enough to allow analyses based on the self-reported outcome.

7.7.1 Background

The overall mission of the WHI is to examine the risks and benefits of three specific prevention interventions and to determine risk factors for the major causes of morbidity and mortality in postmenopausal women. In support of this, WHI has already collected self-reports of a diverse list of medical events from participants, but has had the resources to collect medical records confirming only the event types of highest priority to the primary study objectives. Many of the other conditions represent important health concerns of older women for which WHI participants have already contributed considerable information. Because some of these conditions are very rare, the WHI may constitute a unique resource for information on these health outcomes. The specific self-reported outcomes are listed in *Tables 7.1-7.3 – Self-Reported Outcomes in WHI*.

The purpose of these procedures is to provide an efficient mechanism for obtaining the supporting medical records for the self-reported health outcomes already known to us when an AS designed to study one of these outcomes is funded. Because subcontracting with 40 Field Centers is logistically burdensome and cost prohibitive for each AS to repeat, the proposed process is centralized at the WHI Clinical Coordinating Center (CCC) for institutional review, approval, and implementation, contingent upon approval of their Standard Operating Procedures (SOP) is obtained at participating sites.

For this type of AS (referred to below as a Self-Reported Outcomes AS, or SRO-AS), WHI participants who had previously reported a diagnosis of the outcome of interest would be identified in the WHI database, contacted, and asked to consent to having WHI staff obtain the medical records associated with that outcome. As proposed, CCC staff would contact participants who have reported that outcome, obtain the signed authorization to release their medical records, and collect the pertinent records of consenting participants. This new stage in the CCC WHI contract is a natural progression of its federally designated role into outcomes collection for data repository collaboration.

7.7.2. Overview of Process (Proposed)

The process for consenting and collecting medical information from participants who have reported one of the self-reported outcomes listed in *Tables 7.1-7.3* is described below.

Following review and approval of these procedures by the CCC (Fred Hutchinson Cancer Research Center) Internal Review Board (IRB), each FC will seek local IRB approval for this SRO protocol. Under the original WHI consent, participants have provided data on their health outcomes with the expectation that it will advance scientific knowledge; that expectation applies to the study of SRO, just as it does to the primary outcomes in WHI.

Participants from FCs that obtain local IRB approval of the SRO protocol will be eligible for approach for all future SRO-ASs. Participants from FCs who do not have IRB approval for the SRO protocol will not be included in the centrally supported activities of these types of AS, although individual SRO-ASs may choose on a case-by-case basis to negotiate directly with the local institutions to participate.

Once this SRO-protocol is approved, the process to be followed for each specific SRO-AS is summarized here, with details provided below:

1. The proposal for the SRO-AS is reviewed and approved via the existing standard WHI AS review structure (detailed in *Section 7.7.3* below).
2. Funding is secured for the SRO-AS.
3. The WHI CCC receives IRB approval for each SRO-AS. The Principal Investigator (PI) of the SRO-AS also obtains IRB approval from his/her institution.
4. The CCC IRB approval for the study is sent to all FC IRBs who have approved the SRO protocol as an FYI.
5. The CCC identifies eligible participants with the outcomes of interest for that SRO-AS.
6. The CCC sends a packet to participants with that outcome. The packet includes a cover letter explaining the study, a short questionnaire requesting information on the diagnosis and treatment, and a request to obtain medical records.
7. Consenting participants return the questionnaire, and medical records release to the CCC. The CCC re-contacts non-responders for possible participation.
8. The CCC collects and processes medical records according to the specified protocol described below, including removal of personal identifiers if records need to be reviewed and/or adjudicated by another party.
9. Participants' medical records are stored at the CCC.
10. Data analysis is conducted at the CCC or by the SRO-AS investigators. Any data provided to SRO-ASs investigators will be de-identified by the CCC before release.

7.7.3. Details on Existing Approval Process for WHI Ancillary Studies

To be considered as a potential WHI AS, all AS proposals follow a standard set of requirements and procedures. A WHI AS is any study that requires the collection of additional data from participants enrolled in any WHI component, including data obtained from existing specimens. An AS is conducted with non-WHI funds, with some basic CCC support covered by the WHI contract. The WHI accepts AS proposals from investigators within and outside of the WHI organization. Studies conducted by non-WHI investigators must be sponsored by a WHI PI.

Ancillary Study proposals fall into two general categories: those requesting biospecimen and those without biospecimen requests. The procedures and review process are slightly different for each. For biospecimen proposals, an additional level of review is conducted by the Laboratory Working Group (LWG), the CCC, and the Executive Committee (EC). All proposals are reviewed according to the AS review criteria listed in *Table 7.4 – WHI AS Review Criteria*

Once a proposal has been approved by the ASC, it is sent to the NHLBI Project Office (PO) and the WHI EC for review and approval. The Observational Study Monitoring Board (OSMB) review is also required if the study requires additional consent from participants, and/or will involve additional participant burden. When the PO and OSMB have reviewed and approved the proposal, the PO sends an approval letter to the AS PI and the PI is free to submit an application for funding the AS.

The AS application may include a subcontract to the CCC. Before submission for funding, AS proposals are given a brief review by the AS PI's local institution and by the CCC's IRB (at the Fred Hutchinson Cancer Research Center); an IRB application is then submitted once the AS receives a fundable score.

7.7.4 Details on Approval Process for Self-Reported Outcomes Ancillary Studies (SRO-AS) *(Proposed)*

When an SRO-AS involving one of the outcomes listed in *Tables 7.1-7.3* has been funded, the CCC will notify all PIs at FCs with participants reporting that particular outcome. The purpose of this notification is to let PIs know that some of their participants will be contacted by the CCC regarding possible participation in the SRO-AS. The PI notification will include a cover letter and abstract and brief description of the approved SRO-AS.

Upon receipt of the notification letter, the FC PI will follow the local procedures for notifying his/her IRB regarding the SRO-AS, which may involve the PI sending the CCC IRB approval and study description to their local IRB as an FYI. This process will vary depending on the agreement that has been established at the local level.

7.7.5 Details on Obtaining Consent for participation in SRO-ASs and Medical Records Collection *(Proposed)*

The following process will be followed for each SRO-AS. Consent and medical outcomes reports for participants in these studies are collected centrally by the CCC.

A. Eligibility. The CCC will create a list of participants who have reported the self-reported outcome of interest for each participating FC. This list will be used to create cover letters and mailing labels for eligible participants. Women are eligible for approach if they reported the outcome of interest during the original WHI, with the exception of those who were classified as "absolutely no contact" at the end of WHI, or who became "absolutely no contact" during the Extension Study. For participants on proxy follow-up, the consent packet will be sent to the proxy, with a different cover letter. The next of kin for women who are deceased may also be approached, depending on the type of data needed for that specific AS. This process will be established for each AS separately, as needed.

B. Recruitment. The CCC will mail an initial consent packet to participants who have previously reported the outcome in the study. The packet will include:

- Cover letter (see *Figure 7.13 – Model of Consent Cover Letter*). This letter explains why we are contacting the participant, outlines the contents of the packet, and explains what their participation will entail. A contact person and phone number for both the CCC and the SRO-AS PI are included in the letter.
- Brief questionnaire to confirm the data we have from the participant pertaining to the outcome and to ask for information on the health care provider(s) providing diagnosis and treatment (see *Figure 7.14 – Model of Health History Questionnaire*). This questionnaire would be modified to include questions that meet the specific needs of each SRO-AS.
- Consent Form to participate in the SRO-AS, if required. For those studies that need a signed Authorization to Release Medical Records only, a consent form will not be included. If participation in the SRO-AS requires additional questionnaire or lab data from the participant, a consent form and additional information outlining the study's requirements will be included.
- Authorization to Release Medical Records form (see *Figure 7.15 – Model of Authorization to Release Medical Records*). This form asks the participant to give the CCC permission to obtain medical records that may be related to the outcome of interest. She will be asked to complete and sign this form before mailing it back to the CCC. The medical records release form sent to each participant will be specific to that participant's FC institution, and, because different diseases might require different kinds of documents, possibly by the disease outcome. Release forms will need to meet the Federal HIPAA regulations. The model in *Figure 7.16 – Model Request for Medical Records Information Sent to Healthcare Providers and Institutions* provides a sample of what a typical medical release form looks like.
- Business Reply Envelope for returning the signed consent form and medical release form(s) to the CCC.

C. Follow-up with non-respondents. The CCC will track returned packets in the WHI database. A second packet with letter and medical release will be sent to non-respondents two months after the initial mailing. One month later, a CCC staff member will call non-respondents to answer questions and prompt return of the forms. If participants are not interested in participating at that point, or cannot be reached or found, they will no longer be contacted for participation.

D. Requesting records from medical care providers. The documents to be requested depend on the diagnosis and needs of the SRO-AS. The SRO-AS investigator will provide a list of specific documents needed to the WHI CCC Outcomes Unit. This document set will be listed on the *Request for Medical Records Information* (see *Figure 16*) sent to the health care provider(s) listed on the questionnaire. In most cases the generic release may be sufficient documentation, but in some cases the hospital/doctor may have their own medical release specific to their organization, institution, or state that needs to be signed. In those cases, the CCC will send the provider-specific release to the participant for a signature. Healthcare providers will be asked to send the requested documents to the CCC in the return envelope provided.

E. Review and adjudication of health outcomes. Upon receipt at the CCC, all medical records will be reviewed for completeness and fact of receipt data entered in the WHI database. All records will then be assembled in a packet, copied, and the copies sent out to the adjudicators identified for that SRO-AS. All patient and next-of-kin identifiers will be removed from documents before distribution to adjudicators. Following adjudication, all records and completed forms will be returned to the CCC for data entry or, destroyed if they are duplicates. If during the process, adjudicators determine that additional medical records are needed, the CCC would conduct the steps necessary to obtain those documents and provide them to the adjudicator(s). Following adjudication and data entry, all documents are archived at the CCC.

F. Data Entry and Analysis. The CCC database staff will be responsible for data entry and storage of all data received through this process. CCC statisticians will work with the SRO-AS investigators to analyze data and prepare manuscripts on study results. Any data released to SRO-AS investigators will be de-identified.

Table 7.1
Self-Reported Outcomes in WHI - General

- Alzheimer's disease
- Amyotrophic lateral sclerosis
- Asthma
- Benign breast disease
- Cataracts
- Dementia
- Diabetes (treated)
- Dialysis for kidney disease
- Diverticulitis
- DVT
- Emphysema/COPD
- Gall bladder disease
- Glaucoma
- Heart failure
- Hypertension
- Hysterectomy
- Intestinal polyps
- Inflammatory bowel disease
- Joint replacement
- Kidney stones
- Liver disease
- Macular degeneration
- Multiple sclerosis
- Osteoarthritis
- Osteoporosis
- Parkinson's disease
- Pancreatitis
- Peptic ulcer disease
- Pulmonary embolism
- Rheumatoid arthritis
- Systemic lupus erythematosus
- Thyroid disease
- Venous thromboembolism
- ICD-9 CM codes
- Diagnostic procedures, such as sigmoidoscopy, colonoscopy, biopsy of benign breast lesions

Table 7.2
Self-Reported Outcomes in WHI – Non-Primary Cancers

- Accessory sinus
- Adrenal gland
- Anus
- Appendix
- Biliary tract
- Bladder
- Bones/joints/articular cartilage
- Brain
- Cervix
- Central nervous system (excludes brain)
- Connective/subcutaneous/soft tissues
- Endocrine glands, related structures
- Esophagus
- Eye and adnexa
- Genital organs
- Kidney
- Larynx
- Leukemia
- Liver
- Lung
- Lymph nodes
- Lymphoma, Hodgkins
- Lymphoma, Non-Hodgkins
- Melanoma of the skin
- Multiple myeloma
- Oral (mouth)
- Palate
- Pancreas
- Parotid gland (Stensen's duct)
- Peripheral nerves and autonomic nervous system
- Pyriform sinus
- Respiratory system, intrathoracic, other
- Salivary glands, major
- Stomach
- Thyroid
- Tongue, part of
- Urinary organs
- Uterus, not otherwise specified
- Other, not specified above (from the International Classification of Diseases for Oncology ICD-02 Reference Manual)

Table 7.3
Self-Reported Outcomes in WHI – Non-Primary Fractures

Those that may already have been locally verified

- Ankle
- Carpal bone(s) in wrist
- Clavicle or collarbone
- Elbow, not otherwise specified
- Humerus
- Metacarpal bone(s)
- Patella
- Pelvis
- Radius or ulna
- Sacrum and Coccyx
- Scapula
- Shaft of femur
- Tarsal/metatarsal bones
- Tibia and fibula
- Tibial plateau
- Upper radius/ulna
- Vertebral

Self-reports only

- Elbow
- Foot
- Hand
- Hip
- Knee
- Lower arm or wrist
- Lower leg
- Pelvis
- Tailbone
- Upper arm or shoulder
- Upper leg
- Spine

Table 7.4
WHI AS Review Criteria

I. Scientific Review

A. Significance: Does this study address an important problem? If the aims of the application are achieved, how will scientific knowledge be advanced? What will be the effect of this study on the concepts or methods that drive this field?

B. Approach: Are the conceptual framework, design, methods, and analyses adequately developed, well-integrated, and appropriate to the aims of the project? Does the applicant acknowledge potential problem areas and consider alternative tactics?

C. Innovation: Does the project employ novel concepts, approaches or method? Are the aims original and innovative? Does the project challenge existing paradigms or develop new methodologies or technologies?

D. Investigator: Is the investigator appropriately trained and well suited to carry out this work? Is the work proposed appropriate to the experience level of the principal investigator and other researchers (if any)?

E. Environment: Does the scientific environment in which the work will be done contribute to the probability of success? Do the proposed experiments take advantage of unique features of the scientific environment or employ useful collaborative arrangements? Is there evidence of institutional support?

F. (CT Studies) Relevance to CT: Does the project draw on the randomized nature of the CT design? Is the proposed study optimally addressed in the CT; does it require an experimental, randomized design to address the study question?

II. WHI Priorities and Policy

A. Potential for contributing to the health of post-menopausal women
B. Draws on unique characteristics of the WHI
C. Complement the current portfolio of studies
D. Value of scientific resource contributed to the WHI
E. Years of service to the WHI of the AS principal investigator
F. (CT studies) Draws on unique characteristics of the WHI CT

III. Operational Criteria

A. Acceptable Informed Consent: Accurate, clear and complete; appropriately distinguishes AS participation from WHI participation
B. Acceptable burden to WHI study participants
C. None/minimal burden to WHI collaborating centers
D. Meets approval from partner WHI institutions (e.g., CCC)
E. Appropriate plan for disposition of AS data (e.g., confidentiality, submission of results data to CCC)

Figure 7.13
Model of Participant Consent Cover Letter for SRO-Ancillary Studies

This letter is sent to the participant to explain why we are contacting her, outlines the contents of the packet, and reviews what is needed from her if she chooses to participate in the SRO-AS. The letter is signed by a Co-Investigator of the WHI CCC and includes contact telephone numbers for both the CCC and the SRO-AS PI.

(date)

<<participant name>>
<<address>>
<<city,state,zipcode>>

Dear <<name>>,

Thank you for being a part of the Women's Health Initiative! The WHI was created to learn more about women's health and the causes of disease in women. As an important member of the Women's Health Initiative over the years, you and the other WHI participants have provided valuable health information that has changed medical practice and will continue to help women for generations to come.

The WHI database indicates that during your participation in the WHI, you reported that you had been diagnosed with, or received medical treatment for <<*medical condition*>>. Dr. <<*Principal Investigator*>>, a researcher at the <<*institution*>>, is conducting further research on WHI participants nationwide who have experienced this particular health condition, and is very interested in obtaining additional details about your experience. To do so, we need to review your medical records to obtain more information about your diagnosis and treatment. In WHI, health tracking has generally been done by your local clinical center. For this special WHI study, the WHI Clinical Coordinating Center (CCC) at the Fred Hutchinson Cancer Research Center in Seattle will assist with this work.

We are asking your permission to obtain medical records about this health condition from the health care providers, clinics, and hospitals that may have been involved in your care for this condition.

If you are willing to participate in this effort, we ask that you:

- ☐ Complete and return the enclosed "Health History Questionnaire" to provide some of the details we need for this research and to find out more about the type of health care you received.
- ☐ Sign and return the enclosed "Authorization to Release Medical Records". This will authorize us to access and review the medical records associated with the health condition described above.
- ☐ Return both documents to us using the enclosed postage-paid envelope.

Please be assured that all information we receive is used for research purposes only. Records are kept strictly confidential, and no names or other identifying information will be released except as required by law. Participation in this study will have no impact on your enrollment in the Women's Health Initiative, regardless of whether or not you are currently an active participant.

We greatly appreciate the contributions you have made as a volunteer in the Women's Health Initiative. If you have any questions about this letter or about the study, please call either the WHI Clinical Coordinating Center staff toll-free at 1-800-514-0325, or Dr. <<*Principal Investigator*>> at <<*phone number*>>.

Sincerely,

Andrea LaCroix, RN, MPH, PhD
Co-Investigator, Women's Health Initiative Clinical Coordinating Center
Fred Hutchinson Cancer Research Center

Figure 7.14
Model of Health History Questionnaire for SRO-Ancillary Studies

The *Health History Questionnaire* would include questions designed specifically for each SRO-AS, depending on the needs of the study and the condition being investigated.

Women's Health Initiative
Health History Questionnaire

In a previous health update questionnaire that you completed for the Women's Health Initiative, you indicated that you had the medical condition listed below. We are currently studying that condition and need some additional information about your diagnosis. Please answer the following questions to the best of your ability, even if they are asking about events that occurred several years ago.

On a previous WHI questionnaire, you indicated that you had been diagnosed with the following condition:

Place label listing condition here

1. Please confirm that you were diagnosed with this condition:

   Yes – continue
   No – Please return this form in the envelope provided and thank you for your time

2. To the best of your knowledge, when were you first told by a doctor or other health care provider that you had this condition?

   Month / Year

3. Who is your current doctor / health care provider? If you have more than one that you visit on a regular basis, please list them below.

   Health care provider 1:
   Name
   Address
   Phone

   Health care provider 2 (3, 4):
   Name
   Address
   Phone

The next set of questions ask about visits to your doctor(s), hospital admissions, medical problems, procedures, and tests that you may have had **related to the condition listed above**. In the following questions, do not report visits that are related to other health conditions. We are specifically interested in the medical condition listed above.

4. Was the condition listed above diagnosed or treated during a visit to your doctor's office?

   Yes
   No

   a. Please provide the contact information for doctor who first diagnosed or treated this condition. If the doctor is already listed above, please provide the name only.

      Name:
      Address:
      Phone:

5. Was the condition diagnosed or treated during a hospital stay?

   a. What is the name, address, and phone number of the medical facility where you were diagnosed or treated for this condition?

      Name of hospital:
      Address:
      Phone:

   b. What was the date you entered the hospital? If you do not know the exact date, please provide the month and year.

6. Are you still receiving treatment for this condition?

   Yes
   No

7. If yes, where are you receiving the treatment? If the doctor is already listed above, please provide the name only.

   Name of provider:
   Address:
   Phone:

Thank you for your participation!

Please return all documents in the postage-paid envelope provided.

Figure 7.15
Model of Authorization to Release Medical Records Form for SRO-Ancillary Studies

The *Authorization to Release Medical Records* form sent to each participant will be tailored to meet the specific requirements of each participant's clinical center institution and state. The model below provides a sample of what a typical medical release form will include.

FRED HUTCHINSON CANCER RESEARCH CENTER
A LIFE OF SCIENCE

WHI Clinical Coordinating Center
1100 Fairview Ave. N.
PO Box 19024
Seattle, WA 98109-1024
(800) 514-0325 FAX: (206) 667-5826

AUTHORIZATION TO RELEASE MEDICAL RECORDS

The Women's Health Initiative (WHI) is a 40-center national study sponsored by the National Institutes of Health to follow for cardiovascular disease, cancer, and fractures in post-menopausal women. By signing this document, I give permission to the Principal Investigator and the WHI Clinical Coordinating Center at the Fred Hutchison Cancer Research Center – Seattle, Washington, Andrea LaCroix, RN, MPH, PhD and her staff, to request my medical records.

I hereby authorize any and all medical facilities including:

_____
Name of Physician and/or medical institutions

To disclose medical records relating to the following conditions:

Hospitalizations (overnight admission)	*Procedures and Operations*
Fractures	*X-rays, Radiology reports, Procedure report*
Cardiovascular conditions	*Medical documents including and pertaining to Myocardial Infarction, CABGs, PTCAs, CHF, Strokes, EKGs, and other Cardiovascular disease*
Mammograms	*Reports only- NO FILMS*
Cancers	*Including screenings, Breast exams, Pelvic exams, Pap smears, Ultrasounds, Endometrial biopsies and Pathology reports*

By signing, I, acknowledge that I have read and understood the following:

Duration The authorization will remain in effect until its expiration on October 1, 2010.

Revocation This authorization may be revoked at any time by calling (800) 514-0325. Revocation will be in effect immediately upon notification.

Re-disclosure Information in the above medical records may be shared with researchers at the Fred Hutchinson Cancer Research Center (the coordinating center for the study), the staff at the National Institutes of Health, and regulatory bodies such as the US Food and Drug Administration, and the Fred Hutchinson Cancer Research Center Institutional Review Board. Once disclosed this information may no longer be protected.
The WHI **may not** further use or disclose the information in my medical records unless I sign another authorization giving them permission to do so or unless such use or disclosure is required and permitted by law. Any information that is re-disclosed by the WHI Clinical Coordinating Center will have my personal information blocked on all record

After completion of the study, I will have the right to inspect or copy the information in my study file.

The records requested are required for data collection in the WHI. My compliance, or refusal, to sign this authorization has no affect whatsoever on my enrollment in WHI, nor my status as a participant.

INITIAL HERE IF YOU DESIRE A COPY OF THIS AUTHORIZATION _____
The following information is needed to assure accurate identification and is **ONLY for identification purposes.**

Patient Legal Name (Please Print)	Social Security Number (Optional)
Date of birth	Place of birth (Optional)
If another party is signing for participant, please list relationship:	Mother's Maiden Name (Optional)
Patient's Signature (or signature of party authorized to sign)	Date

Figure 7.16
Model Request for Medical Records Information Sent to Healthcare Providers and Institutions

This is a model of the form that will be sent to the health care provider to request medical records. The specific set of documents to be requested is determined by the condition and the SRO-AS investigator.

Women's Health Initiative (WHI)
Request for Medical Record Information

Date Requested: 05-09-07

To: Medical Records Department
Grossmont Hospital (Sharp)
5555 Grossmont Center Drive
La Mesa, CA 91942
Phone: (619) 740-4029 Fax: (619) 740-4466

RE Patient:	Patient ID:	Date of Service (on or about):	DOB:	SSN: xxx-xx-

Patient Address:

Phone:

WHI Use Only:
WHI Ref:
Visit ID: 9
Ext Date: 12/06/05

Enclosed is a copy of the above patient's authorization to release her medical records to the Women's Health Initiative (WHI) at UNIVERSITY OF CALIFORNIA AT SAN DIEGO. We understand that the patient was treated/admitted at your facility in connection with the following condition(s):

- **Claudication, ischemic ulcers, gangrene**
- **Pulmonary embolism (blood clot in lungs)**

Please send copies of the following documentation:

Hospital Face Sheet
ICD9-CM Codes
History & Physical/Physical Exam
Discharge Summary (if unavailable, please send Progress Notes)
Percutaneous Transluminal Coronary Angioplasty;Stent/Artherectomy
Stress Test by ECG, echo or perfusion scintigraphy report
Thallium or Technetium Studies Report
Operative or Procedure Report
Cardiac Catheterization/Angiogram/Arteriogram/Contrast Ventriculogram
Venogram Report
Impedence Plethysmography
Doppler flow study report
Isotope Scan Report

Please return a copy of this request along with the available documentation to:

UNIVERSITY OF CALIFORNIA AT SAN DIEGO
WHI CCC OUTCOMES UNIT
1100 FAIRVIEW AVENUE NORTH M3-A410
P.O. BOX 19024
SEATTLE WA 98109
Phone: (800) 514-0325 Fax: (206) 667-5829

Section 7
Follow-Up Contacts

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Section 9

Retention

Introduction

Retention in the Women's Health Initiative (WHI) Extension Study is crucial to the success of the study. Retention refers to the overall strategies and procedures used to assure a participant's participation and contact in the study. Retention of study participants as defined by the study protocol is the dominant focus after the participant is enrolled.

This section describes study-wide and local retention activities designed to keep participants interested and active in the study. These activities include having regular, ongoing contact with study participants and continuing a professional, caring relationship with participants during all study contacts.

Every effort should be made to encourage full participation until the end of the study. Before a participant decides to discontinue participation in the study, Field Center (FC) staff should conduct specific retention activities to encourage the participant to continue. Suggestions for dealing with those who are reluctant to continue in the study ("retention challenges") and procedures for locating hard-to-find or "lost" participants are included in this section.

Occasionally a participant will become unable or unwilling to fully participate in the study, necessitating a change in her participation follow-up status. A participant's follow-up status changes if she is not willing or able to participate in full follow-up, if she cannot be located, or if she has died. Procedures for changing participation follow-up status are described in this section.

9.1 General Activities to Promote Retention

Retention of study participants is the primary focus of activity following enrollment in the WHI Extension Study. Retention activities in the Extension Study consist of collecting the annual data forms and tracking hard to find and lost participants. Strategies and procedures to assure a participant's retention and identification with WHI must be used throughout the course of the study, from the initial consent to the last follow-up contact. Below is a list of retention enhancement methods; some are implemented on a study-wide basis (e.g., the newsletter), and some are recommended strategies for FC use (personal information updates).

A table at the end of this section (*Table 9.1 – Summary of Retention Activities*) summarizes retention activities for WHI.

9.1.1 Participant-Staff Relationships

A key element in successfully maintaining long-term participation is the development of a personal relationship between the individual participant and individual members of the staff. Good communication is essential to promoting and maintaining retention in the study. Consistency among staff and clarity of instructions are key to good communication. During all contacts, the participant should be helped to understand the beneficial nature of participation in the study. Encourage her to call to clarify questions and problems that may arise. Assure participants that they should not hesitate to bring up any issues of concern. If a participant calls and leaves a message, be sure to get back to her promptly. Delays in returning phone calls may alienate participants. Also, be sure that the message on the FC answering machine clearly identifies the number as reaching the WHI center. It can be confusing to participants if the message refers to a more generic organization (e.g., "University Medical Center").

9.1.2 Promote Identification with WHI During Routine Contacts

All FC staff should focus on continuing to promote the participant's identity with WHI. Participants already have a strong affiliation with WHI through their years of participation, and this should continue through the end of the Extension Study. The following are suggestions for activities to promote identity with WHI.

During Enrollment

During enrollment into the WHI Extension Study, it is important to fully explain the expectations of participation in the Extension Study. At enrollment, participants receive a packet of materials designed to help them understand the requirements of the Extension Study (see *Section 6 – Enrollment*.) These materials should include a cover letter explaining the study (HT and non-HT participant versions), the Extension Study consent form, and FC contact information. Enrollment is conducted in person for most Clinical Trial (CT) participants, and by mail for Observational Study (OS) participants and those CT participants who did not attend a close-out clinic visit.

During Follow-up

During follow-up, maintaining identification with the study is particularly important for retention. Identification is promoted by regular contact with WHI and by distributing materials that keep the participant connected to the study. The goal is to have some type of contact with every participant at least every six months, whether by mail or telephone. These contacts help promote retention in study activities. Identification after enrollment is achieved through several activities:

- Annual follow-up mailings to collect study data (See *Section 7 – Follow-up Contacts*)
- Participant Newsletter (See *Section 9.2 – Participant Newsletter)*
- Birthday, thank you, anniversary, bereavement, and holiday greeting cards – FCs are encouraged to maintain contact with participants by sending greeting cards to mark special occasions in the participant's life. Purchasing/designing and distributing greeting cards are entirely at FC discretion.

9.1.3 FC Group Events and Activities

Field Centers are allowed to plan events and activities to promote retention, although most are not likely to hold such events during the Extension Study. For example, FCs may choose to invite participants to an event to disseminate CT and OS findings with the goal of promoting retention in the Extension Study. The occurrence of retention events and activities is completely at the discretion of the FCs.

9.1.4 Health Information and Education

Another optional FC activity is to compile a list of local services and programs for health promotion (e.g., smoking cessation) and for special support groups (e.g., bereavement, cancer). Have this available for participants if they call requesting information about resources in your area.

9.1.5 Tracking System for Participants Requiring FC Follow-Up

Several WHIX reports help track a participant's progress in the Extension Study. FCs are required to run these reports, some weekly and some monthly, to see which participants need follow-up. Follow-up may include calling participants who did not respond to the annual mailing, sending out Personal Information Updates (PIU)to participants who have recently moved, and tracking down up-to-date addresses for participants with undeliverable addresses. See *Sections 7.1.2.1 – Running Monthly Follow-up Reports from WHIX, Section 9.1.6 – Maintaining Complete and Deliverable Participant Addresses*, and *Section 9.2.3 – Updating Addresses for Undeliverable Newsletters.*

FCs are also encouraged to develop a system for tracking contacts and progress with "retention challenges", e.g., using the *Form 24 – Retention Worksheet* and *WHIX1238 – Member Retention Activity Tracking Report* (see *Section 9.3.3 – Documenting and Tracking Special Activities for Follow-up Retention Challenges*).

9.1.6 Maintaining Complete and Deliverable Participant Addresses

When a participant's address is found to be no longer valid (either by the Clinical Coordinating Center [CCC] or the FC), the undeliverable address should be flagged on the participant's member screen and activities should be initiated to establish the participant's new address (see *Section 9.4 – Locating "Hard to Find"*

Participants). Each month, FCs should run *WHIX0611 – Address Problems* to help maintain up-to-date and deliverable addresses in WHIX (see *Sections 10 – Data Management* for information on running these reports).

This report provides a list of all participants (or their proxies) with undeliverable addresses (indicated by the undeliverable address flag) in the FC's database. The report does not include those with participation status of "deceased, "no follow-up", or "absolutely no contact". Items that may appear on the report are the participant's name and (undeliverable) address; participant ID; home phone; work phone; a note indicating that the workplace should not be contacted, if applicable; best time to call; phone of other contact; follow-up status; and date the undeliverable address flag was turned on.

This report also provides a list of all participants with a problem address (e.g., the address is incomplete or will not fit on a mailing label). Participants with address lines that are too long should be fixed immediately by using address line 2 for the second line of the address, or abbreviating words in the first line so that it stays within the 30 character width limit of the mailing labels. Those that are incomplete should be investigated as soon as possible. If the zip code is missing, try calling the post office or, if that fails, call the participant to obtain the correct address. If you cannot fix the address right away, set the undeliverable address flag on the "Contact Information Screen" in WHIX. This will prevent follow-up mailings and participant newsletters from being sent to an undeliverable address. Try to fix incomplete addresses within two weeks of their appearance on the report. Participants will continue to appear on this report until either the address has been fixed or the "undeliverable address" flag has been set.

For participants appearing on this report, attempt to correct the address by contacting the participant at home and, if necessary, at work. If these attempts fail, telephone her personal contacts using information listed on the report. If preliminary attempts to contact the participant fail, initiate a formal search to locate the participant (see *Section 9.4 –Locating Hard to Find Participants).*

Undeliverable addresses should be updated as soon as possible, since a participant will not receive any mailings until the address is fixed. The sooner you try to get an address correction, the more likely you will be successful in tracking down the participant. Undeliverable addresses should be corrected within one month of appearing on the report. Participants will continue to appear on this report until the "undeliverable address" flag has been removed or follow-up status changes.

9.1.7 Maintaining Up-to-Date Personal Information on Participants

It is important to maintain contact with participants for the full duration of the study to ensure that study results are valid and, at the very least, to ensure that vital status (dead or alive) is known on each participant at the end of the study. The task of maintaining contact with participants will be facilitated by maintaining up-to-date personal information in each participant's file. It is important to confirm during follow-up contacts that information on the participant's name, address, phone number, personal contact information, and health care provider is still current. This information should always be reviewed with any participant who is known to have moved. Participants should be asked to provide the name of a new proxy and/or personal contact if either the proxy or the personal contacts named at the start of the study are no longer suitable to act as contacts.

FCs should use any telephone contact (e.g., to collect follow-up data) as an opportunity to review the personal information. FCs also has the option of conducting periodic mailings of the PIU to all participants to confirm that the information on file is correct.

9.1.8 Media Relations and Handling Adverse Publicity

All sites would be well advised to pre-plan, as much as possible, their organizational response to media inquiries should a controversial announcement or event occur. Identifying spokespersons, establishing response protocols in advance, and communicating this information to all staff can help to minimize disruption. It may prove helpful to set up protocols and divide responsibilities for handling inquiries from the

press, participants, and other key audiences should the need arise. In some cases, especially when a national or study-wide response is needed, the National Institute of Health (NIH) Project Office is likely to supply talking points and a referral list of national WHI spokespersons to the FCs.

In all situations, crisis or otherwise, credibility is the key to successful media relations. With reporters, always be honest, brief, direct, and calm. Never say "no comment" and never "go off the record". Do not avoid or ignore a reporter's call. Honor deadlines. Be factual, accurate, and timely in your responses. Do not be argumentative or defensive. Cultivate positive and professional relationships with reporters and follow through appropriately. If facts or remarks end up not being accurately represented, contact the reporter immediately and politely request that the correct information be supplied to their audience. This may not always result in a retraction or a correction, but it will put the reporter on notice that you are vigilant, focused on accuracy, and willing to work with them to produce better quality stories for their audiences.

Whenever you are representing WHI on a national level, make sure that your comments apply to the study as a whole, and not to just your own FC. Information that is not accurate for the study nation-wide can generate a lot of work for other centers who may then have to spend time responding to participant inquiries and clearing up misconceptions resulting from the interview or story.

9.2 Participant Newsletter

All participants receive a trial-wide WHI newsletter (*WHI Matters*) once a year during approximately the sixth month after the anniversary of their enrollment month. The goal of the participant newsletter is to present news about WHI in an interesting and readable fashion, to encourage retention of study participants, and to promote participant identification with WHI as an important, national research effort. The newsletter is also useful in keeping up-to-date addresses for participants. All participants, unless otherwise requested, receive the newsletters at their home addresses. Field Centers are responsible for documenting on *Form 9 – Participation Status* those participants who request to be deleted from the newsletter mailing list.

9.2.1 Production and Distribution

The CCC is responsible for the production and distribution of the annual newsletters, including content, design, layout, graphics, production costs, and coordination of printing through the Government Printing Office (GPO). Staff members at the CCC or any of the FCs are welcome to contribute ideas or articles for consideration.

9.2.2 Content

Newsletters include both project-specific and general health-related information in the following general content areas:

- Information from the WHI Director at the NIH describing the progress and importance of the WHI.
- Articles on relevant health topics.
- Description of overall progress on study activities.
- Features and interviews of WHI participants.

The following guidelines are to be followed for all newsletter submissions:

- Articles should be written at a 6th grade reading level; a slightly higher level may be acceptable for more complex articles, such as science or health articles.
- Original sources for articles, such as articles reporting the results of scientific research, will be carefully consulted for technical accuracy and kept on file at the CCC.
- When quoting an individual, the interviewer must ask the individual for permission to quote him or her. Quotes must be used verbatim, with quotation marks. Quotation marks are not used unless a direct quote is cited.
- If quotations are used from sources such as magazines, journal articles, or books, permission must be obtained from the publisher. This information is cited at the end of the article (for example: used with permission, name of source, date). When contacting a source to obtain permission, be sure to identify

yourself as a non-profit research organization; permission will usually be granted without a fee. When reprinting cartoons, permission must be obtained from the syndicate that represents the cartoonist.

The newsletter staff at the CCC make initial discretionary decisions regarding newsletter content, appropriateness of articles, readability level, layout, and emphasis in coverage. Before printing, a draft of the newsletter is sent to the Project Office and Executive Committee for final approval.

9.2.3 Updating Addresses for Undeliverable Newsletters

One purpose of the participant newsletter is to make sure that the address is current for each participant. A mailing label for each participant's newsletter is generated at the CCC based on the address listed on the Personal Information Screen in WHIX. When the address on the mailing label is incorrect and the newsletter is not deliverable, the local Post Office will notify the CCC. This notification is in the form of a photocopy of the mailing portion of the newsletter, along with address correction information (because newsletters are mailed bulk rate, undeliverable newsletters are neither returned nor forwarded to the new address). The CCC is charged for each notification of an undeliverable address ($.70 per address as of 6/05). The CCC will update the contact information screen in WHIX immediately when an address correction notification is received to ensure that future mailings are sent to the correct address and to avoid additional postal charges. A Personal Information Update will automatically be sent by the CCC to the participant's new address, in case any of the contact information has changed.

If a participant has a changed address, the Post Office does not forward the newsletter. The CCC will send another newsletter to the participant when a change of address is provided.

If address correction information is not available (i.e., "forwarding address unknown"), the CCC will set the undeliverable address flag on the "Contact Information Screen" in WHIX. Participants with an undeliverable address will appear on the *Address Problems (WHIX0611)* the next time it is produced (see *Section 9.1.6 – Maintaining Complete and Deliverable Participant Addresses*). FCs should immediately initiate procedures to locate the participant. Try to contact the participant and, if necessary, telephone her personal contacts using information listed on *Form 20 – Personal Information* to get an updated address. If preliminary attempts to contact her fail, initiate a formal search to locate the participant (see *Section 9.4 – Locating Hard to Find Participants).*

If the Post Office indicates that the participant is deceased, the CCC will initiate a *Form 120 – Initial Notification of Death* and contact the FC. The FC should take steps to confirm the death and, if confirmed, process according to procedures outlined in *Section 8 – Outcomes.*

9.3 Field Center Activities for Retention Challenges

Field Centers are required to initiate special retention activities for those participants identified as "retention challenges". A participant is considered to be a "retention challenge" if she is no longer willing to fully participate in follow-up activities. Participants who refuse follow-up contacts are considered to be retention challenges, as are those who do not complete their forms without actually refusing to participate. Both types of follow-up retention challenges require special retention activities.

A participant's follow-up participation status is the degree to which she is willing to participate in follow-up activities. Before changing a participant's follow-up status, FC staff should conduct special retention activities to try to reverse the participant's decision to reduce participation. Follow-up status should be negotiated directly with the participant. A participant who decides to reduce her participation level can usually continue to participate at some level, e.g., she may refuse to complete forms by mail but be willing to complete them by telephone.

Refer to *Section 9.5 – Changes in Participant Status* and *Form 9 – Participation Status* for information about changing participation status.

9.3.1 Identifying Retention Challenges

Most participants will perform their WHI follow-up activities as planned with no retention difficulties. Some participants, however, will want to reduce or eliminate their follow-up participation status due to a variety of reasons. A participant becomes a follow-up retention challenge and requires special activities when she is unwilling to participate in follow-up activities, including phone calls or mailings. These retention challenges need more attention and motivation strategies from FC staff.

Try to identify participants who are retention challenges before they are lost to follow-up or decide to drop out of the study. Regularly review WHIX reports that may identify challenges, such as *WHIX1206 – Enrolled Members Needing FC Follow-up*, and initiate special activities as soon as possible. See *Section 7.1.2.2 – FC Data Collection for Non-Respondents to Mailings* for procedures on initiating contact with participants who have not responded to data collection attempts by mail.

9.3.2 Initiating Special Activities for Follow-up Retention Challenges

When a participant has been identified as a follow-up retention challenge, initiate any special retention activities available to help keep her on full follow-up. The FC should develop its own list of possible special retention activities that fit within the FC budget, preferences, and judgments. Try different activities for each participant, depending on previous experience with the participant and with her particular problems. In addition to the special activities described below, refer to *Table 9.2 – Reasons for Poor Retention* to help better understand some of the reasons participants may have with staying in the study, and *Table 9.3 – Examples of Retention Strategies.*

When speaking with a retention challenge, reinforce the importance of WHI and our appreciation for her contributions to date. Remind her that her contribution is valuable and that every person's information will be necessary to reach the goals of WHI. Negotiate any level of activity she is willing to do – some activity is better than no activity.

It is at the FC's discretion to decide whether or not to complete retention activities in specific situations or for certain women. For example, when a woman says she is too ill to continue in WHI, the FC should decide whether or not to conduct retention activities, depending on the type and severity of her illness and other factors.

Participants who say they want to become inactive often change their minds after a "cooling off" period, so waiting for a few weeks or more may be appropriate. If a participant indicates that she wants no further contact with WHI, retention activities should be put on hold for a few months. After this period, FC staff may attempt to dissuade her from inactivation. Each FC should develop a system for tracking participants during this period.

If you are unable to convince the participant to continue as a full participant, keep open the possibility of future contact. Say "I'll be calling you every so often to see how you are doing", if appropriate. Never close the door to a future contact opportunity. Encourage the participant to take a break from the study and that you'll get back to her at a later time. Try to find ways to maintain period contact with participants: send postcards or call her occasionally to let her know you're interested.

9.3.3 Documenting and Tracking Special Activities for Follow-up Retention Challenges

When a contact has been made to conduct special retention activities with a participant who has a retention problem, complete and data enter a *Form 24 – Retention Worksheet* to help document and track activities (refer to *Appendix A – Forms, Instructions for Form 24 – Retention Worksheet)*. This optional worksheet can be helpful by keeping track of which participants have received contacts, recording the result of the contacts, and identifying participants needing further retention assistance. If additional retention contacts are needed following the initial contact, complete the "recontact date" portion of *Form 24*. The names of participants

needing additional contact, as indicated on *Form 24*, will then appear on the *Member Retention Activity Tracking Report (WHIX1238)* to help CCs keep track of the need for and timing of additional contacts.

A new *Form 24* should be completed for each special retention activity. Note that *Form 24* is for special activities that occur between participants with retention problems and the FC contact; *Form 24* does **not** need to be completed for routine retention activities.

Although use of *Form 24* is optional, its use is strongly encouraged as a way to help track activities, especially by FCs who do not have other retention activity procedures and tracking systems in place. Note that there is not a "right" or "wrong" way to use *Form 24*. FCs should use the form in whatever way it is most useful in helping them track retention activities.

Keep detailed progress notes and flag charts of participants who, through their comments or actions, suggest a possible future problem with retention. For example, if *Form 24* is used, keep a copy with detailed notes in the chart, along with some type of sticker on the outside that indicates that this woman has retention challenges. Have the participant's chart in front of you when you talk with her on the phone. With the chart readily at hand, staff can easily document appropriate progress notes that can be useful in future contacts.

9.3.4 Ending Special Activities for Follow-Up Retention Challenges

Special activities may be discontinued when one of the following occurs:

- The participant agrees to some level of follow-up participation.
- The participant requests no further contact from WHI.

If at the end of special activities, the participant's follow-up status has changed (e.g., activities have failed and she requests "no-follow-up" or less than full follow-up), complete *Form 9 - Participation Status* to indicate the change. See *Section 9.5 - Changing Follow-up Status* for guidelines and procedures on changing follow up status.

If a participant cannot be located, initiate a search to determine her current location (see *Section 9.4 – Initiating a Search to Locate Participants [Form 23]*).

9.3.5 Re-Contacting Non-Participants Occasionally

Contact participants with less than full participation status at least once a year throughout the study to see if they are willing to resume some or all aspects of their participation (see *Section 9.5.3 – Reactivation of Participants with Changes in Participation Status*).

9.4 Locating "Hard to Find" Participants

The term "hard to find" is used to designate a participant the FC has lost contact with and is searching for.

9.4.1 Initiating a Search to Locate Participant (*Form 23*)

If at any stage in the study a WHI participant misses a scheduled contact for an unknown reason, it is important for the FC to re-establish contact with the participant as soon as possible to ensure that the participant does not become lost to follow-up.

A search to locate the participant should be initiated in any of the following circumstances:

- A participant fails to respond to mailed questionnaires and FC staff cannot make contact with the participant either by phone or by mail.
- Mail sent to the participant has been returned to the CC because the participant is no longer at the address (and an updated address is not available) and the participant cannot be contacted by phone.
- A participant is listed on *WHIX1592 – Participants Who Are Lost-to-Follow-up and Participants Requesting No Follow-up*.

A search need not be initiated if the participant is known to be away (on vacation, for example) and will be reachable at the address and phone number listed in her file at a later date. The FC staff should exercise discretion in deciding how soon after a missed contact to begin efforts to locate the participant. In general, a search should be initiated on all participants whose whereabouts have not been established once the time window for the scheduled contact has ended.

To initiate a contact search to locate the participant, complete and data enter the top part of *Form 23 – Search to Locate Participant*.

9.4.2 Strategies to Locate "Hard to Find" Participants

FCs should develop their own forms and procedures for tracking attempts to locate participants once a *Form 23 – Search to Locate Participant* has been initiated. For a list of participants with "open" *Form 23*s, run *WHIX1237 – Call List for Form 23 – Search to Locate Lost Participant*. A record of attempts to locate the participant should be kept in her file (refer to *Figure 9.1 – Sample Form to Track Contact Attempts* for a sample form to keep track of contact attempts). Refer to *Form 23* for procedures on locating the participant and use it to record which steps have been taken to locate her.

The range of strategies used to trace participants, the sequence and frequency in which tracing attempts are carried out, and the amount of effort expended in locating hard to find participants should be decided by each FC, depending on local circumstances and accessibility of useful sources of information. However, all FCs are required to meet the overall retention goals (refer to *Section 11 – Quality Assurance* for retention goals).

In the process of tracing a participant, try to avoid inconveniencing persons from whom information is requested. Be particularly sensitive when making contact with personal contacts of the participant if it is suspected that she may be "hard to find" because she has died.

The following strategies may be used to trace missing participants:

- Attempt to contact the participant by phone. Repeat attempts on several occasions on different days and at different times of day, including evenings and weekends. If the participant is employed, try her work number as well as her home number. If the participant is not in, leave a message for her to call the clinic with the person who answers the phone or on the answering machine. If there is no answer after several attempts, the participant may be away on vacation; try again a few weeks later.
- If the participant's phone number has changed, try to obtain her new number from the phone book, directory assistance, or by using a reverse directory (e.g., Polk, Coles). If the participant has changed to an unlisted phone number, you may request that a supervisor from directory assistance contact the participant and ask her to call the FC. You can also try reverse telephone number assistance offered through directory assistance. For unlisted numbers, this service allows you to request the operator leave a message at the residence (for a fee).
- Attempt to contact the participant by mail. Send her a letter with "Address Correction Requested" printed on the envelope (check with the Post Office for the current appropriate terminology), requesting that she contact the FC.
- If the above is unsuccessful, send a Federal Express or certified letter to the participant's last known address requesting that she contact the FC. Using the restricted delivery option will ensure that the participant is the one who signs for and receives the letter.
- Contact personal contacts and medical care providers named in *Form 20 – Personal Information* by phone or by mail in order to obtain updated address and phone number information on the participant, and to confirm that she is not deceased.
- If attempts at contacting personal contacts and the physician are unsuccessful, try contacting neighbors or the current resident at the participant's last known address (using reverse directories).

- Try using people-finder search engines on the internet. See the WHI Staff home page of the website for a list of search sites.
- If the address correction information has expired, try contacting the Post Office to determine if they have a record of the forwarding address.
- Check with state and local public agencies, as appropriate, including: state death records, local cancer registries (e.g., SEER), State Department of Motor Vehicles, local Social Security Office, and local voter registration records.

9.4.3 Ending the Search to Locate Participant

The search to locate the participant should continue until one of the following has occurred:

- you have contacted the participant;
- you have obtained updated phone number and/or address information;
- you have discovered that she is deceased;
- repeated attempts to contact the participant and her personal contacts using all strategies have been exhausted and you have failed to reach the participant, receive updated phone/address information, or determine that she is deceased.

This last criterion for ending a search will only apply once attempts to contact the participant have been repeated at intervals over a 6 month time period. When you have exhausted reasonably accessible avenues of inquiry for locating lost participants, close out *Form 23 – Search to Locate Participant* by indicating the search result status. Enter the date that the search is ended and the result of the search on *Form 23,* and data enter the form in WHIX to close out the search.

<u>If the participant is found</u>:

If search attempts yield updated address or phone information, update the member screen in WHIX.

Once contact is made with the "hard to find" participant and/or you have updated phone/mail information, data on missing forms should be collected, especially the *Form 33 – Medical History Update*. Once collected, the forms should be data entered immediately to prevent additional forms from being mailed by the CCC. If upon re-establishing contact with the participant, she states that she is no longer willing to maintain full participation status in the study, begin retention activities.

If the participant is found to have moved to an address far from the FC, follow-up by mail and phone should still continue.

If search attempts yield information that the participant has died since the last contact, complete *Form 120 – Initial Notification of Death*, and process according to procedures outlined in *Section 8 – Outcomes.*

<u>If the participant is not found</u>:

Start a new *Form 23* to conduct a search at least once every twelve months for those participants who continue to be "lost".

The CCC will routinely request searches of the National Death Index for all participants with follow-up status "lost to follow-up" (see *Section 9.4.5 – Searches of the National Death Index*).

9.4.4 Procedures for Study-Wide Vital Status Ascertainment

A. Definition of Vital Status

A participant's vital status is considered to be one of the three following categories: known to be alive, deceased, or lost-to-follow-up.

Deceased is defined as follows:

- *Form 120 – Initial Report of Death* or *Form 124 – Final Report of Death* completed.

- Known to be Alive is defined as follows and at least one of the following has happened:
  - a *Form 33* in the last 24 months, or
  - a *Form 23* in the last 12 months, with Item 4-Search Result, code 1 – "participant has been located" marked.

WHIX automatically updates the participant's follow-up status to "lost-to-follow-up" as long as the participant is not "no follow-up" or "absolutely no contact." Names appear on *WHIX1591* under the following circumstances:

- Either no *Form 33* within 24 months or no *Form 23* with "found" box marked within 12 months..
- "No follow-up" participants, when they meet the criteria for "lost" above. However, to ensure that participants do not fall off of reports, follow-up status remains "no follow-up."

Note: Participants with "no follow-up" status are only contacted/searched for annually.

Participants' names will not appear on *WHIX1591* under these circumstances:

- *Form 120 – Initial Report of Death* and/or *Form 124 – Final Report of Death* have been data entered.
- Participants with "absolutely no contact" status.

Note: The lack of *Form 33* drives the definition of lost-to-follow-up. It is possible a participant has completed other forms in the previous 24 months, excluding *Form 33*. By definition, this participant will be included on *WHIX1591 – Participants Who Are Lost-to-Follow-up and Participants Requesting No Follow-up* because outcomes data are missing. For this reason, FCs should make every effort to collect the medical information on *Form 33* each time they have a routine contact with a participant.

B. Procedures

1. Participants Who Are Lost-to-Follow-up (*WHIX1591*)

WHIX1591 – Participants Who Are Lost-to-Follow-up and Participants Requesting No Follow-up, lists all participants defined as Lost-to-Follow-Up (as defined in "Definition of Vital Status" above). The report includes the participant's ID, name, current vital status, last *Form 33* received date, last *Form 9 – Participation Status* and *23 – Search to Locate Participant* information, and prior follow-up status. For each participant listed on the report, FCs are required to conduct a search to locate the participant.

WHIX1591 – Participants Who Are Lost-to-Follow-up and Participants Requesting No Follow-up also includes participants who have a current follow-up status of "no follow-up," since Vital Status ascertainment needs to periodically occur for these women as well.

2. Conducting a search using *WHIX1591 – Participants Who Are Lost-to-follow-up and Participants Requesting No Follow-up*

For each participant listed on the *WHIX1591*, complete a search to locate the participant. The search to locate participant should include:

- Review of the participant's chart, including verification of phone number and retention documentation before making a contact.
- Review of *Section 9 – Retention*, for a comprehensive review of retention strategies.

In general, use a six-month time period as a guideline for the search duration. For future searches, make every effort to conclude in time for the Observational Study Monitoring Board (OSMB) database freezes. (Notification of freeze dates is sent by the CCC.) However, do not compromise the search--if the search is on-going, do not close the search out. Continue to search until all sources are exhausted before you complete *Form 23* and close out the search.

3. Document search results on *Form 23 - Search to Locate Participant*.

Complete the forms based on the search results, as follows:

a. If participant has been in contact with the clinic in the last 24 months:
- Document the contact information on *Form 23*:
  - Record the date you spoke or had contact with participant in Item 1-Initiation date;
  - Enter the current date in Item 4 – Date Search Ended.
  - Complete the rest of the form as appropriate.

b. If FC is in the process of searching for a participant:
- Document the contact information on *Form 23*;
- Attach documentation of the search to the *Form 23*;
- Indicate the date you began the search in Item 2 - Initiation date on *Form 23* and continue searching for participant;
- When the search is complete, record the search results and complete Items 4-6 – Date Search Ended, Search Ended By, and Search Result.

c. If participant is located (includes a participant who is deceased):
- Document search on *Form 23 – Search to Locate Participant*;
- Complete rest of *Form 23*. Mark code 1 – "Participant has been located." in Item 6 – Search Result. If participant is deceased, also complete *Form 120 – Initial Report of Death* and ask a proxy to complete *Form 33*, if possible;
- Update *Form 9* to change a participant's follow-up status by using the "prior status" listed on *WHIX1591* unless a new follow-up status is negotiated directly with the participant.

Note: If a participant listed on the report completes a *Form 33*:
- and you have not initiated a *Form 23*, you are not required to complete *Form 23*.
- if you have initiated a *Form 23*, you must complete the *Form 23* and data enter it to close out the search, regardless of whether or not the participant completed a *Form 33*.

d. Participant is not located:
- Document sear*-ch on *Form 23*;
- Complete rest of *Form 23*. Mark code 4 – "The participant could not be located" in Item 6-Search Result.

4. Document changes in participant follow-up status on *Form 9* – *Participation Status*, if appropriate.

For any participant listed on *WHIX1591*, you need to update the participant's follow-up status on *Form 9*, if:

- participant completes a *Form 33*, or
- you complete a *Form 23*, marking code 1 – "participant has been located" in Item 6 – Search Results."

Note: If the participant was previously on "no follow-up," it is not necessary to change the follow-up status unless she indicates that she wants to change (i.e., resume or increase her study participation).

For participants who appear on *WHIX1591* who have a follow-up status set to "lost-to-follow-up," based on the criteria described in *B.1. Participants Who Are Lost-to-Follow-up* above:

- When you find the participant alive (i.e., collect a *Form 33* or indicate "participant has been located" on *Form 23*), you need to change the follow-up status from "lost-to-follow-up" to her prior status listed on *WHIX1591* unless a new follow-up status is negotiated directly with the participant. To do this, complete *Form 9*, indicating if the participant is on full, partial, custom, or no follow-up.
- When you find the participant is deceased, do not update her follow-up status on *Form 9*. Instead complete *Form 120 – Initial Notification of Death.*

5. **Data enter the *Form 23, Form 9* and *Form 33* before the OSMB database freeze dates, when possible.**

9.4.5 Searches of the National Death Index (NDI)

For participants with follow-up status "lost-to-follow-up", the CCC will periodically send in requests to search the National Death Index (NDI) to the National Center for Health Statistics, in order to determine whether "lost" participants have died since the date of last contact with the CC.

The information required for requesting searches of the NDI is abstracted from the WHIX database by the CCC. In order to maximize the chance of a valid match and to minimize the chance of a false match being made, it is important to have as complete and accurate information as possible in the WHIX database on items used in searches of the NDI. The following information is used when requesting NDI searches:

- Full name of the participant including first name, middle initial, and last name
- Maiden name (or father's surname)
- Social Security Number
- Date of birth
- Sex
- Race
- Marital Status
- Last known state of residence
- Age at death (estimate) or age when the participant was last known to be alive, based on FC records. The CCC will inform CCs of the results of NDI searches once they are available. If a search yields information that a participant has died, the FC will then be responsible for completing *Form 120 – Initial Notification of Death* and processing according to procedures outlined in *Section 8.5 – Fatal Events – Special Considerations.*

The CCC may also make use of other national sources such as the Social Security Administration, Health Care Financing Administration (Medicare), US Post Office National Change of Address Tape, and credit bureaus to ascertain the vital status and/or updated address information of participants who are lost-to-follow-up, if resources permit.

9.5 Changes in Participation Status

Participants are assumed to be on full participation in WHI, unless a change is indicated using *Form 9 – Participation Status*. Participation status indicates the degree to which a participant is willing or able to participate in the WHI Extension Study follow-up activities. A participant changes her follow-up status if she becomes unwilling or unable to participate in full follow-up (e.g., if she refuses phone calls or mailing), if she cannot be located ("lost to follow-up"), if she has died, or if she decides to resume full follow-up after being on less than full follow-up (e.g., partial follow-up).

Participation status is used primarily to indicate what type of follow-up the participant is willing and/or able to have. Temporary changes, such as the inability to respond to one of her annual forms due to an illness or family problem, do not change her participation status. Similarly, ambiguous situations such as a participant failing to return her forms after several mailings does not change her status unless she actually states that she is no longer willing to participate.

Every effort should be made to encourage full participation throughout the study (see *Section 9.1 – General Activities*). Before a woman voluntarily changes status, specific retention activities should be conducted (see *Section 9.3 – Field Center Activities for Retention Challenges*) to alleviate the problem(s). If full participation is not possible, it is important to maintain some form of contact. For a woman who refuses to complete forms by mail, it is important to at least get agreement to contact her by phone once a year to follow her medical history.

Participants with less than full participation status are contacted periodically to determine whether or not they are willing to resume full participation. Procedures for contacting and reactivating participants are in *Section 9.5.3 – Reactivation of Participants with Changes in Follow-up Status*. *Form 9 – Participation Status* is also used to resume those aspects of participation that were formerly limited on *Form 9 – Participation Status.*

When a participant's follow-up status changes, complete a new *Form 9 – Participation Status*. When completing the form, there is no need to complete sections on the form other than the relevant parts that indicate how and why the status has changed.

9.5.1 Changing Follow-Up Status

Follow-up status refers to the participant's ability or willingness to participate in WHI mailings and /or phone calls to complete annual forms. Below are the definitions and procedures relating to change in follow-up status.

9.5.1.1 Full Follow-Up

Use to indicate/resume full follow-up (mail and phone contact permitted).

9.5.1.2 Proxy Follow-Up

If a woman can no longer communicate, for example, due to stroke or dementia, she may, if willing, continue in the WHI through a proxy respondent. Most women have identified a proxy, who is listed on the Personal Information Screen in WHIX. If a proxy has not been identified, the order of priority for selecting a proxy respondent is: 1) spouse or partner; 2) nearest relative; 3) friend; 4) physician. If a participant requests proxy follow-up, indicate "proxy follow-up" on *Form 9 – Participation Status* and identify the name, relationship, address, and phone number of the proxy, as well as the reason the participant is on proxy follow-up. If applicable, check the appropriate box to indicate either no phone calls or no mailings.

9.5.1.3 Partial or Custom Follow-Up

Partial or custom follow-up means that the woman is not able or willing to continue receiving either mail or phone, but is willing to receive the other (e.g., she will complete forms by phone but not by mail).

9.5.1.4 No Follow-Up

"No follow-up" status is used when a participant wants no follow-up (no phone and no mail contact), and retention activities have failed. Retention activities must be conducted before changing status to no follow-up. Only participants who verbally refuse follow-up should be classified as no follow-up. Failure to participate (i.e., consistent failure to complete and return the mailed forms) should not be used to classify a participant as no follow-up.

Contact no follow-up participants periodically to see if they are willing to resume contact. When a participant specifically states that she will not tolerate further contacts, change her status to "absolutely no contact" and do not attempt further contacts.

9.5.1.5 Absolutely No Contact

WHI women, even those currently classified as "no follow-up," should be periodically contacted so that they may reconsider participation in follow-up activities. "Absolutely no contact" means a woman should never again be contacted about participating in follow-up activities. This classification should be reserved for women who are hostile to WHI and unlikely to change. This classification requires PI approval.

9.5.1.6 Lost to Follow-Up

A participant automatically becomes lost-to-follow-up when a *Form 33 – Medical History Update* has not been data entered in WHIX for at least 24 months and a *Form 23* has not been entered in the past 12 months.

See *Section* 9.*4 – Locating "Hard to Find" Participants* and *Form 23 – Search to Locate Participant.*

9.5.1.7 Deceased

When a woman has died and a *Form 120 – Initial Notification of Death* has been data entered, WHIX will automatically change her participation status to "deceased". See *Section 8 – Outcomes* for the remaining procedures.

9.5.2 General Steps in Changing Participation Status

The initial indications that a participant wants to or should change participation status can come from a number of sources: the participant, a family member, or FC staff. The general steps are:

- Identify the problem — What aspects of the participant's WHI participation does the participant or FC staff want to change? What are the reasons?
- Determine if retention activities need to begin by evaluating if this is a temporary problem or an ongoing one. If ongoing, conduct retention activities as described in *Section 9.3 – Field Center Activities for Retention Challenges.* If, following the retention efforts, the participant still requires a change in participation status, thank her for her WHI activity to date and complete *Form 9 - Participation Status.*
- Determine if a search for a lost participant is needed. If so, complete and data enter a *Form 23 – Search to Locate Participant* as described in *9.4 – Locating Hard to Find Participants*.

As noted above, when a problem with participation status has been identified, one of three forms may be used: *Form 23 – Search to Locate Participant* (upper part), *Form 24 – Retention Worksheet* or *Form 9 – Participation Status*. In this way, those women with less than full participation status can be tracked.

9.5.3 Reactivation of Participants with Changes in Participation Status

Reactivation is the procedure by which participants who have changed their follow-up status are re-contacted to increase their follow-up activity and/or to obtain follow-up information. The purpose of reactivation is to:

- Return participants to their routine follow-up schedules
- Resume some form of follow-up contact for participants who have previously elected to have no follow-up or who have been lost to follow-up

All enrolled participants will be included in data analysis; ensuring that WHI participants continue appropriate follow-up contacts is important. Thus, participants who change their follow-up status will be allowed, and even encouraged, to return to active participation in the study whenever feasible.

9.5.3.1 Eligibility for Reactivation

All participants who have less than full follow-up status are eligible for reactivation of activities. Participants on less than full follow-up status should be contacted periodically by mail or phone to see if they would be interested in resuming follow-up activities. Do not contact participants for reactivation if they have elected "no follow-up" until at least one year has passed since their last contact. You may reactivate these participants, however, if they initiate the process and are otherwise eligible.

When a participant changes her follow-up status, the FC staff can note the reasons for the change on *Form 9 – Participation Status*. Use this information and any other information available from the participant's file to determine whether it is appropriate to encourage reactivation. For future reference, mark the charts of no-contact participants indicating whether they are eligible for reactivation.

9.5.3.2 Reactivation From No Follow-Up Status

When a participant, who has previously requested no follow-up, shows interest in returning to the study, schedule reactivation as soon as possible. Do not wait for the next usual contact window.

- For a participant who has had no phone or mail contact for one year or more, schedule a telephone appointment to complete a *Form 33 – Medical History Update*, as soon as possible. Following reactivation, she will resume her normal follow-up schedule.
- Ask the participant, "*Do you have any questions that I can answer now?"* Encourage her to call if she has any questions before the telephone appointment. Give the FC phone number to the participant.
- Thank the participant for her time, tell her that you enjoyed talking with her and that you hope she participates in future follow-up activities.

9.5.3.2.1 Reactivation From "No Phone" Contacts

If a participant calls or writes to indicate that she might be interested in resuming phone contacts, discuss the possibility with her by phone and ask if her concerns have changed since she requested the "no phone" contact. If she agrees that phone contact is now okay, complete a *Form 9 – Participation Status* to indicate the change in her status.

9.5.3.2.2 Reactivation From "No Mail" Contact

If a participant indicates that she might be interested in resuming mailed contacts, discuss the possibility with her by phone and ask if her concerns have changed since she requested the "no mail" contact. If she agrees that mailings are now okay, complete a *Form 9 – Participation Status* to indicate the change in her status.

9.5.3.2.3 Reactivation From Proxy Follow-up

If a participant or her proxy indicate that proxy follow-up is no longer needed (e.g., she recovers from an illness that prevented her from completing the forms), complete a *Form 9 – Participation Status* to indicate the change in her status.

Figure 9.1
Sample Form to Track Contact Attempts

1. Phone calls to the participant:

Phone Number	Date	Home or Work?	Time of Day	Outcome

2. Mailings to participant:

Date of Mailing	Details (what was mailed)?	Outcome

3. Phone calls to personal contacts

Name of first contact: _____

Phone Number	Date	Time of Day	Outcome

Figure 9.1 (continued)

Phone calls to personal contacts

Name of second contact: _____

Phone Number	Date	Time of Day	Outcome

4. Phone calls to participant's personal health care provider:

Name of health care provider: _____

Phone Number	Date	Time of Day	Outcome

Table 9.1
Summary of Retention Activities

Ongoing Retention Activities - All Participants
Participant/Staff Relations • Use FC staff with good interviewing skills when making phone contacts • Make sure interactions are always pleasant and reassuring • Give clear and consistent instructions
Participant Materials • Include logo and catch-phrase on recruitment and retention materials • Use at least 12-point font and sufficient white space • Make materials attractive and appealing • Make materials clear, consistent, and understandable • Prepare written materials at a 6th grade reading level • Spell and grammar check materials • Provide clear, easy-to-follow instructions for completing activities • Provide phone number and contact name in case participant has questions
Enrollment • Conduct thorough informed consent discussions • Provide enrollment packet that describes study expectations and FC contact information
Follow-up Contacts • Contact participants who are difficult to reach at several different times and days • Encourage some participation, even if participant is unwilling to stay on full follow-up • Initiate special retention activities for participants who are difficult to schedule for contacts • Mail out a friendly postcard annually to participants who have requested "no follow-up" (but not to those who have requested "absolutely no contact") • Try to get participants who miss follow-up contacts back on schedule as soon as possible • Encourage proxy contact if participant dies or becomes ill • Send Birthday, thank you, anniversary, bereavement, holiday cards (optional) • Annual participant newsletter mailed by CCC
Maintaining Up-To-Date Addresses • Maintain deliverable addresses in WHIX (run *WHIX0611 – Address Problems* monthly and correct any problems) • Fix problem addresses as soon as possible; call participant or post office if necessary • Set "undeliverable address flag", if necessary

Table 9.1 (continued)

Searching for Lost Participants

- Initiate search for lost participants using *Form 23 – Search to Locate Participant* and data enter
- Conduct appropriate activities as necessary:
  - attempt to reach by phone
  - attempt to reach by mail
  - contact personal contacts
  - contact physician
  - contact other sources
- Continue to repeat attempts over a 6 month period if early attempts are unsuccessful
- Update WHIX with any new contact information (e.g., new address)
- When search is completed, indicate search result on *Form 23 – Search to Locate Participant* and data enter
- Complete *Form 9 – Participation Status* if appropriate
- Periodically re-open search for "lost-to-follow-up" participants

Procedures for Conducting Special Activities for Retention Challenges

- Regularly review reports that may indicate retention problems
- Conduct all activities necessary and appropriate to the situation
- Track activities by completing *Form 24 – Retention Worksheet*
- Complete *Form 9 – Participation Status* if appropriate

Participation Status

- Initiate retention activities, if appropriate, before changing status
- Conduct search for participant, if appropriate, before changing status
- Complete *Form 9 – Participation Status* if participant's follow-up status changes
- Periodically contact "no follow-up" participants, as appropriate, to see if they are willing to change status

Follow-up of Non-Respondents (See *Section 7 – Follow-up Contacts*)

- Run *WHIX1206 – Enrolled Members Needing CC Follow-Up* monthly for list of non-respondents requiring FC telephone data collection
- Make telephone contact to ascertain correct address and collect *Form 33 – Medical History Update*
- Update address in WHIX, as appropriate
- Collect data from proxy, if participant is deceased, unable to communicate, has poor cognitive functioning
- Complete *Form 9 – Participant Status* if participant, as appropriate (e.g., if participant is deceased)

Table 9.2
Reasons for Poor Retention

Interactions between participants and study staff are critical to maintaining or regaining retention and performance. During these interactions, staff may discover the participant's reasons for wanting to change her participation status, or for lack of response to the mailed questionnaires. Learning the reasons for wanting the change may help you determine your strategy to help keep the participant in the study. Some common reasons are:	
Lack of Knowledge	The participants may not have the knowledge necessary to fully participate. Participants forget instructions and may not remember what to do if something goes differently from the standard procedures. Participants may also change their behavior based on incorrect knowledge.
Lack of Long-Term Cues	The participant may drift from the study because of infrequent contact, or no recall as to why she joined in the first place.
Lack of Skills	The participant may not have the necessary skills to complete the forms. For example, memory skills are critical to completing information about health outcomes. They may also suffer from loss of vision and/or hearing. Participants need to feel comfortable calling the FC to ask questions and to report problems. Make it clear that calling is appropriate and not a burden.
General Health Issues	A participant's health may deteriorate over the course of the study, which may change her priorities. Or, she may think that her participation is not needed, now that her health is declining.
Environmental Issues	The participant's environment may not be supportive of or may actively discourage full participation. Changes in home and family priorities, lack of time, logistical difficulties, unemployment, financial needs, stress, and other life changes may interfere with retention. There may be a lack of support from family or a feeling that their participation doesn't contribute to science or the good of others.
Life Events	Often life events may occur that can get the participant off the track and she may forget to complete her study forms. These types of events tend to be more episodic than environmental issues.

Table 9.3
Examples of Retention Strategies

The following is a list of strategies that FC staff may use in an attempt to keep the participant fully participating. Use any strategies that seem appropriate. None of the activities are required and FC staff is encouraged to design their own activities.

- Initiate contacts with the participant:

  Emphasize the participant's important personal contribution to WHI: Make participant feel important and valuable to the study.

  Describe the scope and significance of WHI: Review the WHI goals and participant's contribution to goals.

  Emphasize the importance of participant: Remind participants of early commitment and consent.

  Remind the participant that WHI is research, not health care: Remind participants to see a primary care provider.

  Express appreciation for the participant's effort in the project so far: Thank participant at every opportunity.

  Ask participant to discuss study participation with family or friends: Encourage participant to tell others of her commitment to WHI.

  Invite the participant to talk with FC Staff or PI about questions/concerns: Schedule a time for participant to discuss with the Principal Investigator.

  Ask if the participant wants the Principle Investigator to talk with her personal physician: Schedule the Principle Investigator to call the participant's health care provider.

  Discuss barriers to participation and help find ways to reduce: Brainstorm with the participant to address barriers.

  Anticipate and reduce negative effects of retention: Probe for negative effects, such as barriers, time factors. Help the participant find ways to reduce these difficulties.

- Discuss alternatives to make participation easier:

  Help with filling out form: Provide assistance by telephone, if needed.

  Offer telephone only contact substitution (as last resort): Offer to collect data over the telephone, if possible.

  Review instructions for required activities: Make sure the participant clearly understands what is expected of her and that she isn't dropping out due to confusion or frustration.

- Give informational materials/referrals:

  Disease prevention literature: Provide participant with relevant information about some of the diseases being studied in WHI, as well as other prevention literature (e.g., quitting smoking), as appropriate.

  Disease etiology literature: Provide participant with any available interesting and relevant literature on the causes and prevention of disease.

  Tip sheets and other health information: Provide any general health information or information specific to successful WHI participation, as available and appropriate.

  Health care referrals: Provide participant with a list of other health care referrals, if appropriate, to help address her health concerns, even those not related to WHI (e.g., referrals for domestic abuse, smoking cessation, etc.).

  Physician letter: Provide participant with letters of support from physicians or other health care providers in the community. Or, give her a letter to take to her own physician explaining WHI and have her discuss her participation with him/her, appropriate.

Section 9
Retention

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Section 10

Data Management

Introduction

The Women's Health Initiative (WHI) Extension Study computerized database and data management system (WHIX), is designed around personal computers (PCs). The equipment and software are standardized at each site. This uniformity simplifies the development, installation, and support of the system.

At each Field Center (FC), one or more dedicated PCs connect to WHIX on a virtual private network via the Internet. The study database resides behind a secure and access-limited website. The Clinical Coordinating Center (CCC) is responsible for setting up and maintaining each PC as well as the WHI-Operations website and the WHIX database. The CCC supports, maintains, and creates tape back-ups for the WHIX Central Database. The CCC also provides training for the FC Staff on its use.

Each FC uses the central database, WHIX, to capture and manage WHI Extension Study data. Participant data is entered into the database at the CCC and the FC. Data is entered by traditional key-entry and mark-sense scanning. Each FC can produce reports for site-specific data using a menu of pre-programmed reports. Each WHIX PC can be used for any of these functions except mark-sense scanning. Scanning is done at the CCC only. FCs can determine the best location of each PC based on their own needs. The WHI Operations website (including WHI e-mail) can be accessed from any PC with internet access. However, any PC that runs WHIX must be located at the FC.

Data from all FCs are maintained in a central database (WHIX) at the CCC. The FC identifier is retained on all data so that analyses and reports can be generated by the FC. Participant forms such as *Form 33 – Medical History Update* and *Form 150 – Hormone Use Update* are scanned into the central database at the CCC. FCs enter forms such as *Form 33D – Medical History Update Detail* and *Form 85 – Mammogram*. Outcomes adjudication forms are entered at the CCC.

10.1 Overview

This section describes WHI Extension Study data management procedures and the WHIX computing system including standard hardware and software, and procedures for handling WHIX data after initial data collection has been performed. It serves as the primary WHIX reference for FC staff.

- *Section 10.1 – Overview* gives an overview of the WHIX Computing System for all FC staff that will use the system. It includes a description of the user accounts and how to log on, and contains an overview of standard WHIX software. Security issues relative to PCs and the Internet are also outlined.
- *Section 10.2 – General Data System Maintenance* describes the assumed duties of the FC staff and outlines some WHIX tasks such as requesting WHIX user accounts.
- *Section 10.3 – WHIX Menu* introduces the WHIX database, and gives an overview of the menu system.
- *Section 10.4 –Member Data Entry Screen* describes the WHIX *Member Data Entry* screen where participant and encounter information is entered.
- *Section 10.5 – Data Entry* gives specific procedures for performing data entry, including key-entry from forms and entering outcomes data.
- *Section 10.6 – Outcomes* contains instructions for tracking outcomes in WHIX.
- *Section 10.7 – Queries and Reports* gives procedures for performing queries and running reports in WHIX, describes general report types available and describes how to run, view, and print reports.

10.1.1 Standard Hardware and Software

To help ensure the quality of WHIX data and to simplify the development and maintenance of the entire system study-wide, standard computer hardware and software are used at all WHIX FCs.

The CCC provides the following hardware and software to each FC:

Hardware includes:

- Pre-configured PC
- HP Laser Jet 2420dn printer
- Bar code readers (previously provided for original WHI study)
- Adapter to enable use of barcode reader gun with WHIX PC

Software includes:

- Windows XP® and Internet Explorer 6.0
- Office 2003®, which includes Word, Excel, Access and PowerPoint
- Outlook® E-mail—the WHIX e-mail system
- Windows Explorer—provides a way to manage files and folders
- WHIX—the WHI Extension database
- Current version of Adobe Acrobat® Reader (for WHIX reports)
- Ant-virus and anti-spam software.
- JInitiator, the Java runtime engine required to run WHIX.
- Ethernet
- Read-write CD player for local backup

Other features:

- On-site maintenance for PC (from vendor)
- Ghost image on CD for system recovery

10.1.1.1 Microsoft Office®

Clicking the **Start** button opens the *Start* menu and provides access to various applications, programs, system tools, Windows Explorer and more.

The **Programs** folder in the *Start* menu enables a user to locate and open an application quickly.

To start a program using the **Start** Button:

1. Click **Start**.
2. Select **Programs**.
3. Select the desired **Application**.

Notice that a variety of Microsoft applications are readily accessible through the Programs folder and that several items in the Programs folder are accessible from the Desktop.

10.1.1.2 Outlook® E-mail

Provided as a way for the CCC and FCs to communicate with one another.

10.1.1.3 Windows Explorer

Windows XP Explorer provides a way to view files or documents in a "tree" structure. A user can view the contents of any device—such as the workstation C: drive or network drives—that are connected to the computer as well as view the contents of any folder.

To open **Windows Explorer**:

1. Click on the **Windows Explorer** icon on the toolbar.

The Explorer window is divided into two "panes". The left pane displays devices and folders in a "tree structure". The right pane displays the contents of the device or folder that is selected in the left pane.

A **plus sign** (+) in front of a device or folder in the left pane indicates that the device or folder contains other folders. Click on the plus sign to expand the tree structure in the left pane and view the other folders contained in the selected device or folder. When the list is expanded, the plus sign turns to a **minus sign** (-). Click on a device or folder icon in the left pane to view its contents in the right pane.

10.1.1.4 Managing Print Jobs

To cancel or pause a print job:

1. Click the **Printers** icon to open the Printers Window.
2. **Double-click** the appropriate printer icon. A dialog box will appear displaying a list of files that have been sent to that printer.
3. **Right click** the print job you want to delete from the list of print jobs.
4. Select **Cancel Printing** to stop the printing of your document and delete the print job. Select **Pause Printing** to stop the printing of the document without deleting it from the print queue.

10.1.2 Security and Confidentiality

Confidentiality of participant data is an important concern to study operations. Data security is necessary to protect participant's right to privacy. Security measures are implemented in the computing system to protect this information. Each FC must take additional measures at their site to protect data on paper forms and to ensure the security of computer systems. The standardized system is outlined below along with the steps that each FC must implement to further protect the system.

10.1.2.1 Network and Database Accounts

Access to the WHI-ops network and the WHIX Database requires a valid user ID and password. The FC Principal Investigator (PI), Field Center Manager (CM) or Outcomes Coordinator (OC) should contact the CCC Network Administrator to request an employee ID and password for access to the network and should contact their CCC Data Liaison for access to the WHIX database.

When a WHIX account is set up, the user's study role and site is recorded in the database. This assignment determines the data and features to which the user will have access. WHIX accounts are maintained centrally at the CCC. Only one account per individual is allowed.

10.1.2.2 Computer System Access Security

To keep passwords secure, WHIX accounts will be locked after 3 unsuccessful login attempts in succession. Usernames and passwords should never be shared. If a staff member is to be absent for a period of time, arrangements should be made with the CCC for alternate staff to have access rather than sharing passwords. The CCC should be notified within 24 hours of an employee's termination so that the account can be disabled. Accounts that are inactive for more than 45 days will be automatically disabled.

Passwords should contain at least one non-alpha character, such as $robot2!. Passwords should never be written down, and should be easy to remember. WHIX passwords must adhere to the following criteria:

- Must be at least 8 characters long, starting with a letter and containing at least one number
- Should not use any word contained in English or foreign language dictionaries.
- Must not have been previously used.
- Must be changed every 3 months. (WHIX will prompt you to change your password.)

System mechanisms cannot completely prevent unauthorized access to or release of confidential information. The following steps are required to further reduce this risk:

- Have all staff who have access to participant data sign a confidentiality agreement at their FC.
- Restrict access to WHIX only to designated PCs at the FC.
- Limit access to the WHIX database to properly trained and authorized FC personnel.
- Store participant files in a secure area.
- Shred confidential documents when they are no longer needed. Documents with participant identifiers, including WHI ID numbers, may not be placed in regular trash or recycling.
- Log off any unprotected PC when leaving the area, even for short periods; log off isolated and secured PCs whenever leaving for an extended period

10.2 General Data System Maintenance

The CM and OC are responsible for overseeing the data management system at each FC. These responsibilities include:

- Training staff on proper data management procedures.
- Requesting network and WHIX accounts.
- Updating FC-specific information in WHIX.
- Notifying the CCC of problems and responding to requests from the CCC for information or data changes.

10.2.1 Employee IDs and Accounts

10.2.1.1 Network and E-Mail Accounts

Network and email accounts must be requested from the CCC network staff using the form provided on the WHI-Operations website. WHIX accounts are separate from network and email accounts; however, you must have a network account in order to have a WHIX account.

10.2.1.2 WHIX Employee IDs

Every employee who needs access to WHIX or who does work for the WHI Extension Study that gets entered in WHIX (such as interviewing participants to collect *Form 33D – Medical History Update Detail* or completing *Form 85 – Mammogram)* must have an employee ID number. Employee IDs are 5-digit numbers that are assigned by the CCC. Employees who had employee IDs in WHILMA were issued new employee IDs in WHIX if the FC requested them.

Requesting Employee IDs

The FC PI, CM or OC must contact their FC's CCC Data Liaison to request an employee ID number for an employee who does *not* need access to WHIX (employee IDs will be automatically created for employees for whom a WHIX account is requested). Include the following information in the request:

- First and last name of employee
- Start date
- FCs for which the employee will be performing work (if more than one)

10.2.1.3 WHIX Accounts

WHIX accounts are created and managed by the CCC Data Liaisons. Each WHIX account consists of a username and a confidential password. Each person using the WHIX database, even part-time and temporary employees, must have their own individual WHIX account. WHIX accounts must not be shared. FC staff is responsible for any data that is accessed, entered, changed or deleted using their account, so it's important to keep passwords confidential and not allow sharing of accounts for any reason.

WHIX passwords must be changed every 3 months. WHIX users will be prompted to change their password every 3 months, and accounts will be disabled if the password is not changed. WHIX users may change their passwords at any time using the Change Passwords feature in the *Tools* menu of the WHIX main menu screen (see *Section 10.3.4 – Change Password*).

Requesting a WHIX Account

To request a WHIX account for a WHI employee who already has a WHI network account, the PI, CM or OC must send an email to their FC's CCC Data Liaison with the following information:

1. First and last name of person needing the account
2. Job title

3. Start date
4. Brief description of tasks that the person will be performing in WHIX (i.e., forms data entry, outcomes data entry, running reports, etc.).
5. FCs to which the employee needs WHIX access (if more than one).

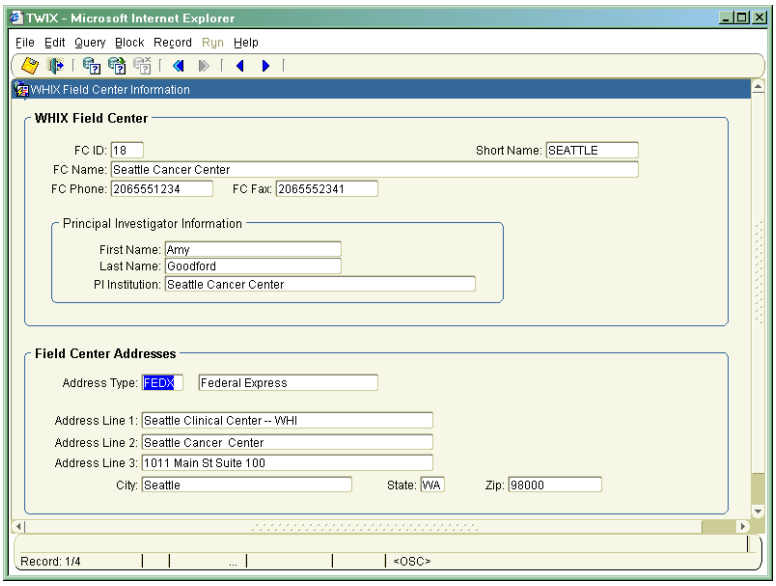
Notify your CCC Data Liaison immediately when a staff member terminates employment with WHI so that their database account can be disabled.

Provisional (temporary) accounts will be granted on a limited basis to non-WHI employees such as ancillary study staff who need to access WHIX. To request a provisional WHIX account, the PI, CM or OC must email the Data Operations Manager at the CCC.

10.2.2 Updating Field Center Address and Phone in WHIX

At the *Field Center* menu, select **Field Center Information** (*Figure 10.1*).

Figure 10.1
Field Center Information Screen



10.2.2.1 WHIX Field Center Block

The *WHIX Field Center* block displays general information such as *FC name, phone, fax*, etc. You can edit any information in this block except *FC ID and Short name.* There is space for only one phone number and one fax number. The same phone number will print on the *Outcomes Request for Medical Information Report* (*WHIX0980*). The CCC does not update information in this screen. At this time, only the Outcomes address is being used. It is up to the FC to keep this information current.

10.2.2.2 Field Center Addresses

The *Field Center Addresses* block displays up to four different addresses for your FC:

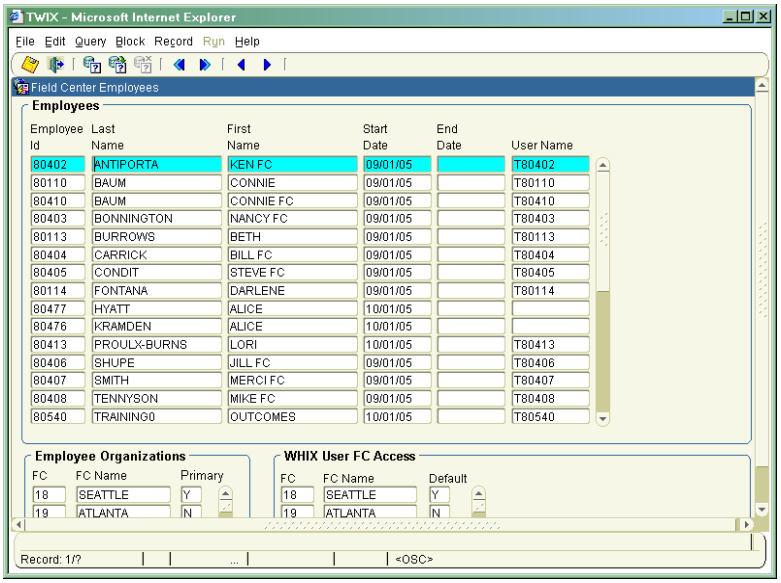
- FEDX – for Federal Express shipments
- MAIL – for USPO mailings
- OUTC – this address prints on the *Request for Medical Information Report (WHIX0980)*
- SHIP – for shipping, if different than FedEx or mail

Place the cursor in the *Address* block and use the up and down arrow keys to scroll through the four addresses. You can edit any field in the *Address* block except *FC Name*. Keep in mind that when the address prints out, the FC Name in the *WHIX Field Center* block will always be the first line of the address, so you should not repeat the FC name in the first line of the address.

10.2.2.3 Field Center Employee Screen

The *Field Center Employee* Screen (*Figure 10.2*) lists all WHI Extension staff, past and present, who have a WHIX employee ID. To access the *Field Center Employee* screen, at the main WHIX menu, select **Field Center/Field Center Employee**.

Figure 10.2
Field Center Employee Screen



This screen displays employee names, ID numbers, usernames, start dates and end dates. Items in this screen are updated at the CCC and can't be edited by FC staff.

10.2.3 Communication with the Clinical Coordinating Center

Each FC has a liaison at the CCC who can be contacted with questions about network administration, WHIX, Outcomes and other study operations. Refer to the "CCC Contacts" link on the "Directory and Lists" page of the WHI Operations website (www.whiops.org) to determine who to contact about a specific issue or problem.

10.3 WHIX Menu

Women's Health Initiative Extension Study data are stored in a database developed in Oracle. The data are entered, retrieved, and managed through a menu-driven user interface. The name of the WHI Extension Study database is WHIX. Throughout the following sections, WHIX is used to refer to all aspects of the database - the menu from which you choose commands, the screens where you enter data, the report-running system, and the tables where the WHI Extension Study data are held. All of these items are explained in this or later sections of the manual.

This section gives basic WHIX terminology and an overview of the menu system.

10.3.1 Logging Into and Out of the Network

- Using the Internet Service Provider at your FC, connect to the internet. *Note:* You can only access WHIX by using a PC provided by and/or configured by the CCC.
- Access the WHI Operations website at www.whiops.org.
- Enter your network user name and password into the *WHI-Login* screen (*Figure 10.3*). *Note:* Your network user name and password are separate from your WHIX username and password.

Figure 10.3
WHI Operations Log-in Screen

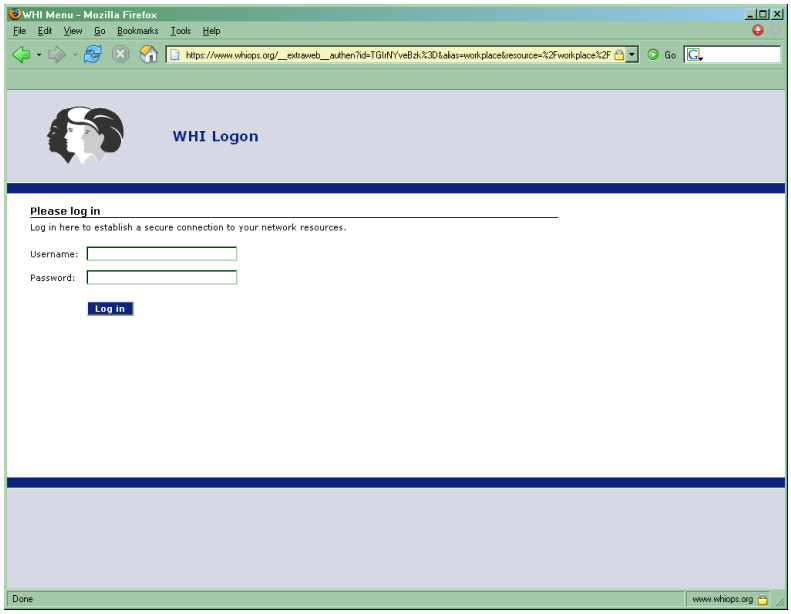
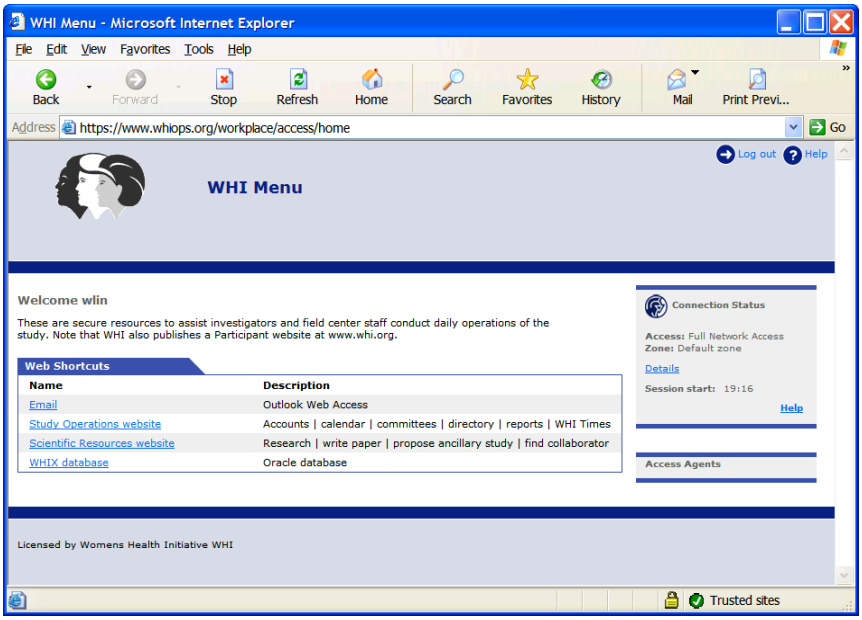


Figure 10.4
WHI Operations Main Menu



10.3.1.1 Logging into WHIX

- From the WHI Study Operations main menu, click on the *WHIX database* link (*Figure 10.4*).
- Enter the WHIX username given to you by the CCC.
- Enter the WHIX password given to you by the CCC.

The first time you log in, you will be prompted to change your WHIX password and are required to do so:

- Enter your old password and press Tab.
- Enter a new password and press Tab.
- Re-type your new password and click the **OK** button to open the main WHIX menu. *Note:* You will be prompted to change your WHIX password every 3 months.

WHIX allows three attempts within a 5-minute period to correctly enter a username and password. After three unsuccessful attempts, the user is locked out of WHIX for 30 minutes. This is to prevent an unauthorized user from gaining access to WHIX by attempting to guess your password.

10.3.1.2 Logging Off/Shutting Down

To log out of WHIX:

- At the WHIX main menu, select **Session/Exit**.

To log out of the Network and shut down the computer:

1. Close all open files and applications, including WHIX.
2. Click the **Start** button.
3. Choose the **Shut Down** button. The *Shut Down Windows* dialog box pops up asking for confirmation.
4. The *Shut Down Windows* dialog box will appear.
5. Click the **OK** button.

10.3.2 Navigating Within the WHIX Screens

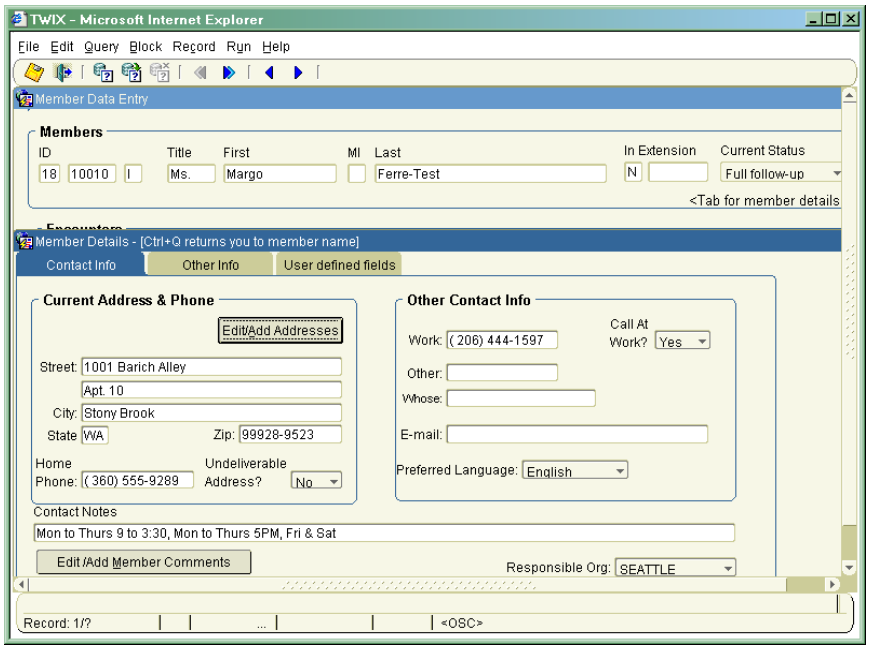
Although WHI data are entered on many different screens within WHIX, the screens contain the same basic components. The same navigation techniques are used to move around any data entry screen.

This section looks at some basic WHIX screen components and actions.

10.3.2.1 Basic Screen Components

- **Title Bar** – The bar at the top of the window or screen that displays the name of the program and/or screen.
- **Menu Bar** – The bar below the title bar that displays the names of the menu options that are available in that screen.
- **Tool Bar** – The bar below the menu bar that displays a row of "buttons". Each button represents a command. Clicking on a button executes the command in that screen.
- **Resizing Buttons** – Buttons in the upper right hand corner of the window that can be used to adjust the size of the active window.
- **Block** – A group of related fields. Each screen will contain at least one block. Some screens contain multiple blocks.
- **Field** – An area on the screen that can display a value or accept an input value.
- **Pop-Up Screen** – A part of a block that is not displayed automatically when the block is raised. WHIX contains several pop-up screens. For example, the *Member Details* tab page is a pop-up screen (*Figure 10.5*). This is part of the *Members* block, as opposed to being a separate block. A pop-up screen is reached by pressing **Tab** from the last enterable field (in this case the "Last Name" field) of the previous part of the block.
- **Status Line** – The line at the very bottom of the WHIX screen. It displays information about an action WHIX has taken, such as the number of records retrieved by a query.
- **Pop-Up Box** – A dialog box that pops up when you request a certain action and requires that you confirm the action before WHIX carries it out. This is different from a pop-up screen because it is not part of the block and is used to enter commands only. You do not enter data into a pop-up box.

Figure 10.5
WHIX Screen Components

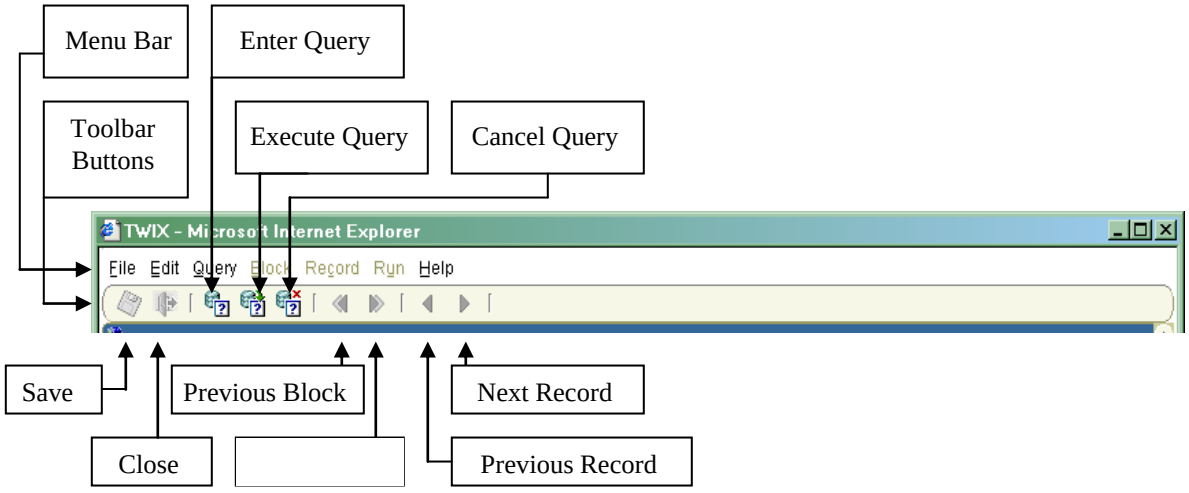


10.3.2.2 Basic Screen Actions and Toolbar Buttons

Some of the more common actions in a WHIX screen are listed below. See *Table 10.1 – Common WHIX Menu Options* for more details and additional actions. The buttons on the *Member Data Entry* screen toolbar representing each command are shown in *Figure 10.6*. Keyboard shortcuts are in parenthesis.

- **Save** or **Commit (F10)** – Stores new, changed, or deleted records from the work space to the database.
- **Close** – Closes the screen.
- **Enter Query (F7)** – Clears the current block and allows you to enter search criteria.
- **Execute Query (F8)** – Retrieves all records in the block that match your search criteria.
- **Cancel Query (Control Q)** – Exits from or cancels a query.
- **Previous Block (Control Page Up)** – Moves to previous block.
- **Next Block (Control Page Down)** – Moves to next block.
- **Previous Record** – Moves to previous record in the current field.
- **Next Record** – Moves to next record in the current field.

Figure 10.6
Toolbar in the Member Data Entry Screen



Note: Buttons that are "grayed out" are not available for use. For example, if you are in the first block of a screen, the **Previous Block** key will be grayed out since there is no previous block.

10.3.2.3 Common Menu Options

The *Member Data Entry* menu bar (see *Figure 10.6*) lists the menu headings: *File, Edit, Query, Block, Record, Run,* and *Help*. Single-clicking on a menu heading opens that menu and displays the subheading choices in it. The first five menu headings—*File, Edit, Query, Block,* and *Record*—contain subheading choices that are standard in most WHIX screens. Items in the *Run* menu are unique to each screen. Users should familiarize themselves with the commands in the *Run* menu of every WHIX screen that they use.

Common menu options are summarized in *Table 10.1*.

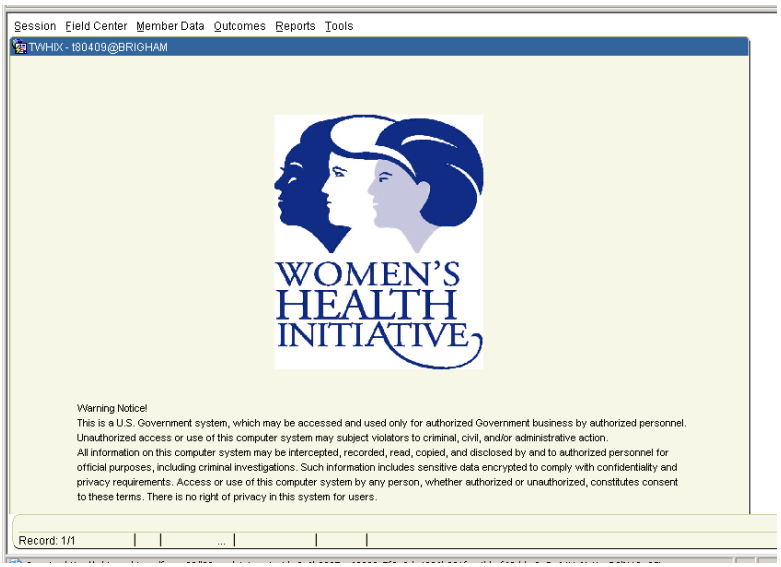
Table 10.1
Common WHIX Menu Options

Menu Heading/Subheading	Function (select this item to….)
File/	
Save	…saves or commits data
Close	…closes the screen
Print	…opens the page setup/print dialog boxes and sends a copy of the screen to the printer
Print setup	…opens the page setup dialog box
Edit/	
Cut	…deletes data from a field
Copy	…copies data from a field
Paste	…inserts cut or copied data into a field
Display list of values	…view all the allowable values for a field
Query/	
Enter query	…clears the current block and enter search criteria
Execute query	…retrieves all records in the block that match your search criteria
Cancel query	…exits from or cancel a query
Last criteria	…retrieves the last search criteria that you entered in a block
Count query rows	…view a count of the number of records that will result from a query
Block/	
Previous block	…moves the cursor to the previous block that contains at least one enterable field
Next block	…moves the cursor to the next block that contains at least one enterable field
Clear	…clears information in the current block from the screen (*Note:* This is NOT the same as deleting data—data that is cleared from the screen is not removed from the database.)
Record/	
Previous	…moves the cursor to the previous record in the current block (when more than one record has been retrieved.)
Next	…moves the cursor to the next record in the current block (when more than one record has been retrieved)
Insert	…inserts a new record after the current record
Scroll Up	…moves up within a group of records
Scroll Down	…moves down within a group of records
Delete	…removes the current record from the database. You must Save the deletion to make it permanent
Duplicate	…copies a record into a blank field. This feature has been disabled in WHIX
Clear	…clears the current record from the screen (*Note:* This is not the same as deleting a record. A "cleared" record is not removed from the database.)

10.3.3 Navigating Within the WHIX Menu System

WHIX has a drop-down menu interface which contains main menu headings that you can open to reveal additional menu choices. There are 6 items in the WHIX main menu: *Session, Field Center, Member Data, Outcomes, Reports* and *Tools*.

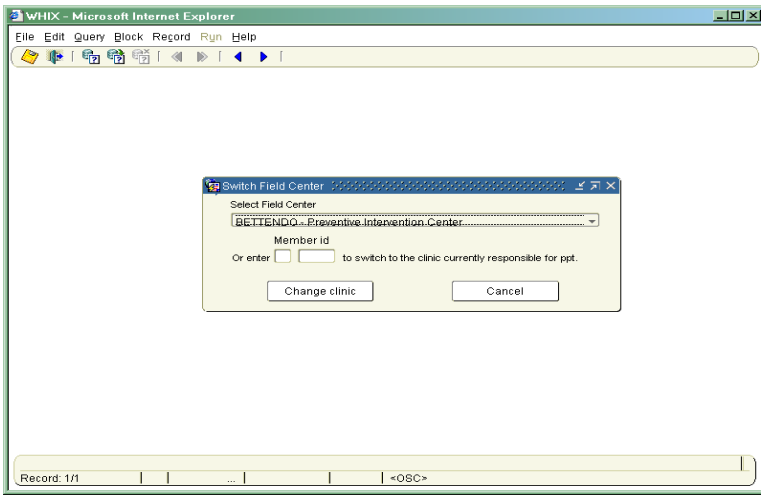
Figure 10.7
WHIX Main Menu



10.3.3.1 Session

Session is the first menu item in the WHIX main menu (*Figure 10.7*). If you are working with participant data from more than one WHI FC (for example, participants from a main site and a satellite site) use this menu to access the additional FCs. Select **Switch Field Center View** *(Figure 10.8)* from this menu to open a drop-down list that displays the FCs to which you have access. You can also enter a participant ID and WHIX will switch to the FC that is responsible for that participant. WHIX allows you to access data from only one FC at a time.

Figure 10.8
Switch Field Center View



10.3.3.2 Field Center

The *Field Center* menu contains the following menu options:

- Field Center Information (see *Section 10.2.2 – Updating Field Center Address and Phone in WHIX*)
- Field Center Employees (see *Section 10.2.2.3 – Field Center Employee Screen*)
- User Defined Fields

WHIX provides 15 fields that FCs can define and use to enter and store member information that is not tracked elsewhere in WHIX. The use of "user defined fields" is optional. For example, a FC may choose to keep track of the month a participant has her mammogram each year by entering this information in a user defined field.

The FC needs to go through two steps to enter information in the user defined fields:

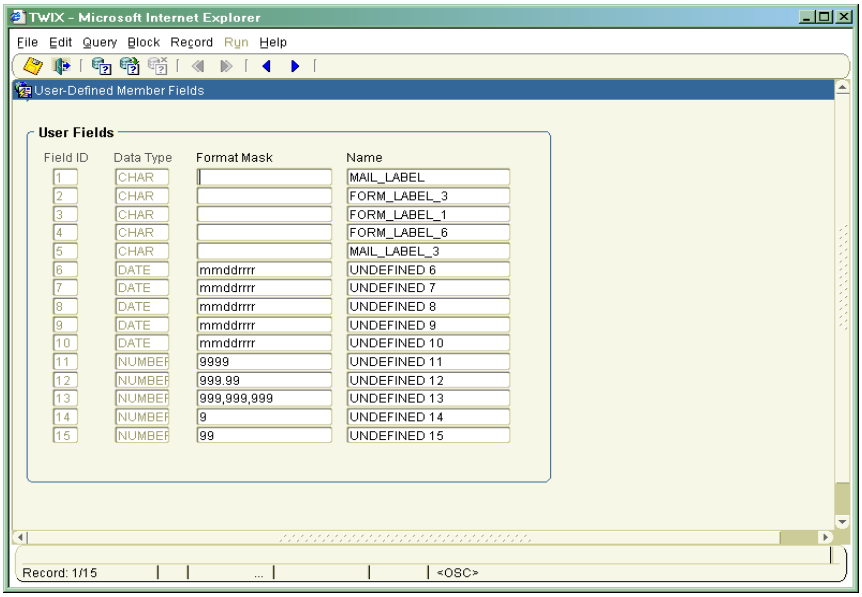
1. Use the *User Defined Member Fields* screen (*Figure 10.9*) to define each field.
2. Use the *User Fields* block of the *Member Details* screen (*Figure 10.10*) to enter the participant information.

10.3.3.2.1 Defining User Defined Fields

There are four fields in the *User Defined Fields* block: *Field ID*, *Data Type*, *Format Mask* and *Name*. You can enter or change data only in the "Format Mask" and "Name" fields.

- "Field ID" defines the order in which the field appears on the screen and the order in which the data is entered.
- "Data Type" defines the specific type of data that can be entered in a given field. For example, fields 11-15 have a number data type. These fields will only accept input of numeric values.
- "Format Mask" defines the manner in which data must be entered for that field. For example, the date field number 8 has a format mask of "mm/dd/rrrr". This means the data in this field must be in the date format of 2-digit month, 2-digit day and a 4-digit year such as 12/01/2006. WHIX will not accept data in a different format and will display an error message.
- "Name" is the name by which the field is known. This is the field title which appears on the screen when the *User Fields* block is open from the *Member Details* screen.

Figure 10.9
User-Defined Member Fields



To define a user defined field:

1. Move to the name you wish to change. Press **Tab** to move between the Format Mask and Name for a given field. Use the arrow keys to move between fields.
2. Overwrite the current text such as "MAIL_LABEL" with the name you have defined for the field. The field name can be up to 20 characters long.
3. Repeat for each name you wish to define.
4. Move to the Format Mask you wish to change, if any. Keep in mind that that any data entered into these fields must be in the format you specify here.

    - Possible components of the Format Mask for a "DATE" field include:

      "mm", "dd", "nh:mi", "mon", "rrrr", "_", "/", ".". Note that "rrrr" represents a 4-digit year.

    - Possible components of a Format Mask for a "NUMBER" field include:

      "0-9", "$", ".", ","

    - A Format Mask can be up to 20 characters long.
    - You don't need to provide a Format Mask for "Character" ("CHAR") fields.

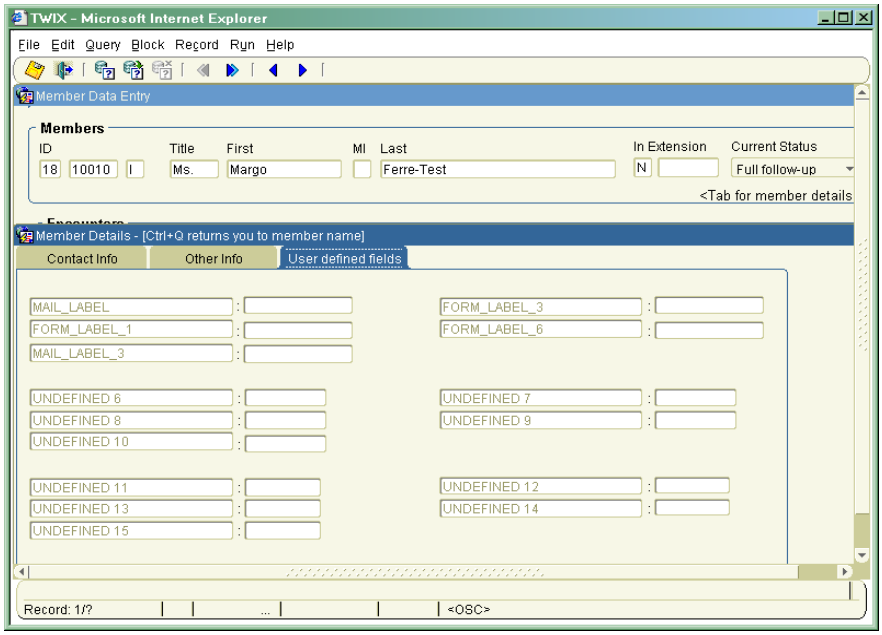
5. Repeat for each field whose format you wish to define.
6. When you have made all desired changes to the field names and Format Masks, click the **Save** button to commit the changes.
7. Press **Ctrl-Q** to close the screen and return to the WHIX main menu.

10.3.3.2.2 Entering and Viewing Data in User-Defined Fields

To enter data in a user-defined field:

1. At the *Member Data Entry* screen, retrieve the record of the participant whose information you are entering.
2. Press **Tab** until you reach the *User-Defined Fields* tab of the *Member Details* tab page (*Figure 10.10*). The names of the fields that are displayed match those you defined in the *User Defined Member Fields* screen (*Figure 10.9*).

Figure 10.10
User-Defined Fields



- Press **Tab** to move between fields.
- Enter information in the user-defined fields as appropriate.
- When you have entered all information for a participant, click the **Save** button to commit the information

10.3.3.3 Member Data

See *Section 10.4 – Member Data Entry Screen.*

10.3.3.4 Outcomes

See *Section 10.5 – Data Management and Data Entry*.

10.3.3.5 Reports

See *Section 10.6 – Queries and Reports.*

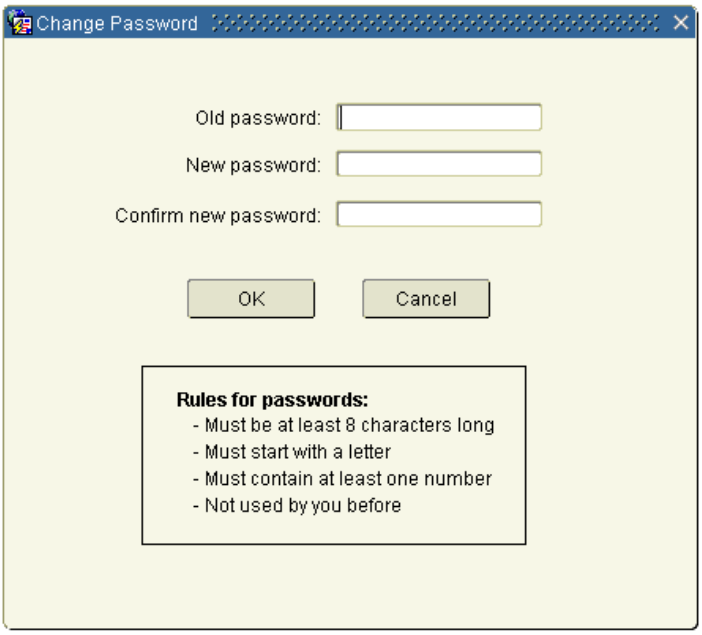
10.3.3.6 Tools

10.3.4 Change Password

To change your WHIX password, at the *Tools* menu, select **Change Password** (*Figure 10.11*). *Note: You must follow the rules for passwords shown in Figure 10.11* and in *Section 10.1.2.2 – Computer System Access Security.*

1. Type your old password in the "Old Password" field.
2. Type your new password in the "New Password" field.
3. Repeat your new password in the "Confirm Password" field.
4. Click the **OK** button.
5. WHIX will save your new password and give you a confirmation message that your password has been successfully changed.

Figure 10.11
Change Password Screen



10.4 Member Data Entry Screen

The *Member Data Entry* screen in WHIX is where basic information about a member, such as her name, address, and phone number are found. A *member* or *participant* in WHIX is defined as a woman who has consented to the Extension Study. Participants who were randomized or enrolled in the original WHI study are also displayed in the *Member Data Entry* screen even if they aren't enrolled in the Extension Study. This screen is also where you enter primary information about all participant tasks, such as the date of each task, the staff member who performed it, and the contact type.

The *Member Data Entry* screen is divided into two blocks, the *Members* block and the *Encounters* block.

To access the *Member Data Entry* screen:

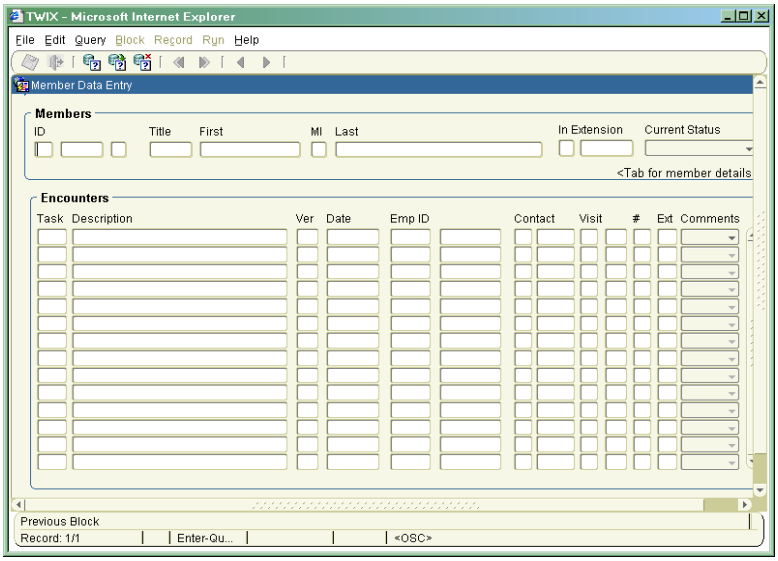
1. Bring up the WHIX main menu.
2. Select **Member Data**.
3. Select **Member Entry**. This opens the *Member Data Entry* screen (*Figure 10.12*).

10.4.1 Members Block

The *Members* block in the *Member Data Entry* screen *(Figure 10.12)* displays information about a participant, and is where a participant's personal information can be retrieved.

The *Members* block also contains the *Member Details* pop-up window (*Figure 10.13*). The *Member Details* window displays the participant's address, phone number, and other demographic information. To open this window, position the cursor in the "Last Name" field in the *Members* block and press **Tab**.

Figure 10.12
Member Data Entry Screen



10.4.1.1 Member IDs

When you open the *Member Data Entry* screen, the cursor is in the "ID" field and the screen is automatically in "query" mode.

You can't change any part of a participant's ID number. All Member IDs begin with the unique 2-digit ID of the FC that randomized or enrolled the member. If you wish to retrieve a participant's record by querying for the Member ID, you must include all three of its components, the FC ID, member suffix, and check digit. Each Member ID number remains permanently assigned to that participant. If a participant previously

transferred to a different FC, she kept her full Member ID, including her original FC's ID, so that participants who have transferred into your FC from another FC have a different 2-digit FC ID number. *Note:* Always query by ID number rather than participant name, to prevent data entry or retrieval errors due to duplicate names.

10.4.1.2 Retrieving an Existing Participant Record

To enter data for a participant, or look up information in her record, you need to retrieve that participant's record. The quickest way to retrieve the record is from the *Member Data Entry* screen using the participant's barcode label.

1. Click the **Enter Query** button on the toolbar.
2. To scan the participant's barcode label:
   - Hold the scan gun approximately three inches above the barcode and press the button on the handle.
3. Click the **Execute Query** button on the toolbar.

If you do not have a barcode to retrieve participant records, you can key-enter the participant's Member ID.

To manually retrieve a participant record:

1. At the *Member Data Entry* screen, click the **Enter Query** button on the toolbar. This puts you into **Enter Query** mode. Notice the cursor is in the FC "ID" field. Enter the 2-digit FC ID of the participant's Member ID. The cursor automatically moves to the member suffix field once the 2-digit FC ID is entered.
2. Enter the 5-digit member suffix. The cursor automatically moves to the "Check Digit" field.
3. Enter the one character check digit.
4. Click the **Execute Query** button on the toolbar. The Execute Query command causes WHIX to search all records to find the one that matches the criteria you have specified, in this case the unique FC ID, member suffix, and check digit combination.

WHIX displays the desired participant record on the screen.

You can update a participant's name at any time by replacing the existing information in the *Title* or *Name* fields with new information and clicking the **Save** button.

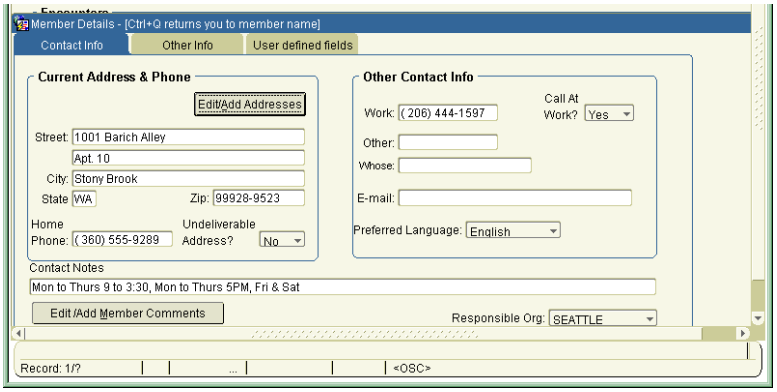
10.4.1.3 Updating Address and Phone Information

To change an existing home address or enter additional addresses:

1. Retrieve the participant record in the *Member Data Entry* screen.
2. Press the **Tab** key 7 [seven] times (i.e., tab past the "Last Name" field). The *Member Details/Contact Info* tab page is displayed (*Figure 10.13*).

You cannot update the last field in this block, "Responsible Org". It displays the name of the FC currently responsible for the participant. In most cases, this will be the same as the FC ID of her Member ID. For participants who have transferred to a new FC, this will be the name of the FC to which she has transferred.

Figure 10.13
Members Detail/Contact Info



To update address or phone information, click the **Edit/Add Addresses** button in the *Current Address & Phone* block. This opens the *Member Address* screen shown in *Figure 10.14*, where you can enter addresses and phone numbers for a participant. You can enter and save any number of addresses; however, only two addresses will be displayed on the screen at any one time.

Only one home address can be flagged as "current" at any one time. Enter a Y in the "Current Address" field for the address that is currently valid. Leave the *Current Address* flag for the other (non-current) addresses as "N". The address that is flagged as current will appear in the top address field on the screen and is the one that WHIX will use when printing member address labels.

To enter more than two addresses for a participant, position the cursor in the lower address block and press **F6.** The lower address block clears and the cursor automatically moves to the *Current Address* flag field for the lower address. Click in the lower address block and type the address. Click the **Save** button to commit the address. To view addresses that you have entered that are not displayed on the screen, position the cursor in the lower address block and press the **down-arrow** key.

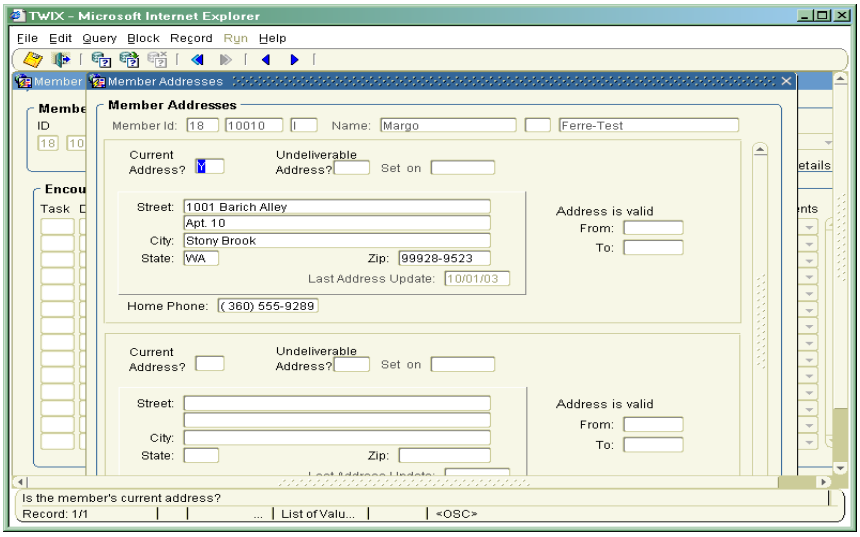
Next to each address are optional date range fields where you can enter a date range during which the address is valid. Note that the date range that you enter is not linked to the *Current Address* flag; that is, WHIX will not automatically switch the *Current Address* flag based on a date range that you have entered. You must manually change the *Current Address* flag when a participant changes her address.

The *Member Addresses* screen also displays the most recent date that the *Undeliverable Address* flag was set (see *Section 10.4.1.5 – Undeliverable Address/Preferred Language Field*) and the most recent date that each home address was updated.

10.4.1.3.1 Add Member Comments

To enter free text notes about a participant click the **Edit/Add Member Comments** button in the lower left-hand corner of the *Contact Info* tab page. This opens the *Member Comments* page, where you can enter and save up to 4000 characters of text. The information entered here can be printed out on the *Member Comments Report (WHIX0552)*. To print this report form the *Member Data Entry* screen, go to the *Run* menu and select **WHIX0552 – Member Comments Report**.

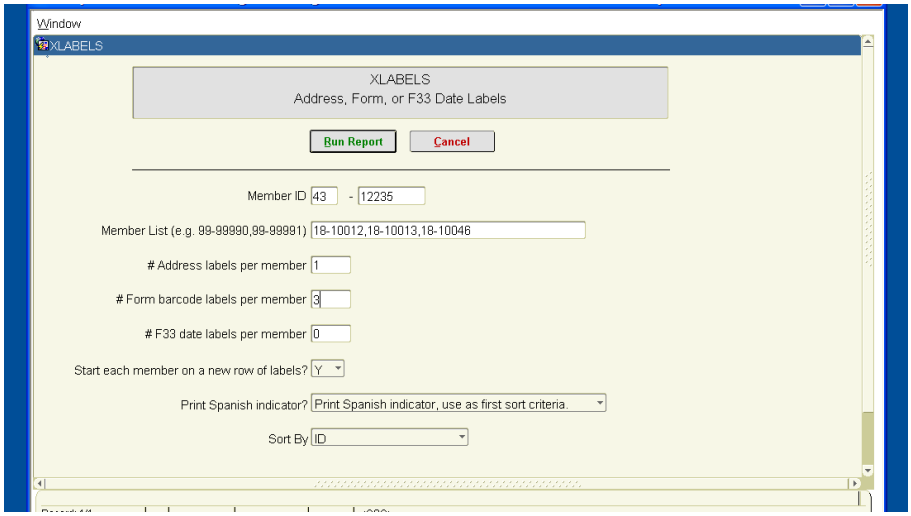
Figure 10.14
Member Addresses Screen



10.4.1.4 Member Reports/Labels

At the *Run* menu in the *Member Data Entry* screen (*Figure 10.12*), you can create address, form (barcode), and *Form 33* date labels in one report Address, Form, and *Form 33* Labels (XLABELS) for participants that you specify. Go to Run/Address Labels or Run/Form Labels. In the *Report Parameter* screen, enter participant ID numbers (without the check digit), separated by commas as shown in *Figure 10.15 – Address, Form or Form 33 Date Label* parameter screen. Enter the number of each type of label you want to print and choose a sort order. The example shown in *Figure 10.15* would print 1 address label and 3 form (barcode) labels for each of the 3 participants listed in the *Member List* parameter, sorted by ID number, and would start each participant on a new row of labels. There is also an option to print an "S" on the address labels of participants who have their preferred language flag set to "Spanish". The "Print Spanish indicator" parameter allows you to print the indicator and also use preferred language in the label sort order.

Figure 10.15
Address, Form or *Form 33* Date Label Parameter Screen



10.4.1.5. Undeliverable Address/Preferred Language Field

The *Undeliverable Address* flag allows the CCC or FC to indicate that a participant's address is incorrect or insufficient for mailing purposes. Setting the flag to "Yes" will prevent the CCC from mailing forms and other materials to the participant. To set the *Undeliverable Address* flag in WHIX:

1. In the *Member Data* Entry screen, retrieve the record of the participant whose address is undeliverable.
2. Press **Tab** four times. This opens the *Member Details* screen. Click the *Contact Info* tab.
3. Click the **Edit/Add Address** button.
4. Position the cursor in the "Undeliverable Address?" field, shown in *Figure 10.14.*
5. Enter a "Y".
6. Click the **Save** button.

To reset the *Undeliverable Address* flag to the default (address deliverable), follow steps 1-4 above, delete the "Y" and click the **Save** button on the toolbar.

Participants who have the *Undeliverable Address* flag set to "Y" will appear on *WHIX0611 – Address Problems* (*Section 10.7 – Queries and Reports*).

After entering new information in the *Member Addresses* screen, click the **Save** button on the toolbar. Press **Ctrl-Q** to close the *Member Addresses* screen and return to the *Contact Info* tab page.

10.4.1.6 Updating Other Contact Info

The *Other Contact Info* block of the *Contact Info* tab page *(Figure 10.16)* displays the participant's work phone, if any, the phone number and name of an alternate contact person, the participant's e-mail address (optional) and her preferred language. You can enter new information in any of these fields and click the **Save** button.

To indicate that a participant's preferred language for follow-up materials is Spanish:

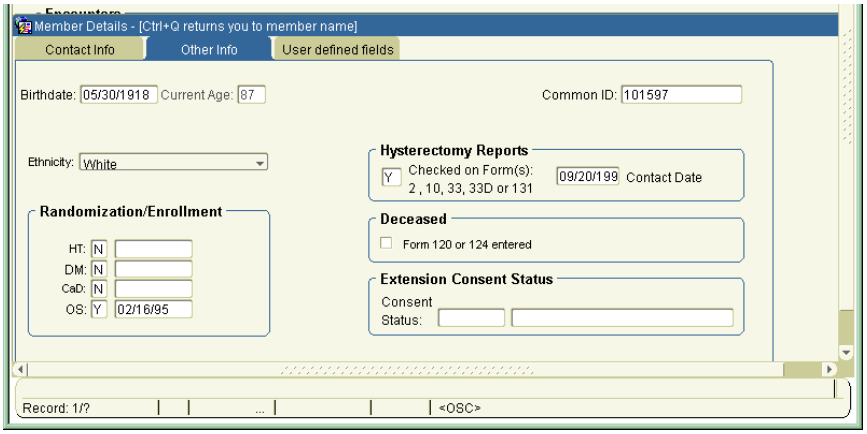
1. In the *Member Data Entry* screen, retrieve the record of the participant whose preferred language is Spanish.
2. Press **Tab** four times. This opens the *Member Details* screen. Click the *Contact Info* tab.
3. Position the cursor in the "Preferred Language" field.
4. Click the *down-arrow* and select **Spanish** from the drop-down list.
5. Click the **Save** button.

To reset the *Preferred Language* flag to English, follow steps 1-3 above, select **English** from the drop-down list and click the **Save** button on the toolbar.

10.4.1.7 Other Info Tab

The *Other Info* tab displays the participant's birth date, current age, common ID, ethnicity, hysterectomy status, her study component and date randomized or enrolled in the original WHI study, her vital status (per *Form 120 – Initial Report of Death*) and her Extension consent status. You cannot make changes to any of these fields.

Figure 10.16
Other Contact Info Tab



10.4.2 Encounters Block

The *Encounters* block is where WHIX displays primary information about each task that is performed on a participant. A task is a specific form or procedure from which you collect data to enter into the database. The *Encounters* block contains data such as the type of task and the date it was performed. For key-entered forms you enter and save this information before you enter the details of the task. *Figure 10.17* shows the *Encounters* block and data items.

To access the *Encounters* block:

1. In the *Members* block of the *Member Data Entry* screen, retrieve the record of the participant for whom you are entering an encounter:

   - Click the **Enter Query** button on the toolbar.
   - Scan the participant's barcode label.
   - Click the **Execute Query** button on the toolbar.

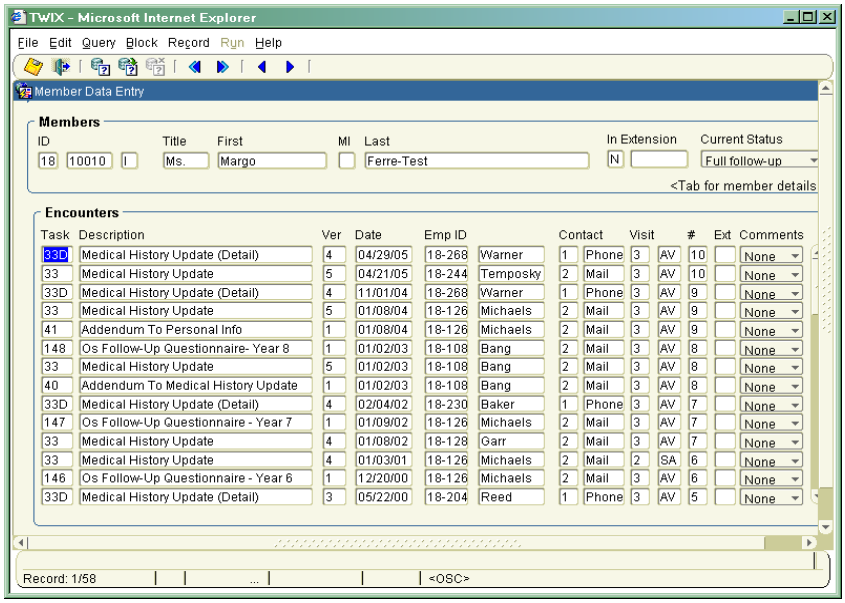
2. Click the **Next Block** button on the toolbar to move to the *Encounters* block.

   - The form version number is displayed next to the form name, and the latest version number for a questionnaire is automatically entered after entering the task ID. For example, when you key-enter a *Form 33D, 120,* or *85*, the version number is automatically entered as the most current version of the form. You must change this if you are key-entering a form version other than the most current version.
   - The numeric codes and text descriptions of visit types are displayed in abbreviated form: 1 – phone, 2 – mail, 3 – visit, and 8 – other.
   - Visit types are displayed in abbreviated form (for Extension and pre-Extension forms): SV = screening visit, SA = semi-annual visit, AV = annual visit, and NR = non-routine, 6W = 6-week, DI = diet intervention, IN = interim, and AM = amendment.
   - There are 2 visit year fields displayed on the screen—year #, which is calculated from the original WHI randomization or enrolled date and "Ext" which is the participant's year in the Extension Study. Both fields are automatically calculated and filled in for Extension Study tasks (version 8 and above). For pre-Extension Study (pre-form version 8) tasks, only the year # is calculated. Both year fields display after completing the visit type and pressing the **Tab** key.
   - The "Comments" field is the last field in the block. The comment field choices are: *Alert, Reviewed* and *None*. The "Comments" field indicates that a participant form that was scanned at the CCC had a note or comment written on it by the participant. If a comment is written on a form, the CCC will mark the FCA (Field Center Alert) bubble in the Office Use Only box. FC staff need to review the note on an electronic image of the form. Once the form has been reviewed, FC staff can set the

comment field to indicate that the review is complete. The *Forms with Comments to Review* screen lists all forms that have the *Comment* flag set to "Alert" (see *Section 10.4.2.3 – Review Forms with Comments).*

- FCs will not receive hard copies of forms scanned at the CCC. You can view and print the PDF image of a CCC scanned form by double-clicking on the **Task** ID.

Figure 10.17
Encounters Block



To enter encounter information for a participant:

1. Enter the Task ID from the form header. This is the same as the form number. Press **Tab**.
2. Notice the task description and version are filled in automatically. Enter the contact date from the form. Press **Tab**.
3. This brings you to the "Employee ID" field. Enter the 5-digit Employee ID from the form. Press **Tab**. The employee's name is filled in automatically.
4. From the form, enter the 1-digit code for the contact type from the form. Press **Tab**.
5. Enter the 1-digit code for visit type from the form. WHIX will not allow you to enter an unexpected visit type. For example, you cannot enter "4 – Non-Routine" as the visit type for an Annual Visit task. Press **Tab**.
6. WHIX will automatically fill in the visit year.
7. Click the **Save** button to save the task information.
8. Before WHIX saves the encounter, it prompts you to confirm the Member ID of the participant for whom you are entering the encounter in the Verify Member ID window. Scan or key-enter the Member ID for the participant for whom you are entering an encounter.

You are now ready to begin entering the data from the form. Click the **Next Block** button on the toolbar to reach the *Questionnaire Responses* block and begin key-entry. See *Section 10.5 – Data Management and Data Entry* for complete information on this process.

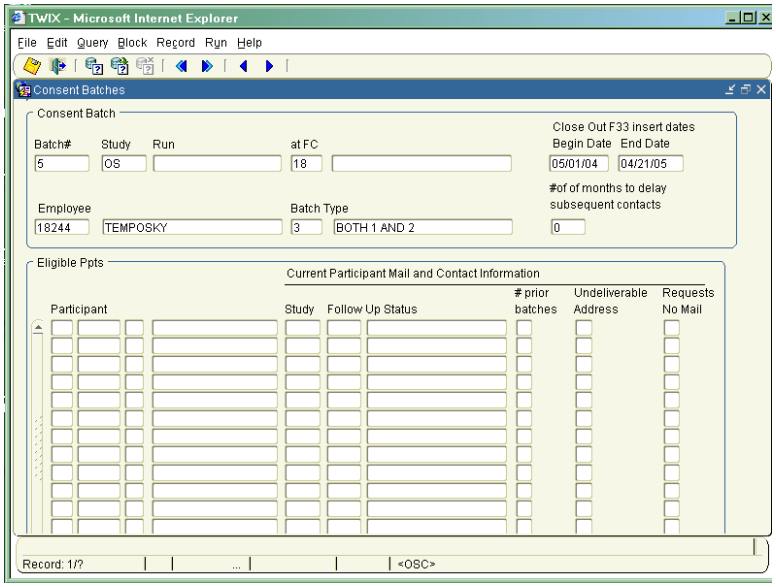
See *Section 10.5.2.2 – Making Corrections to Key-Entered Data* for information regarding changing data entered in the *Encounters* block.

10.4.2.1 Extension Consent Batching Screen

The *Extension Consent Batching* screen (*Figure 10.18*) is an optional screen designed to help you identify participants who need an Extension consent form and also to track repeat mailings of extension consent forms to participants. The system is based upon a maximum of 3 mail contacts and one non-mail contact for a total of 4 contacts.

Each participant can be in up to 4 batches. Once the batches are created, address and form labels can be printed for each participant in the batch. A participant barcode label must be placed on each copy of each consent form before the forms are mailed to the participant.

Figure 10.18
Extension Consent Batching Screen



To use this screen:

1 Select **Extension Consent Batching** from the *Member Data* menu.
2. Enter your employee ID.
3. Choose the type of contact that you want for your batch:

   - **First Contact** will retrieve participants who are not in a previous batch
   - **Subsequent Contact** will retrieve participants who are in at least one but not more than 3 previous batches
   - **Both 1 and 2** will retrieve participants from both of the first 2 groups

4. Do not enter a date range in the "Close-out F33 insert dates" field. A close-out *Form 33* is no longer required for participants to appear in a batch.
5. Enter a number in the "# of months to delay subsequent contacts" field. This is the number of months that you want to pass between participant contacts. For example, if a participant has been in a "first contact" batch on 12/20/05 and you leave this field set at the default of 2 months, the participant will not appear in a "subsequent contact" batch until 02/20/06 (assuming that no Extension Consent Status form is entered in WHIX before that date).
6. Click the **Save** button. A batch number will be automatically assigned by WHIX.

7. Select **Populate batch with participants** from the *Run* menu. The participant IDs retrieved by WHIX will meet the following criteria, in addition to the criteria you specified above for type of contact and # of months between contacts:
   - Does not have a follow-up status of 5 – No follow-up, 6 – Deceased or 8 – Absolutely no contact
   - Does not have a *Form 111* or *Form 112* entered in WHIX

The screen displays whether each participant has the *Undeliverable Address* flag set to "Y" or if they have "no mail" follow-up status. You must populate and run each batch before you will be able to create your next batch (i.e., each batch must display a "run" date and time at the top of the screen).

Several reports can be accessed from the *Run* menu in the *Extension Consent Batching* screen. In the *Consent Batch* block, you can run the following reports:

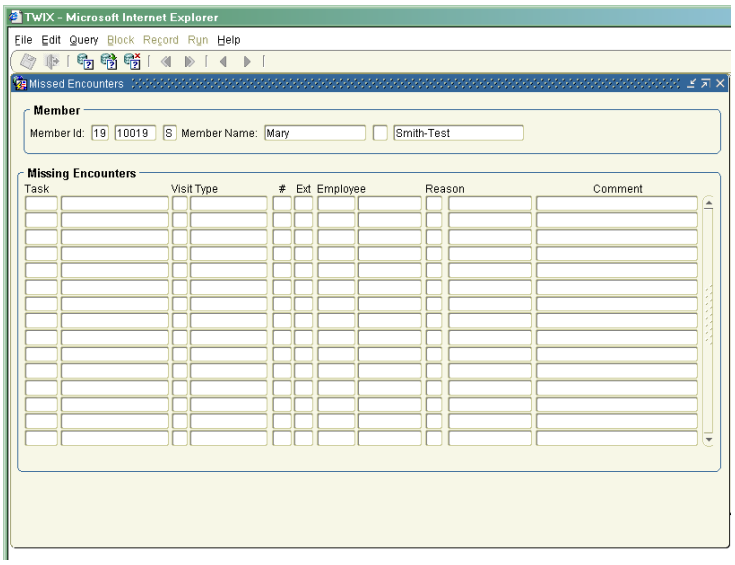
- *Consent Batch report (WHIP0871)* – lists all of the participants in a batch, along with the date of their close-out *Form 33* (if any), current follow-up status and contact information.
- *Consent Batch labels* – by default, prints an address label and 5 barcode labels for each participant in the batch. You can modify the number of each type of label printed in the parameter screen.
- *Personal Information Update report (WHIX0441)* – prints this report for each participant in a batch. Note that if you have a large batch, this report can take up to10 minutes or more to run.

In the *Eligible Participants* block of this screen you can run the *Personal Information Update report (WHIX0441)* for an individual participant. To do so, put the cursor on the line containing the individual participant's ID number and select the report from the *Run* menu.

10.4.2.2 Missed Encounters Screen

The Missed Encounters Screen allows you to enter information for a missed Extension *Form 85 - Mammogram.*

Figure 10.18a
Missed Encounters Screen



To use this screen:

1. Select **Missed Encounter Screen** from the run Menu.
2. Enter the form number and WHIX will fill in the visit type and year.
3. Choose a reason for the Missed Encounter—Refused, No clinic visit, Out of Window or Other.
4. You can enter a comment of up to 255 characters.

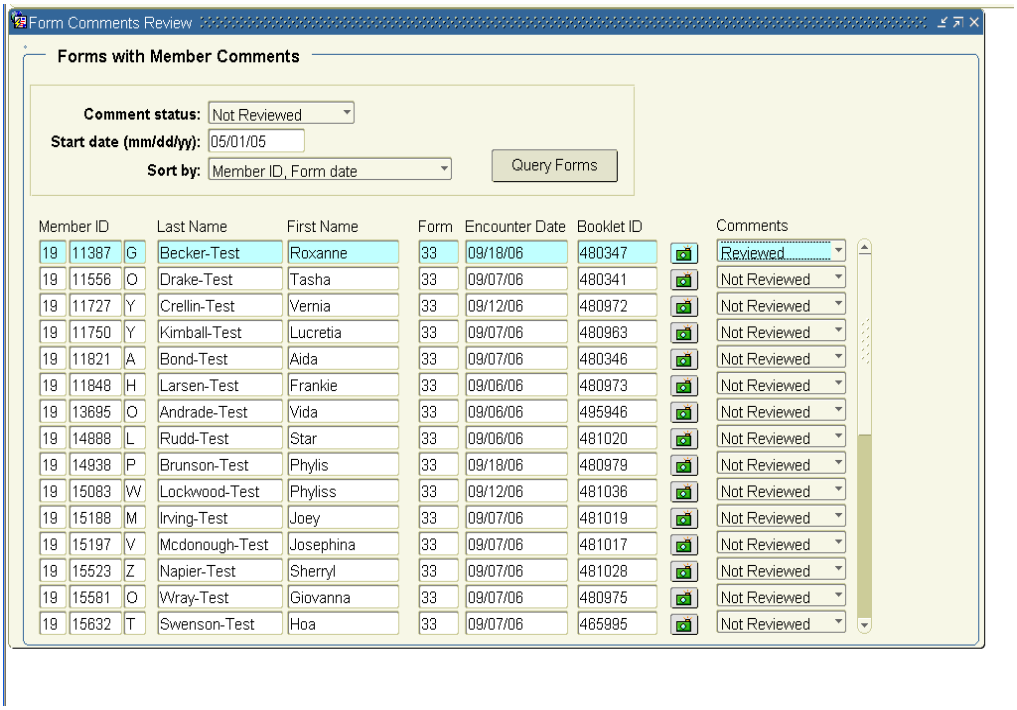
Note: The screen will show all missed encounters ever entered for a participant.

MAMM001—Extension Mammogram Tracking shows the date of the latest missed encounter, the reason missed and any comments (see *Section 10.7.3.4*).

10.4.2.3 Review Forms with Comments

The *Review Forms with Comments* screen lists participant forms that have the "comments" flag set to "alert", indicating that the participant has written something on the form that needs to be reviewed. In this screen you can review the comment that is written on the form and set the flag to "reviewed".

Figure 10.18b
Review Forms with Comments Screen



To access the *Review Forms with Comments Screen* (see *Figure 10.18b*):

1. Select *Review Forms With Comments* from the *Member Data* menu.
2. Set the *Comments status* parameter to select forms that have not been reviewed or forms that have been reviewed or both.
3. Enter a date in the *Start date* parameter that reflects the earliest contact date of the forms that you want to review.
4. Select a sort order from the *Sort by* drop-down list parameter. By default, the list will sort first by participant ID number, then by form date.
5. Click the **Query Forms** button to display a list of forms matching your parameters.
6. Click on the camera icon next to each form to view an image of the paper form and read any written comments.
7. To re-set the comment flag from "not reviewed" to "reviewed", click the down-arrow key in the comments field and select the appropriate choice.

The comments field is the only field that can be updated in this screen. All other fields are display-only. It's not possible to query participants by entering search criteria in the individual data fields.

10.5 Data Management and Data Entry

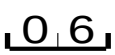
Data enter into the WHIX via key-entry from a study form or electronically via scanning of a mark-sense form. Quality of data is assured by a variety of methods including training of data collection and management staff, review of completed forms before entry, edit checks built into the data entry system and participant file audits. The CCC also performs routine audits of the central database. FCs must store hard copies of data collection forms in a readily accessible and secure manner, and respond to data queries from the CCC. Carefully recorded, entered, and maintained data are critical to the success of the study.

10.5.1 Data Management

10.5.1.1 Recording Data on Forms

WHI maintains standard procedures for entering data on forms. Here are some guidelines:

- Use a pre-printed participant ID label (with barcode) on the front page of each form.
- Complete key-entry and mark-sense forms in black or blue ink.
- Right-justify numerical data, using preceding zeros if necessary, for example:



- It is recommended that you use standard rounding rules to round values to the appropriate number of decimal points unless otherwise instructed by the forms instructions (see *Appendix A – Participant and Field Center Forms).* If a value ends in a fraction less than .5, round down to the next lowest whole number. If a value ends in a fraction equal to or greater than .5, round up to the next highest whole number. Record numbers as fractions ***only*** when there is a decimal point pre-printed on the form.

  If a participant gives a range of numbers in response to a question, and the interviewer is unable to pinpoint a value using interviewing techniques, take the midpoint of the range and use the standard rounding rules to round off as needed.

- When boxes are provided for recording an answer, clearly mark your choice with an "X". If the instructions indicate to "mark all that apply," mark as many of the responses following as are appropriate.

- Make sure that each item on a form is answered (except those items appropriately skipped in a skip pattern, e.g., "If yes, go to question 4"). If the information is unknown or unavailable, write "unk" next to the question and initial.

10.5.1.1.1 Recording "Unknown" Responses on Forms

Occasionally a participant will be unable to remember a date or other event that is requested on a form. Interviewers and other FC staff should use probing techniques (see *Section 5.1 – Interview Procedures*) to obtain the woman's "best guess" response to questions. When all attempts fail to obtain a date, the estimation procedure described below is used. This method produces a conservative estimate for dates; therefore it is best if the FC can encourage a woman to provide a reasonable date rather than estimating one.

- If the woman can't remember the year, record the current year.
- If the woman can remember the year, but not the month:
  - Record the current month if the recorded year is the current year.
  - Record "12" (December) if the recorded year is other than the current year.

In either case, make a note next to the question indicating that the response is an estimate. If the woman can remember the month and year but not the day of the event, use the 15th of the month as an estimate. Initial and date the note.

10.5.1.1.2 Recording Data on Mark-Sense Forms

The following guidelines should be used when recording data on mark-sense forms:

- Fill in the bubbles neatly and completely.
- Place the participant's ID label exactly where indicated on the front of the form.

10.5.1.2 Review of Forms

Review and edit all completed forms before entry into WHIX. Check for:

- Responses omitted unintentionally.
- Answers that do not follow the specified skip pattern.
- Codes/answers incorrectly marked or circled.
- Inconsistencies between questions.

Return incomplete forms to a staff person so that they can contact the participant and fill in incomplete information.

10.5.1.3 Editing Key-Entry Forms

Do not erase data on key-entry forms. If information is missing or inconsistent on a form given to data entry, the data entry person must return the form to the staff person responsible for the form so the information can be added or corrected. Data entry staff must not make corrections, additions, or deletions to items on forms

The data entry system is set up so that certain routine checks of the data are made at the time of entry at the FC. A warning message is displayed on the screen if a value is outside of the expected range. Warning messages may be overridden by pressing the enter key. A "fatal" error occurs when a value that is not an "allowable response" is entered in WHIX (for example, a text response is entered when a numeric value is expected). You must delete the incorrect response and enter a correct response before proceeding with key-entry of the form.

10.5.1.4 Common Data Items

Field Center (FC) Number

For WHI, the Clinical Coordinating Center (CCC) assigned a unique 2-digit code number to each Clinical Center (CC), and each CC remote site. FCs and remaining remote sites will keep the same 2-digit code as the CC code.

Sorted by ID Number

ID - FC Short Name	ID - CC Short Name	ID - CC Short Name
11 BETTENDO	29 TUCSON	57 STONYBRK
12 BIRMING	30 UCDAVIS	58 CHAPHILL
13 BOWMAN	42 STANFORD	60 CHI-RUSH
14 BRIGHAM	43 MILWAUKE	61 CINCINNA
15 BUFFALO	44 GWU-DC	62 DETROIT
16 CHICAGO	45 HONOLULU	63 IRVINE
18 SEATTLE	46 GAINESVI	64 MIAMI
19 ATLANTA	47 HOUSTON	65 NEVADA
21 IOWACITY	48 WORCESTR	66 PORTLAND
22 LAJOLLA	49 NY-CITY	67 SANANTON
23 PAWTUCK	50 COLUMBUS	68 LA
24 MEMPHIS	51 MEDLAN	72 NEWBRUNS
25 MINNEAPO	53 OAKLAND	73 DESMOINE
26 NEWARK	55 TORRANCE	
28 PITTSBUR	56 MADISON	

Sorted by FC Short Name

CC Short Name - ID	CC Short Name - ID	CC Short Name - ID
ATLANTA - 19	HONOLULU - 45	NY-CITY - 49
BETTENDO - 11	HOUSTON - 47	OAKLAND - 53
BIRMING - 12	IOWACITY - 21	PAWTUCK - 23
BOWMAN - 13	IRVINE - 63	PITTSBUR - 28
BRIGHAM - 14	LA - 68	PORTLAND - 66
BUFFALO - 15	LAJOLLA - 22	SANANTON - 67
CHAPHILL - 58	MADISON - 56	SEATTLE - 18
CHICAGO - 16	MEDLAN - 51	STANFORD - 42
CHI-RUSH - 60	MEMPHIS - 24	STONYBRK - 57
CINCINNA - 61	MIAMI - 64	TORRANCE - 55
COLUMBUS - 50	MILWAUKE - 43	TUCSON - 29
DESMOINE - 73	MINNEAPO - 25	UCDAVIS - 30
DETROIT - 62	NEVADA - 65	WORCESTR - 48
GAINESVI - 46	NEWARK - 26	
GWU-DC - 44	NEWBRUNS - 72	

Participant ID Number

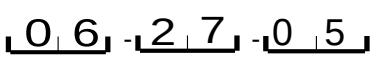
The participant ID number is a unique, 8-digit number which identifies each WHI Extension participant.

The format of the participant ID number is F C 9 9 9 9 9 – A where "FC" is the 2-digit FC number of the participant's original Field Center.

Dates

A date is required at the beginning of each form (usually the date of contact such as date of the phone contact, follow-up, or event). On the paper forms, this is shown as:

Record dates in MM-DD-YY format, where two digits are recorded for month, two for day, and two for year. In some cases, only month and year are requested (MM-YY or MM-YY). Add leading zeros as necessary to fill in the boxes:



Codes for dates are:

Month	Day	Year
01 - January	01	Last two digits of year
02 - February	02	05
03 - March		06
04 - April		07
05 - May	31	etc.
06 - June	30	
07 - July		
08 - August		
09 - September		
10 - October		
11 - November		
12 - December		

Employee ID

The WHIX employee ID number is a 5-digit number assigned to each FC staff member. See *Section 10.2 – General Data System Maintenance* for a description of when and how the numbers are assigned.

Contact Type

Contact type is required at the beginning of most forms. You use it to indicate the type of contact you had when you completed the particular form.

1 – Phone
2 – Mail
8 – Other

Mark "1 – Phone" if you completed the form based on a phone contact. This occurs when you call the participant or the participant calls the FC.

Mark "2 – Mail" if you receive information about the participant in the mail. An example of a mail contact is when a participant mails a questionnaire to the FC.

Mark "8 – Other" if none of the above contacts apply.

Visit Type

Visit type is required at the beginning of most forms. Indicate the type of contact for which the participant or the FC staff are completing the form, even if the contact is not at the scheduled contact.

3 – Annual Contact
4 – Non-Routine Contact

Text Fields

Some forms contain text fields. The most common text fields are 1) names, 2) addresses, and 3) specify fields for questions answered "Other, specify".

Key-enter all text fields in upper/lower case format. Pay particular attention to the proper capitalization of participant's names and addressees. The text may be used to generate address labels. Use all upper case only for those fields that usually require all upper case letters (for example, the 2-letter state abbreviation).

Spanish Translation

The self-administered and interviewer-administered forms have both an English and Spanish version. Both the English and Spanish versions of the forms have the same form number, with the Spanish version differentiated with an "S" after the form number.

Both the English and Spanish versions of the forms are key-entered into the same data entry screen. The key-entry screens for these forms contain a data item at the end of the screen in which to indicate if the form is in English or Spanish.

- If the form is an English version that you key-enter, you can leave the item blank or key-enter "1 – English".
- If the form is a Spanish version, you must key-enter "2 – Spanish".

10.5.1.5 Quality Assurance

Data management procedures and processes are monitored on-site for quality by CCC staff. See *Section 11 – Quality Assurance* for a detailed description of CCC data management operations and for reports and procedures that FCs can use to help monitor the quality of data management.

10.5.2 Data Entry

Some data enter the WHIX database via key-entry of study forms. The *Form Responses* screen and basic key-entry procedures for most WHI forms are identical. The exceptions are *Form 9 – Participation Status, Form 23 – Search to Locate Participant and Form 24 – Retention Worksheet.* Refer to *Appendix A* for detailed instructions on administering, completing, and coding individual WHIX forms. See *Section 10.5.2.3.1 – Form 9, Section 10.5.2.4.1 – Form 23,* and *Section 10.5.2.4.2 – Form 24* for instructions on key entering these forms.

Note: When entering data, at no point should a data entry staff person edit data on a form. If the data entry staff detects an omission or error on a form, they should return the form to the staff person responsible for the form rather than making any edits.

10.5.2.1 Key-Entry Procedures

Key-entry of a standard WHIX form begins at the *Member Data* menu.

To key-enter a form:

1. Follow the steps in *Section 10.4.2 – The Encounters Block* to access and enter data into the *Encounters* block.
2. Click the **Next Block** button on the toolbar to reach the *Form Responses* block and begin key-entering the remainder of the form. *Note:* The *Questionnaire Event* block is already filled in with the participant's name and the data from the *Encounters* block.
3. The *Form Responses* block has five fields:

   Order – the sequential order of the fields. Every data item has a unique field order number.
   Question – the text of the question.
   Question [Number] – the number of the question on the form.
   Value – the value that the data entry staff member types in from the form.
   Value Description – a description of the response code.

When you first enter this block, the "Value" field for the first data item is active and ready for key-entry from the form. You cannot enter data in any other fields in this block.

4. Pay careful attention to the question number on the screen—the first response on the form is not always the first to be key-entered and not all responses on a form are necessarily key-entered. Type the checkbox code, number, or text response to each question that has a corresponding number on the screen. Press **Enter** after keying each response to move to the next field.

   Enter checkbox codes as they appear on the form. If you enter an invalid checkbox value and press **Enter**, an error message appears. WHIX will not allow you to proceed with key-entry until you delete the invalid value or replace it with a valid value.

   Enter numeric fields as completed on the form. Leading zeros do not need to be key-entered for numeric values. Enter times in the format HH:MM, based on a 12-hour clock. If you enter a numeric response (for example, an age) outside of the expected range, you get a warning message that in most cases can be overridden. In such cases, click the **OK** button on the warning message box to acknowledge the warning message. Re-enter the number if necessary or press **Enter** again to move to the next question. In other cases, you get a warning message that can not be overridden; for example, when you enter a 3-digit number in a field that only allows two digits. In these cases, acknowledge the error message by clicking the **OK** button on the warning message box and then enter a valid value in that field before you proceed to the next field.

5. Key-enter all text fields in upper/lower case format. WHIX automatically converts fields requiring upper case to upper case.

6. Skip patterns in the key-entry program generally match the skip patterns on the form. Skip patterns are only activated if you press **Enter** (not the down-arrow key) to move to the next field. Some types of questions responses such as "Mark all that apply" require pressing **Enter** to move past responses not marked on the form.

7. At the end of many questionnaire key-entry screens are two more standard data items: *Form Administration* (at the end of self-administered and interviewer-administered forms) and *Language*.

   - Form Administration is documented on the form itself. Values include codes for self, interview and assistance. Key the Form Administration code from the form.
   - Language codes are not recorded on the form. Self-administered and interview forms are printed in both English and Spanish. Enter "2" if the form is in Spanish; enter "1" or leave blank if it is in English.

8. Click the **Save** button to save.

10.5.2.2 Making Corrections to Key-Entered Data

10.5.2.2.1 Alerts

All skip pattern errors, missing responses, and values out of range on a form will be marked with a red asterisk (*), indicating an *alert*, in the *Responses* block. The report *Unresolved Alerts (QA001)* (see *Section 7 – Queries and Reports*) will list items that must be investigated and updated. When you move the cursor to a data item that is marked with a red asterisk, a description of the corresponding problem is displayed in the *Alerts* block at the bottom of the screen. Alerts will only show for pre-Extension forms if you edited a form between June 1, 2005 and September 12, 2005.

When you edit or delete a previously-saved response, an audit box pops up and you are required to select a reason for the edit from a drop-down list. Select the reason that most closely describes the reason for the change from the following choices:

- Data entry error
- Misreport by respondent
- Merging forms

- Completing data entry
- Additional data obtained
- Other

There is space in the pop-up box to enter a brief text comment. You are required to enter a comment detailing the reason for the change if you select **Other** as the reason for the change. Entering a comment is optional if any another reason is chosen. Both the reason and the comment will appear in the *Alerts* block at the bottom of the screen. Changes made by the CCC to pre-Extension forms (such as birth date changes on *Form 2 – Eligibility Screen*) are also displayed in the *Alerts* block. The audit system will serve as a record of the data change; you do not need to hand-edit a hard copy of the form. Once a response has been edited or deleted and saved, that field will be highlighted in yellow as long as you remain in the *Responses* screen.

The Encounters Block

You cannot change or delete encounter data for pre-Extension tasks, except for ancillary study enrollments. To change a participant's date of birth if originally reported incorrectly on *Form 2 – Eligibility Screen*, you must contact your CCC Data Coordinator Liaison.

You can update employee ID, contact type and visit type for Extension tasks that you have key-entered. Encounter data from forms entered at the CCC can't be updated.

To update encounter information:

1. In the *Encounters* block retrieve the record for the task whose encounter information you wish to update.
2. Press **Tab** to reach the appropriate field.
3. Replace the existing encounter information with the new information.
4. Click the **Save** button on the toolbar to confirm the new encounter information.
5. Scan or key-enter the Member ID of the participant whose task information you have updated. Click the **Save** button on the toolbar.

You cannot update the task number or contact date. If you have key-entered these values are incorrectly, you must delete and re-key the entire form including any questionnaire data items that you have key-entered in the *Questionnaire Responses* block.

To delete an Extension encounter that contains key-entered data:

1. In the *Encounters* block retrieve the record for the task whose form responses you wish to delete.
2. Click the **Next Block** button on the toolbar to move from the *Encounters* block to the *Questionnaire Responses* block.
3. In the *Questionnaire Responses* block, select **Delete** from the *Record* menu.
4. A box will pop up asking you to confirm that you want to delete the questionnaire. Click **Yes** to delete both the responses and the encounter data.

The Form Responses Block

To change or update individual responses from an Extension form:

1. In the *Encounters* block, retrieve the record for the task for which you are changing a form response.
2. Click the **Next Block** button on the toolbar to reach the *Questionnaire Responses* block.
3. **Tab** or scroll to field containing the answer that you wish to change.
4. Replace the existing data with the updated information.
5. Click the **Save** button on the toolbar to save the new data.
6. Press **Ctrl-Q** to return to the *Encounters* block.

Note: You cannot change or delete encounter data or form responses for pre-Extension encounters, except for ancillary study enrollment tasks.

10.5.2.2.2 "Unknown" Responses

The interviewer or another staff member responsible for administering the form should mark "unknown" in the margin for responses that a participant can't provide. The key-entry person then leaves these items blank in the database.

10.5.2.3 Personal Information Update

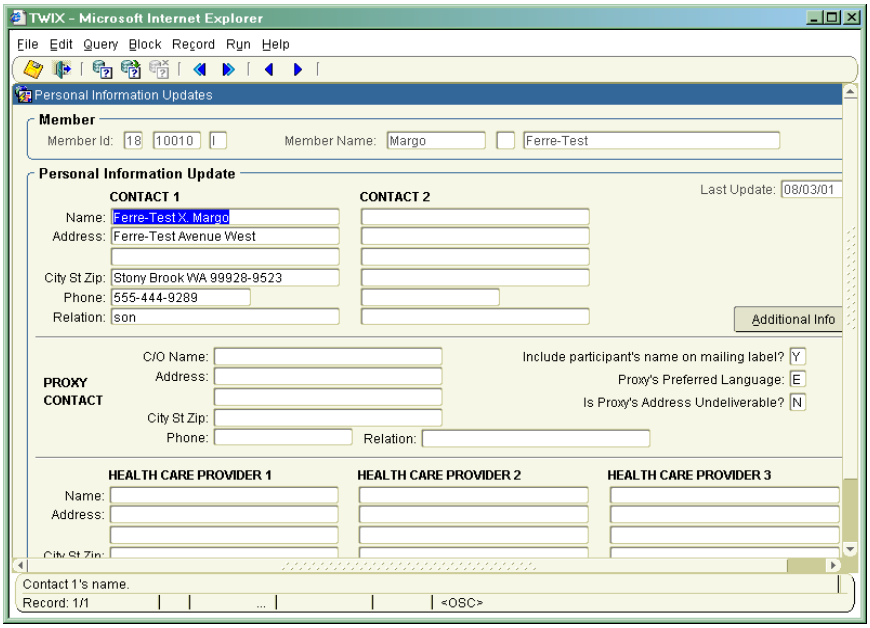
The *Personal Information Update* screen (*Figure 10.19*) contains the secondary contact and proxy information for the participant as well as the contact information for up to 3 health care providers. Mailings to participants whose follow-up status is set to *4 – proxy contact* will be sent to the proxy's address as entered in this screen. By default the mailing label will have both the participant's name and the proxy's name on it. If you don't want the participant's name to appear on the mailing label, set the *Include participant name on mailing label* flag to **N** in the proxy information area of this screen. You can also modify the proxy's preferred language (English or Spanish) and set the proxy's *Undeliverable Address* flag to Y in this screen. If the proxy address is set to undeliverable, no mailings will be sent. If the proxy doesn't wish to receive mailings, set the participant's status to "no mail" rather than setting the proxy address to undeliverable.

This information and the second home address, the valid dates for each address and the email address will print out on the *WHIX0441 – Personal Information Update Report*.

To add or update other contact information from the *WHIX0441 – Personal Information Update Report*:

1. Retrieve the participant record in the *Member Data Entry* screen.
2. Select the *Personal Information Update* screen from the *Run* menu. To add or change the proxy contact, health care provider(s), or "other contact" information, position the cursor in the appropriate field, delete the old information , key-enter the new information and click the **Save** button. To view the father's name, participant's legal name and social security number, click on the **Additional Information** button.

Figure 10.19
Personal Information Update Screen

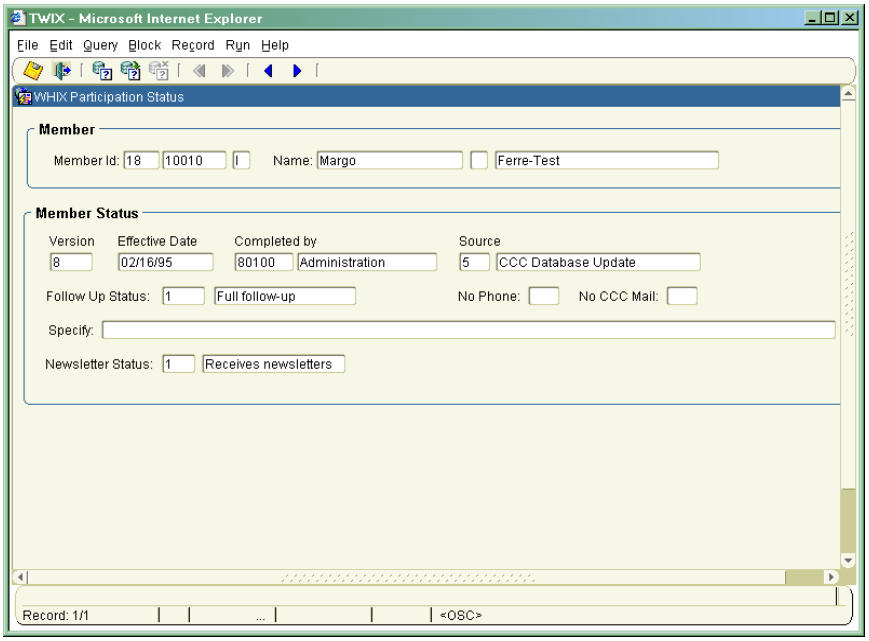


10.5.2.4 Updating Participation Status

10.5.2.4.1 Member Status Screen (*Form 9 – WHI Extension Study Participant Status*)

To enter a *Form 9 – WHI Extension Study Participation Status*, in the *Member Data Entry* screen, select *Member Status* screen (*Figure 10.20*) from the *Run* menu *(*see *Section 4 – Member Data Entry Screen).* The screen displays follow-up and newsletter status. The most recent follow-up status is displayed. View previous statuses from *Form 7 – Participation Status* by selecting *Display pre-extension statuses* from the *Run* menu while in the *Member Status* screen.

Figure 10.20
Member Status Screen



To enter *Form 9*:

1. Select **Create New Member Status Entry** from the *Run* Menu.
2. WHIX automatically fills in the version number.
3. Enter the contact date from the *Form 9* into the "Effective Date" field. This date cannot be earlier than the date of the most previous Participation Status Update and cannot be a future date. Press **Tab**.
4. Enter the Employee ID number from the *Form 9*. Press **Tab**.
5. Enter the Source code that corresponds to the source of the status change information. Press **F9** for a list of source codes.
6. Enter a new follow-up status if recorded on the *Form 9* (see *Appendix A – Forms* for a description of follow-up statuses). Press **F9** for a list of follow-up statuses. If a participant's follow-up status is 2 (Proxy Follow-up), 3 (Partial Follow-up) or 4 (Custom Follow-up), as indicated on the *Form 9*, after entering the proper code, press **Tab** to reach the "No Phone" and "No CCC Mail" fields. Enter the codes for these fields if indicated on the form.

   WHIX automatically changes the Newsletter status to "No" when the follow-up status is 6 (Deceased). *Note:* You are not able to enter a follow-up status of 6 – Deceased or 7 – Lost to Follow-up. These codes are set automatically by WHI*X* (see below).
7. If the participant's Newsletter status has changed, enter the new status.
8. Click the **Save** button to commit the participant status change.

The follow-up status codes 6 – Deceased and 7 – Lost to Follow-up can't be entered by the FC.

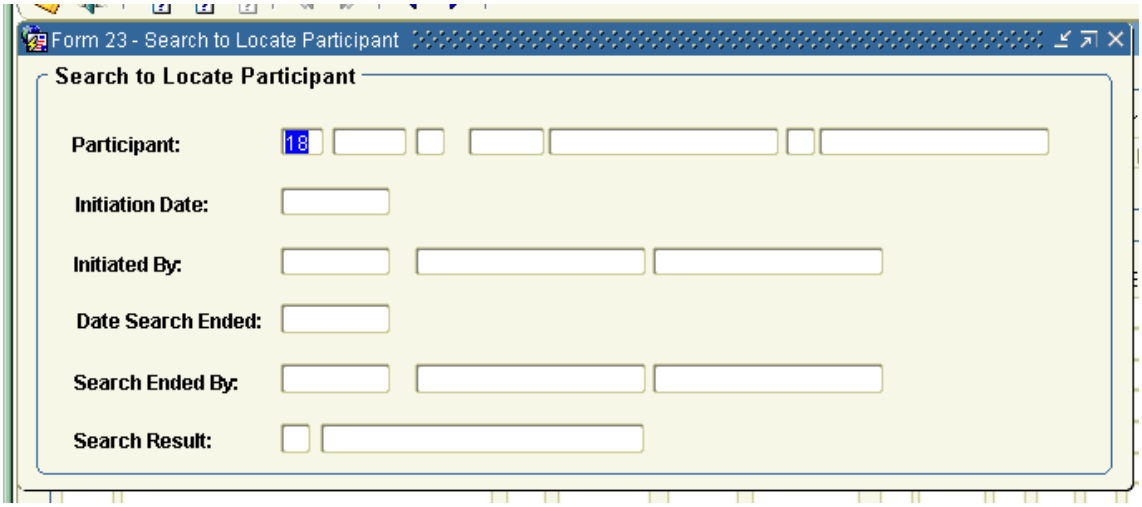
A participant's follow-up status will automatically be updated to 6 – Deceased when a *Form 120 – Initial Notification of Death* is entered in WHIX.

10.5.2.5 Entering Retention Forms

10.5.2.5.1 *Form 23 – Search to Locate Participant*

The *Participants Search Result* screen, shown in *Figure 10.21* is used to key-enter *Form 23 – Search to Locate Participant*. *Note:* Refer to the form instructions for *Form 23*, included in *Appendix A – Forms*, for information on when the form should be used and how to complete the form.

Figure 10.21
Search to Locate Participant Screen



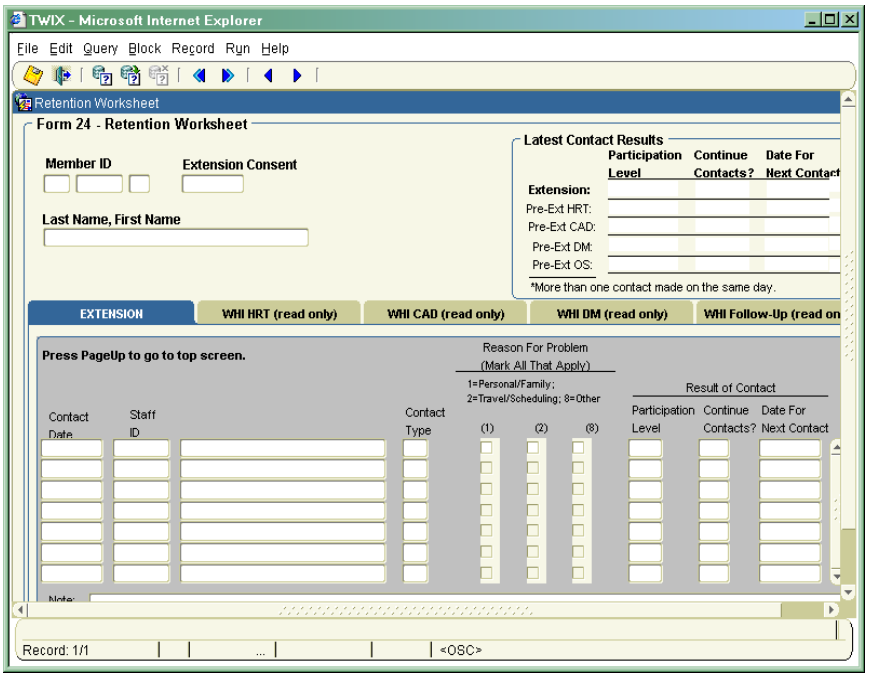
To key-enter a *Form 23 – Search to Locate Participant*:

1. Retrieve the participant's record in the *Member Data Entry* screen.
2. Choose *Form 23 – Search to Locate Participant* from the *Member Data/Member Entry/Run* menu or the Member *Data/Retention* menu.
3. Scan or key-enter the participant's Member ID from the form. Press **Tab**.
4. Enter the date the participant search was initiated from question 1 on the form. Press **Tab**.
5. Enter the Employee ID of the staff member who initiated the search.
6. Click the **Save** button to commit. When the participant search has ended, key-enter the additional information that has been gathered in WHIX.
7. Choose *Search Results* from the *Member Data/Retention* menu.
8. Query to retrieve the participant record that you are updating.
9. Press **Tab** until you reach the "Date Search Ended" field.
10. Enter the date the participant search ended from question 6 on the form. Press **Tab**.
11. Enter the Employee ID of the staff member who ended the search. Press **Tab**.
12. Enter the 1-digit "search result" code.
13. Click the **Save** button to commit.
14. Update the participant's address and/or participation status as appropriate. Update the participant's address through the *Member Data Entry* screen (see *Section 10.4*) and participation status in the *Member Status* screen (see *Section 10.5.2.4.1*).

10.5.2.5.2 *Form 24 – Retention Worksheet*

The *Retention Worksheet* screen, shown in *Figure 10.22* is used to key-enter *Form 24 – Retention Worksheet*.

Figure 10.22
Retention Worksheet



To enter a *Form 24 – Adherence and Retention Worksheet*:

1. Retrieve the participant record in the *Member Data Entry* screen.
2. Choose *Form 24 – Retention Worksheet* from the *Member Data/Member Entry/Run* menu or the *Member Data/Retention* menu.
3. The cursor is in the "Member ID" field. Key-enter or scan the participant's Member ID from the *Form 24.* Press **Tab.**
4. The **Extension** tab is in front. You can click on the other tabs: WHI HRT, WHI CAD, WHI DM and WHI Follow-up to view previous retention contacts during the WHI study. You cannot enter data in those tabs.
5. The cursor is in the "Contact Date" field. Enter the contact date from the *Form 24*. Press **Tab**.
6. The cursor is in the "Staff" field. Enter the contact date from the *Form 24*. Press **Tab.**
7. The cursor is in the "Contact Type" field. Enter the 1-digit contact type code from the *Form 24.* Press **Tab.**
8. Enter the "reason(s)" from *Form 24* by clicking in the appropriate "Reason" field(s). Tab to the "Participation Level" field.
9. Enter the "Participation Level" code from *Form 24*. Press **Tab**.
10. Enter the "Continue Contacts" code from *Form 24*. Press **Tab**.
11. Enter the "Date for Next Contact" from *Form 24* (if applicable).
12. Click the **Save** button.

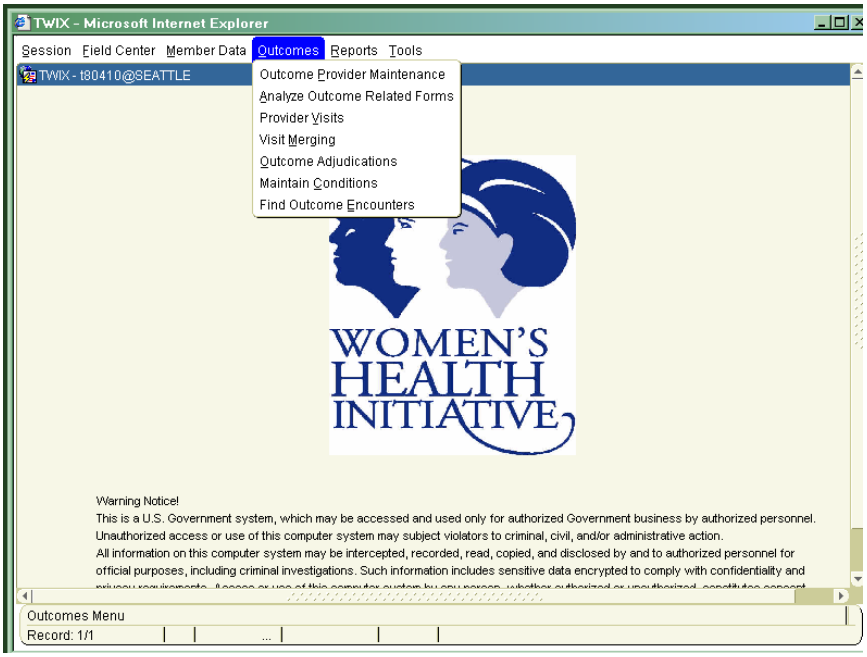
10.6 Outcomes Data Management

10.6.1 Overview

The Outcomes Data Management system in WHIX consists of the following three components:

- The A*nalyzer,* which programmatically reviews *Form 33D – Medical History Update Detail* and *Form 120 – Initial Notification of Death* to determine whether the forms are incomplete and need further follow-up; whether there are potential outcomes or *conditions;* or there are no outcomes self reported by a participant or proxy. The *Analyzer* also determines if an adjudication case needs to be created based on study defined rules.
- *Provider Visits*, where visits (i.e., health care providers) are created and linked with conditions (i.e., medical condition or procedure), and appropriate medical records documents are requested for the condition.
- The *Adjudication* component, where medical documents or *adjudication case packets* are tracked. Adjudications are closed locally if they are on the 'bunionectomy' list or if they are a duplicate of a previous case, or are closed and forwarded to the CCC for adjudication.

Figure 10.23
WHIX Outcomes Menu

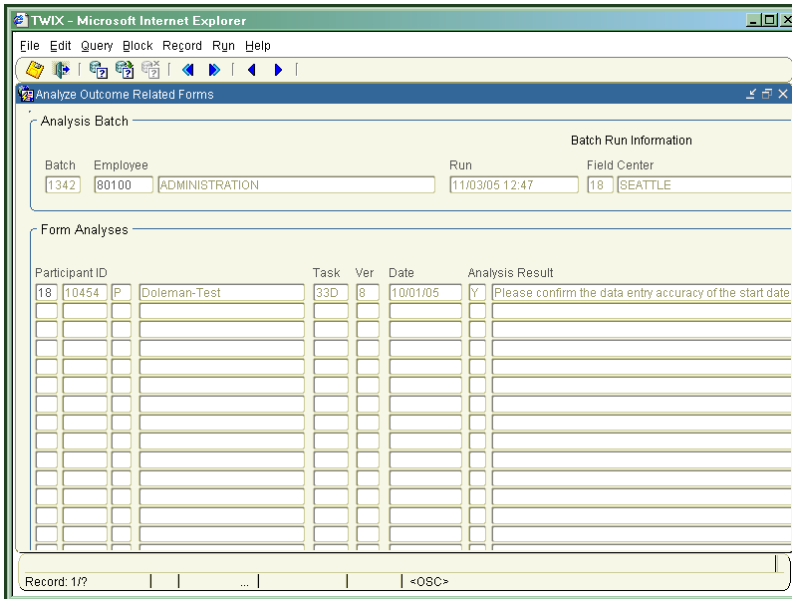


10.6.1.1 Analyze Forms

The analyzer portion of the WHIX Outcomes subsystem (*Analyze Outcomes Related Forms*) looks at *Form 33D – Medical History Update (Detail)* and *Form 120 – Initial Notification of Death* for the existence of possible outcomes defined as a "condition" in the WHIX system. The Analyzer is automated so that unanalyzed forms are analyzed each night by the CCC, and analysis results can be viewed by the FC. *Note:* FCs do not have the ability to analyze forms locally.

WHIX indicates whether conditions were found in the "Analysis Result" field for each analyzed form, as shown in *Figure 10.24*. At the WHIX main menu, go to *Outcomes/Analyze Outcomes Related Forms* screen.

Figure 10.24
Analyze Outcome Related Forms Screen



Analysis results include the following:

- If no conditions of interest are indicated on the form, "N" is displayed.
- If at least one condition of interest is indicated on the form, "Y" is displayed.
- If more information is needed before the form can be analyzed to determine if a condition is indicated (for example, a key question on the form has not been entered in WHIX), "I" is displayed. In these cases, the number of the question that needs information is displayed as a comment. If there is more than one blank question or discrepancy on the form, only the number of the first question found with an error is indicated in the comment.
- Any form with an "I" analysis result ("Information Needed") should be returned to the employee who reviewed it for editing. Resolution may also require follow-up with the participant to clarify or complete needed information. An "I' result is also returned if the analyzer detects a visit that is not associated with any conditions.

  Note: You can move to a record and select **View Questionnaire** from the *Run* menu to view the *Form 33D* or *Form 120* questionnaire responses. If the form is edited and the corresponding changes are made in WHIX, the form will be included in the next analysis batch.

  Note: You can delete a record that has an "N" or "I" result from an analysis batch if the record is not associated with any conditions.

- If a *Form 33D* or *120* needs to be re-analyzed because of corrected information, you must first make the edit on the form and change the response in WHIX.
- A *Form 33D* or *Form 120* cannot be re-analyzed if conditions already exist for that form. You must delete the existing conditions, visits and adjudications from the outcomes subsystem before re-analyzing the form. (See *Section 10.6.1.6 – Deleting Conditions and Visits* and *Section 10.6.2.8 – Deleting an Adjudication Case).*
- Conditions that are associated with more than one "routine" *Form 33D* cannot be combined into one visit unless one of the visits is flagged as a duplicate visit.
- When a form that was previously analyzed with an "N" or "I" result is re-analyzed, the previously analyzed records for that form will be automatically deleted from the old batches.
- The *WHIX0983 – Forms to Pull by Outcome Analysis Batch* report lists (for a given analysis batch) the analysis results for each encounter that requires follow-up (such as forms with an "I" result or forms with

a "Y" result where conditions were identified). You can access this report from the *Analyze Outcome Related Forms* screen by going to the *Run* menu.

- To query for a particular analysis batch, enter the batch number in the "Batch" field and click on the **Execute Query** button.
- *Form 33D* with unresolved missing information resulting in an "I" analyzer result: If all attempts (using multiple strategies) have been unsuccessful at resolving the information error and an outcome of interest is documented on the form, manually insert the condition and provide visit and link it to a manually created adjudication case as described in *Sections 10.6.1.2.1 – Manually Creating a Provider Visit, 10.6.1.5.2 – Creating a New Condition,* and *10.6.2.2 – Manually Creating an Adjudication Case Packet in WHIX*. Once adjudicated, *Form 33D*s with missing or discrepant information will fall off of the WHIX0622.

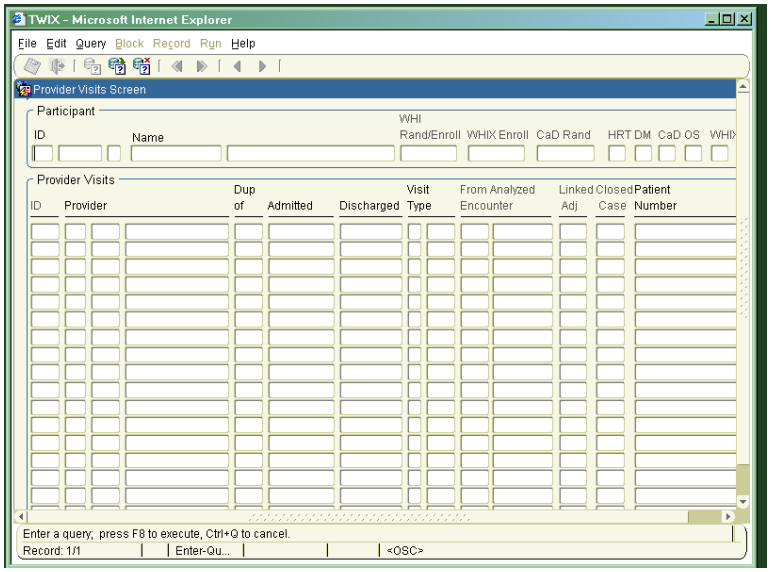
10.6.1.2 Provider Visits Screen

When the Analyzer returns a result of "Y" (yes, conditions found), WHIX, *in most cases*[1], automatically creates details for any visit or condition associated with that form.

Based on information provided on the form, WHIX assigns each provider visit indicated on the form a unique, sequential *Visit ID and case number*; a visit type of "inpatient", "outpatient," or "other"(if location of death is unknown), and links each visit with one or more conditions.

This information from the Analyzer is all found in the *Provider Visits* screen. This is also the screen where you can manually create provider visits when necessary and where you request and receive provider documentation. To access this screen, select **Provider Visits** from the *Outcomes* menu. This opens the *Provider Visits* screen, shown in *Figure 10.25*.

Figure 10.25
Provider Visits Screen



[1] Exception-- if you analyze a *Form 33D* on which the participant has indicated more than 3 overnight hospitalizations of 2 or more nights in Question 9 or more than the number allowed in each specified outcome section, the participant is asked to list the additional information on last page of *Form 33D*. WHIX links the first 3 hospitalizations to conditions and displays the following comment in the *Form Analysis* block: "WARNING: Form indicates > 3 hospitalizations". The Outcomes Coordinator must then manually create and link any additional visits that the participant indicated on the form and investigate the hospitalizations. Forms indicating more than 3 hospitalizations will appear on the *Forms to Pull* report (*WHIX0983*) for that batch. This prompts the Outcomes Coordinator that additional follow-up may be required for those forms.

The *Provider Visits* block displays all provider visits reported from any analyzed form for a specific participant. You can distinguish the provider visit(s) corresponding to analyzed forms by looking at the form number and encounter date in the "From Analyzed Encounter" fields. WHIX automatically creates an adjudication case for every visit. The adjudication case number is displayed in the "Adj ID" field. The "Adj Closed" field displays "Y" if the visit is in a closed adjudication case and "N" if the visit is not in a closed case.

Changing an Existing Provider ID

You can change a Provider ID in the *Provider Visits* screen for an existing visit by entering a different provider ID in the "Provider" field. However, if you have already requested documents from the original (incorrect) provider, you will need to delete the request dates (and received dates, if applicable) before you can change the Provider ID.

Adding a New Provider

If you need to add a new provider, see *Section 10.6.3 – Provider Maintenance* for details about adding new provider information. *Note:* You may also reach the *Outcome Provider Organizations* screen by selecting *Providers* from the *Run* menu in the *Provider Visits* block of the *Provider Visits* screen.

Duplicate Visits

Duplicate visits are created in WHIX (usually) when the same provider visit is reported on two different *Form 33D*s. Rather than deleting one of the visits, flag it as a duplicate and then close the case that contains the visit using the appropriate closure code (see *Section 10.6.2.7 – Closing a "Non-WHI Extension Outcome"*). To flag a visit as a duplicate of another in the Provider Visits screen, enter the number of the original visit in the "Dup of" column of the duplicate visit. For example if you have two visits, visit #1 and visit #2 that are duplicates of one another and you want to indicate that visit #2 is a duplicate of #1, enter "1" in the "Dup of" column for visit #2. The adjudication case containing visit #2 can then be closed with the "duplicate" closure code as described in *Section 10.6.2.7*.

10.6.1.2.1 Manually Creating a Provider Visit

To manually add additional provider visits (if necessary):

1. From the *Provider Visits* block, select **Insert** from the *Record* menu, this will insert a new, blank record.
2. To identify a provider, press **F9** to see a list of providers entered at your FC. Move the cursor to the correct provider and click the **OK** button. Press **Tab** twice to reach the "Admit Date" field.
3. Enter the admit date for the visit. Press **Tab**.
4. Enter the discharge date, if known. Press **Tab**.
5. Enter the visit type: 1 – Inpatient; 2 – Outpatient; or 3 – Other. ("Other" should only be used for non-healthcare facility "providers" that are linked to a death condition). Press **Tab**. *Note: the visit must be linked to a condition before documents are inserted by WHI* (see *Section 10.6.1.5 – Link Provider Visits to Existing Conditions).*
6. Enter the provider's patient ID or medical record number (optional). **DO NOT enter the participant's Social Security number in this field.**
7. Click the **Save** button on the toolbar.

Note: When you manually create a provider visit, the "From Analyzed Encounter" fields will be blank. They will not contain a form number (e.g., *Form 33D* or *Form 120*) or an encounter date because the visit was not created by the WHIX analyzer.

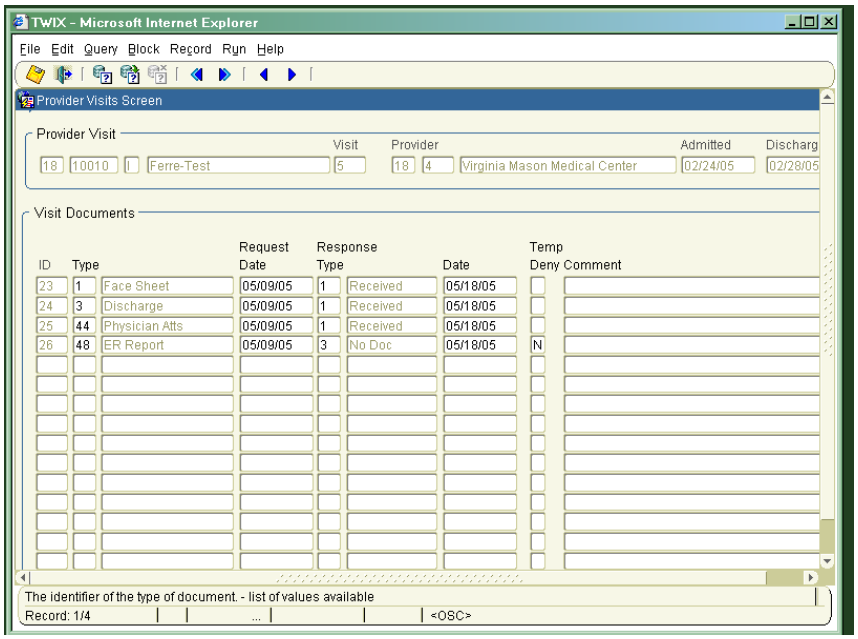
10.6.1.3 Request the Medical Documentation

To request documents, press the **Next Block** button from the *Provider Visits* block. Move to the provider visit for which you need documents and press the **Next Block** button. This opens the *Visit Documents* block, shown in *Figure 10.26*.

The standard document set for the condition and visit type is displayed.

Note: WHIX inserts documents associated with the visit. If you have changed the visit type code, (e.g., from inpatient to outpatient), the document set may change. Documents that have already been requested will not be deleted. The number of documents being added to or deleted from the document set is displayed on the message line.

Figure 10.26
Visit Documents Block



To request a document set for a provider visit:

1. Select **Enter Request Dates** from the *Run* menu to "request all" of the documents. WHIX fills in the "Date Requested" field with the current date. You can change this date, if needed, by pressing **Tab** to reach the "Date Requested" field and changing the date as appropriate for each document.
2. Click the **Save** button on the toolbar.
3. Select **WHIX0980 – Request for Medical Record Information** from the *Run* menu.

   This report serves as a cover sheet to be sent to the provider institution when requesting medical records. It lists your FC's name and address, the participant's name, address, Member ID, the hospital admission date, the list of documents that you are requesting and the date requested. When you open the parameter screen for the *WHIX0980* report from the *Visit Documents* block, the parameters have already been filled in with the current participant and visit information.

4. Enter date parameters if necessary and click the **Run Report** button to run the report and print the report.

Inserting Visit Documents

If desired, you can insert additional documents into the request list. Select **Insert** from the *Record* menu to reach a new blank record. Press **F9** to see a list of available documents. Scroll down the list to find the document you wish to request and click the **OK** button to select the document.

Deleting Visit Documents

If you need to delete a document from the request list, move the cursor to the document you wish to delete and select **Delete** from the *Record* menu. Whenever possible, please do not delete documents from the standard document set created by WHIX.

10.6.1.4 Receive the Medical Documentation

As you receive documents from a provider, log in the institution's response to the request (i.e., documents have been received, are not available, or are temporarily or permanently denied).

1. From the *Outcomes* menu, choose *Provider Visits*.
2. You are in the *Members* block and in query mode when the screen opens. Retrieve the record of the participant whose provider documents you wish to log in:
   - Enter the participant's Member ID.
   - Click the **Execute Query** button.
3. Click the **Next Block** button on the toolbar to reach the *Provider Visits* block.
4. In the *Provider Visits* block, select the record for the institution and visit for which you have received a document request response. Click the **Next Block** button to reach the *Visit Documents* block.
5. The cursor is in the "Type" field for the first requested document in the document set. Press **Tab** twice to reach the "Response Type" field.
6. Enter the code appropriate to the response received regarding that document. (You can press **F9** to see the list of values, highlight your choice and click the **OK** button to select it.)

   Allowable response codes are:

1	Received	Received
2	Not Yet	Document not yet completed
3	No Doc	Document does not exist
4	No Release	Release is not valid
5	No Patient	Patient is not found
6	No Visit	Visit for patient not found
7	Other Deny	Denied for Other Reason

7. Press **Tab**. The "Receive Date" field is automatically filled-in with the current date. You may overwrite this with another date if appropriate.
8. Press **Tab** to reach the "Temp Deny" field. If you did not receive the document from the provider, indicate if the denial is temporary ("Y") or permanent ("N"). If you entered reasons 2 or 4 for the denial type, this field is automatically filled-in as "Y". If you entered reason 3, this field is automatically filled-in as "N". These codes can be changed if appropriate. Use of this field is optional. *Note:* Records marked "Temp deny" will not appear on *WHIX 0980* unless the request date for the document is after the "Temp deny" response date.
9. Press **Tab** to reach the "Comment" field. Enter any comment about the document. This field is optional. Comments will print on the *Investigation Document Summary* (*WHIX0988*) that is sent to the CCC.
10. Press **Tab** to return to the "Type" field, then **Down-arrow** to move to the next document.
11. Repeat steps 6-10 for each requested document.
12. Click the **Save** button on the toolbar to save the document information.

Select **Labels** from the *Run* menu to print an identification label for the documents that you have received (optional). WHIX prints one label identifying the participant and a visit for each document. The label should be placed on the first page of each document before the documents are forwarded to the CCC.

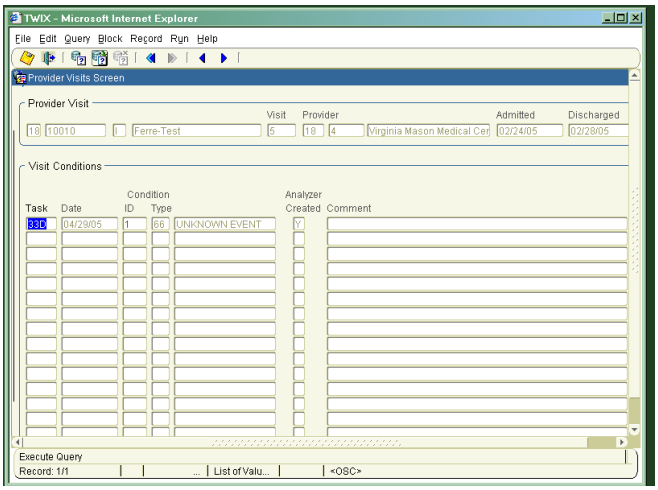
10.6.1.5 Link Provider Visits to Existing Conditions

WHIX automatically creates conditions based on information entered on the participant's *Form 33D* or *Form 120*. In most cases, these conditions are automatically linked to provider visits. However, WHIX also allows you to manually link conditions to a provider visit in the *Provider Visit* screen. New conditions can be created only in the *Maintain Conditions* screen. (See *Section 10.6.1.5.1 – Maintain Conditions Screen.*)

To view a condition created by the analyzer:

1. In the *Provider Visits* block, move to the visit whose linked conditions you wish to view. (See *Section 10.6.1.2 – Provider Visits Screen* for more information.)
2. Press the **Next Block** button <u>twice</u> to reach the *Visit Conditions* block, shown in *Figure 10.27*.

Figure 10.27
Visit Conditions Block



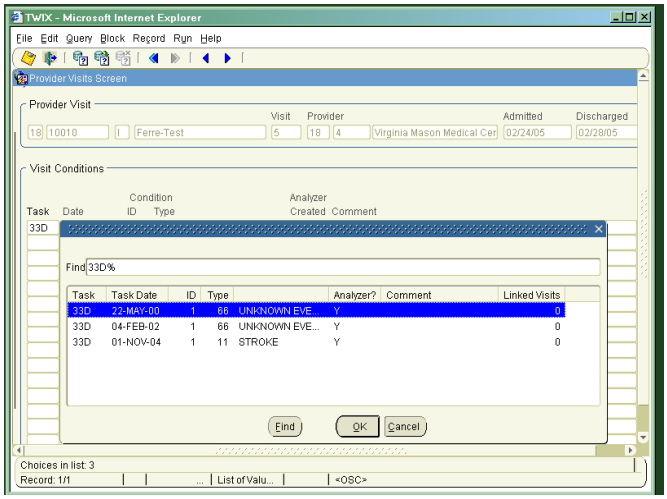
WHIX has automatically linked conditions to the provider visit based on information found on the analyzed form. You can link additional existing conditions to the provider visit if appropriate.

To link an existing condition to the provider visit:

1. In the *Visit Conditions* block, select **Insert** from the *Record* menu to reach a new, blank record.
2. Press **F9** to open the list of conditions reported for the participant. This lists all conditions that have been indicated for the participant on any form (*Figure 10.28*).
3. Select the reported condition that you wish to associate with the current visit and click the **OK** button to select.

WHIX inserts the selected condition into the visit. Any provider documents that are associated with the newly-inserted condition and are not already part of the document set for this visit will be added as visit documents.

Figure 10.28
Reported Conditions Block



Note: WHIX expects all conditions linked to a single visit to be associated with the same *Form 33D* or *Form 120* encounter. If you attempt to link a condition reported on one form with a visit reported on another form, WHIX issues a warning advising you to confirm that associating that condition and visit is appropriate. In general, conditions reported on one form should not be linked to a visit that is reported on a different form.

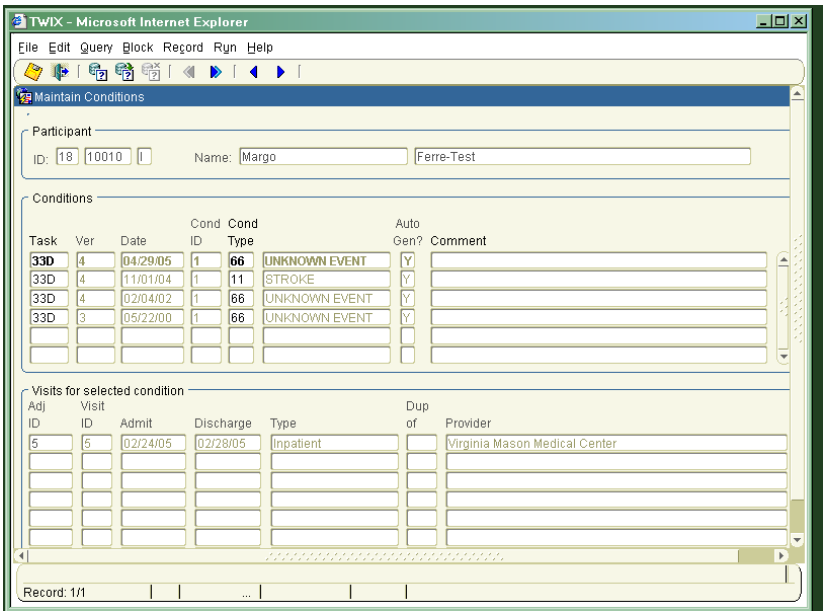
10.6.1.5.1 Maintain Conditions Screen

In the *Visit Conditions* block select **Maintain Conditions** from the *Run* menu (or select **Maintain Conditions** from the WHIX *Outcomes* menu).

The *Maintain Conditions* screen, shown in *Figure 10.29* shows all conditions that have been reported for a given participant. This screen is the only screen from which you can create a new condition. For each condition, WHIX lists:

- The task information and encounter date for the form with which the condition is associated;
- Shows whether the condition was automatically created by the analyzer or manually-inserted;
- Shows the provider visit or visits to which the condition is linked.

Figure 10.29
Maintain Conditions Screen



10.6.1.5.2 Creating a New Condition

To insert a new condition in the *Maintain Conditions* screen (see *Figure 10.29*).

1. Position the cursor in the first blank field of the *Conditions* block. (You may need to scroll down to reach a blank line).
2. Press **F9** to see a list of all outcomes encounters entered for this participant.
3. Move to the encounter that should be associated with the condition you are inserting and click the **OK** button to select.

   Note: You must associate all inserted conditions with an analyzed outcome form. Press **Tab** to reach the "Condition Type" field.

4. Enter the appropriate code for the condition type, or press **F9** to see a list of all available condition types and then click the **OK** button to select from the list.
5. Click the **Save** button on the toolbar to confirm the creation of the new condition.

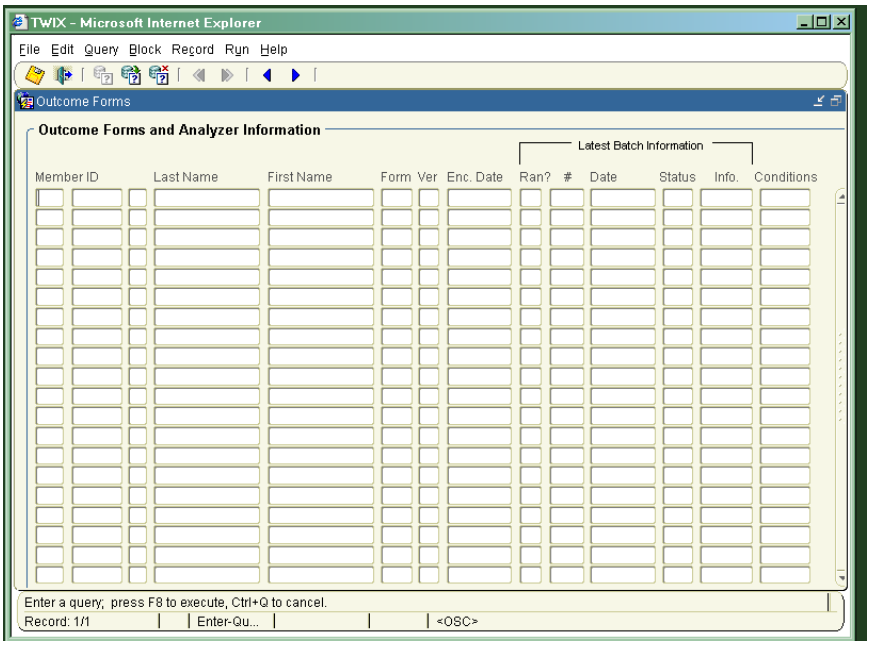
WHIX creates the condition, assigns it a sequential Condition ID, and inserts "N" in the "Auto Gen?" field to indicate the condition was not found by the Analyzer. Once you have created a new condition in the *Maintain Conditions* screen, you must link it to a provider in the *Provider Visits* screen (see *Section 10.6.1.5 – Link Provider Visit to Existing Condition*).

You can also reach the *Maintain Conditions* screen from the *Visit Conditions* block of the *Provider Visit* screen by selecting *Maintain Conditions* from the *Run* menu.

10.6.1.5.3 Outcomes Forms and Analyzer Information

The *Outcome Forms and Analyzer Information* screen, shown in *Figure 10.30*, allows you to see *Form 33s* (v.1 and 2 only*), Form 33D*s, and *Form 120*s that have been entered for a given participant.

Figure 10.30
Outcome Forms and Analyzer Information Screen



The *Outcome Forms and Analyzer Information* screen lists the following information:

- Member ID
- Participant Name
- Outcomes Form Type and Version Number
- Outcomes Form Encounter Date
- Latest Batch Info
    - Ran? —indicates whether a *Form 33D* or *Form 120* has been analyzed. The screen shows analyzed *Form 33Ds*, but does not show unanalyzed *Form 33Ds*.
    - #: indicates the analysis batch number
    - Date: indicates the analysis batch run date
    - Status: indicates the analysis result—Y, N, I, or blank
    - Info.: gives details of an "INFO" analysis result
- The Number of Conditions Associated with the Encounter

To retrieve participant information in the *Outcome Forms and Analyzer Information* screen:

Choose *Find Outcomes Encounters* from the *Outcome* menu.
The screen is in query mode when it opens. Enter search criteria and click the **Execute Query** button on the toolbar to retrieve.

Examples of search criteria you might enter are:

- A particular participant's Member ID to retrieve all outcome forms that have been entered for that participant.
- A date in the "Encounter Date" field to find all outcome forms with a particular encounter date.
- A Batch ID in the "Batch #" field to find all forms analyzed in a given analysis batch.

Options available through the *Run* menu enable you to reach the following screens from the *Outcomes Forms and Analyzer Information* screen: *Maintain Conditions*, *Merge Visits*, *Provider Visits*, and *View Questionnaire*.

10.6.1.6 Deleting Conditions and Visits

WHIX allows the "cascade deletion" of all conditions, visits and adjudications that the Analyzer has associated with a particular *Form 33D* or *Form 120*. This is helpful if a data-entry error on a form resulted in inappropriate conditions or provider visits being created.

To cascade delete the analysis and adjudication information:

1. Retrieve the appropriate record in the *Form Analyses* block in the *Analyze Outcome Related Forms* screen.
2. Select **Delete** from the *Record* menu. When prompted, click the **Yes** button to confirm the cascade delete.

WHIX then deletes all conditions, visits, documents, and adjudications associated with the selected Outcomes encounter.

Note: You cannot use the "cascade delete" feature if:

- Any documents have been received or forwarded to the adjudicator
- The adjudication has been completed by the adjudicator or closed by the FC
- The adjudication has been sent for central adjudication
- Any outcome forms exist for the adjudication

See *Section 10.6.2 – Adjudication* for additional information.

10.6.1.7 Entering *Form 33 – Medical History Update (Ver. 8)*

Form 33 tracks a participant's self-reported outcomes and is used to determine which participants need to complete a *Form 33D.* When a *Form 33* is scanned, a corresponding encounter is created in the *Encounters* block of the *Member Data Entry* screen.

The CCC mails the annual *Form 33* for the Extension Study. The forms are returned by the participant and centrally scanned at the CCC, which makes the form images available to the FCs. FCs can also complete and key-enter *Form 33s* that they administer to participants or forms that are accidentally returned by the participant to the FC, instead of the CCC.

Note: If you attempt to save a *Form 33* in the *Encounters* block and an encounter for a *Form 33* with the same visit type and year already exists, a message—"Another encounter with this Task ID and visit type exists for this participant," is displayed and the task information is not saved. Contact your CCC Outcomes Liaison to resolve this discrepancy so you can proceed with data entry of the form, if necessary.

There are two outcomes reports that help you to determine which participants should complete a *Form 33D* based on their *Form 33* responses.

- *Outcome Screening Actions Required for Form 33*s *Report* (*WHIX0621*) shows *Form 33*s that are incomplete and WHIX does not have enough information to determine if a *Form 33D* is required. For example, a *Form 33* that reports a heart or circulation problem, but is missing a response to the hospitalization stay question.
- *Form* 33s *with Potential Outcomes Report* (*WHIX0622*) shows *Form 33*s that need a *Form 33D*.
- Both *WHIX0621* and *WHIX0622* include participant phone number and contact information so that you can call the participant and collect the necessary data.

Note: A *Form 33* and its corresponding *Form 33D* must have the same date range or visit year in order for the *Form 33* to drop off of *WHIX0622*.

10.6.1.8 Entering *Form 33D – Medical History Update (Detail) (Ver. 8)*

Form 33D is key-entered at the FC through the *Encounters* block of the *Member Data Entry* screen. The outcomes Analyzer automatically links conditions to provider visits reported on this form, in most cases. For this to happen, you must enter the provider information when entering *Form 33D*.

Note: If you attempt to save a *Form 33D* in the *Encounters* block and an encounter for a *Form 33D* with the same visit type and year already exists, the message—"Another encounter with this Task ID and visit type exists for the participant," is displayed and the task information is not saved. Contact your CCC Outcomes Liaison to resolve this discrepancy so you can proceed with data entry of the form, if necessary.

Never edit a *Form 33D* for which conditions and/or visits exist. First, delete the existing conditions and visits, then edit and re-enter the *Form 33D*.

The provider information questions on *Form 33D* contain optional space for writing the Provider ID prior to the form's key-entry. This is the shaded "Office use only" box. The Provider ID is the ID number assigned by WHIX when you enter provider information in the *Provider Maintenance* screen in WHIX. You can also enter provider information and assign Provider IDs via the *Form 33D Data Entry* screen.

If a question has a provider ID option, you can enter the provider ID into *Form 33D* in one of three ways:

1. If the provider ID is recorded on the form, key enter the ID number and press **Enter**.
2. If the provider ID is not recorded on the form, but the provider has already been assigned an ID number in WHIX:
    - From the *Member Data Entry* screen, press **F9** from the *Questionnaire Responses* block for the *Form 33D*. This will open the medical providers list of values.
    - Use the scroll bar at the side of the list box to scroll through the list and find the provider; or query for the provider by clicking the **Enter Query** button on the toolbar, entering the provider name and clicking the **Execute Query** button.
    - Select the appropriate provider with the mouse and click the **OK** button.
3. If the provider number is not recorded on *Form 33D* and has not been assigned a provider ID number in WHIX:
    - From the *Member Data Entry* screen, press **F9** from the *Questionnaire Responses* block for the *Form 33D*. This will open the medical providers list of values.
    - Click the **Add New Provider** button on the list box to bring up the *Provider Maintenance* screen.
    - Enter the name and address of the new provider.
    - Click the **Save** button. This saves the data, assigns the provider ID and enters the provider ID into the *Form 33D Questionnaire Responses* screen.
    - Press **Ctrl-Q** to return to the *Form 33D Data Entry* screen.

See *Section 10.6.3 – Provider Maintenance* for further details about entering and retrieving provider information.

10.6.2 Adjudication

The Outcomes Adjudications subsystem allows you to group one or more provider visits (i.e., conditions linked to a provider) into a uniquely identified adjudication case packet. This enables the OC to:

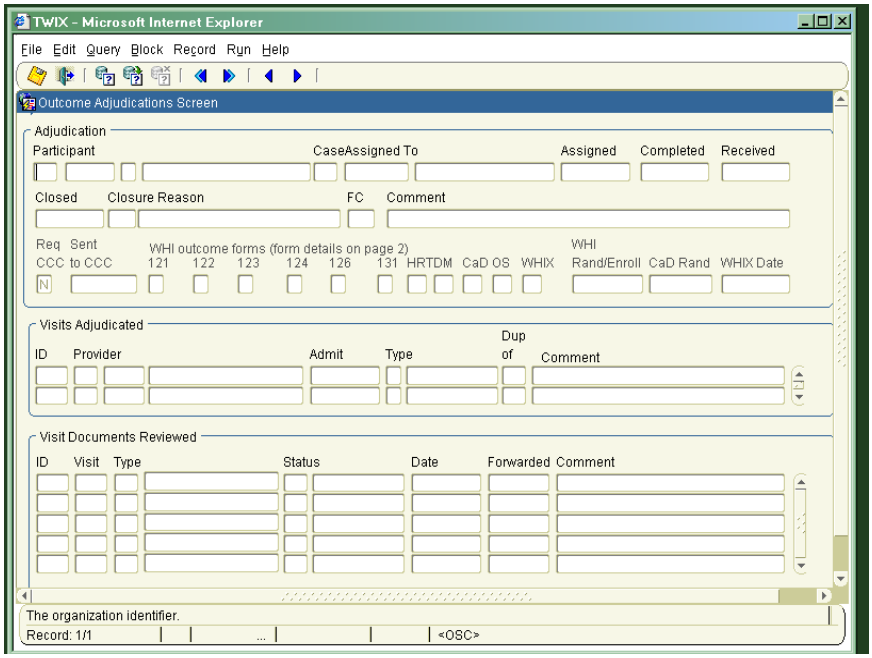
- Track documents included in each adjudication case packet.
- Create the *Investigation Documentation Summary (WHIX0988)* which serves as a cover sheet to provide information to the CCC about the documents included in the case packet.
- Enter the *Form 125 – Summary of Hospitalization Diagnosis*, if necessary, close the case; create the Member Outcomes Status Report (*WHIX1215*) and forward it to the CCC if the case is closed with a closure code of 9 – "Extension Case Forwarded to the CCC".

Note: An adjudication case packet is automatically created for conditions the Analyzer finds on *Form 33D* and automatically linked to provider visits. A separate adjudication is created for each visit created by the Analyzer. Several visits may be placed into a single adjudication case packet. The FC OC determines when it is appropriate to manually add additional visits into an adjudication case packet.

10.6.2.1 Retrieving an Existing Adjudication Case Packet in WHIX

1. From the *Outcome* menu, choose *Outcome Adjudications*. The *Outcomes Adjudications* screen opens with the cursor in the "Participant" field of the *Adjudications* block (*Figure 10.31*).

Figure 10.31
Outcome Adjudications Screen



1. Query for the participant whose adjudication information you wish.
   - Click the **Enter Query** button (or F7).
   - Enter the participant's Member ID and, if known, the adjudication case number.
   - Click the **Execute Query** button (or F8).

Note: If you do not specify an adjudication case number, all existing adjudication cases for this participant are retrieved. Use the **Up-and Down-arrow** keys to scroll through the participant's adjudication cases to reach the one for which you are entering data. (*Note:* Adjudications with no "assigned date" are retrieved first, in ascending order by case number. Adjudications with assigned dates are listed next in descending order by assigned date).

10.6.2.2 Manually Creating an Adjudication Case Packet in WHIX

Sometimes you will need to manually create an adjudication case for a provider visit that was not created by the WHIX Analyzer. To manually create an adjudication case:

1. From the *Outcome* menu, choose *Outcome Adjudications*. The *Outcomes Adjudications* screen opens with the cursor in the "Participant" field of the *Adjudications* block (*see Figure 10.31 – Outcome Adjudications Screen*).
2. Enter the participant's Member ID. Press **Tab** twice.
3. Enter the 5-digit Employee ID for the staff member to whom the case is assigned, starting with the two-digit organization ID. (*Note:* When you are manually creating an adjudication case, you must assign the case before you save). If desired, you can press **F9** to see a list of all Employee IDs at your FC and then select the appropriate **ID** from the list.
4. If desired, press **Tab** to reach the "Comments" field. Enter a comment about this participant or adjudication case. You can enter comments up to 100 characters in length.
5. Click the **Save** button and save the adjudication assignment. A message will appear--"Updating closing FC to selected access clinic (your FC number)". Click "**Yes"'** (or press Enter). WHIX assigns a sequential adjudication number to the case.
6. If you wish to add another visit to the case, click the **Next Block** button on the toolbar. This takes you to the *Visits Adjudicated* block. Press **F9** to view a list of visits that are not already assigned to an adjudication case for the participant.
7. Select a visit from the list and click the **OK** button to include it in the case. A message box will appear "Some documents still pending". Click **OK** and **Save**.
8. Repeat Steps 8-9 for any additional visits you wish to include in the case. The manual creation of the new adjudication case is complete.

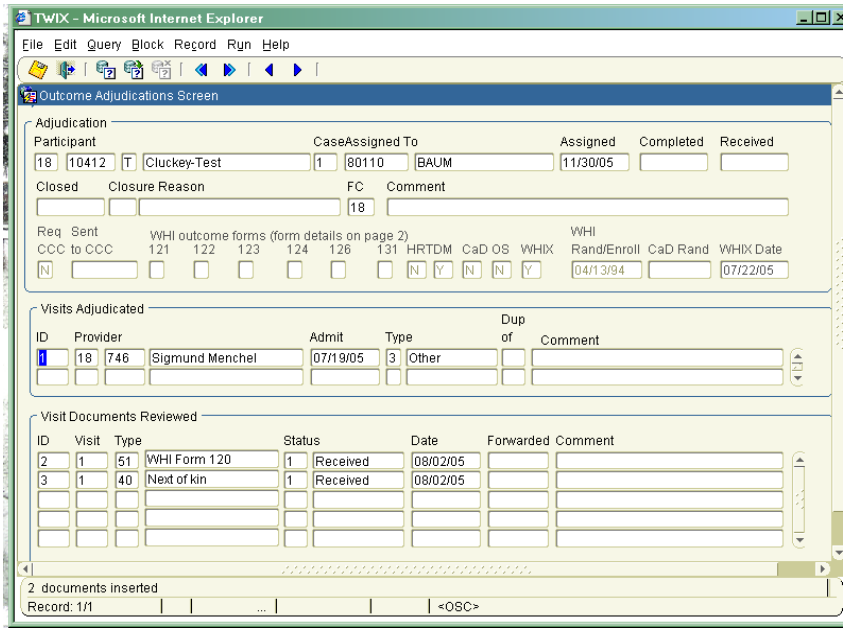
10.6.2.3 Forwarding Documents into the Adjudication Case

When you have received the necessary documents for each of the provider visits associated with a case, you must print from WHIX the associated reports to send with the documents to the CCC.

To complete an adjudication case in WHIX:

1. Retrieve the adjudication case in WHIX as described in *Section 10.6.2.1 – Retrieving an Existing Adjudication Case Packet in WHIX*.
2. From the *Member Adjudication* block, click the **Next Block** button to reach the *Visits* A*djudicated* block. All visits associated with the case are displayed in order by visit number. Documents for the visit(s) are not displayed in the *Documents Reviewed* block when you first open the screen.

Figure 10.32
Documents Reviewed



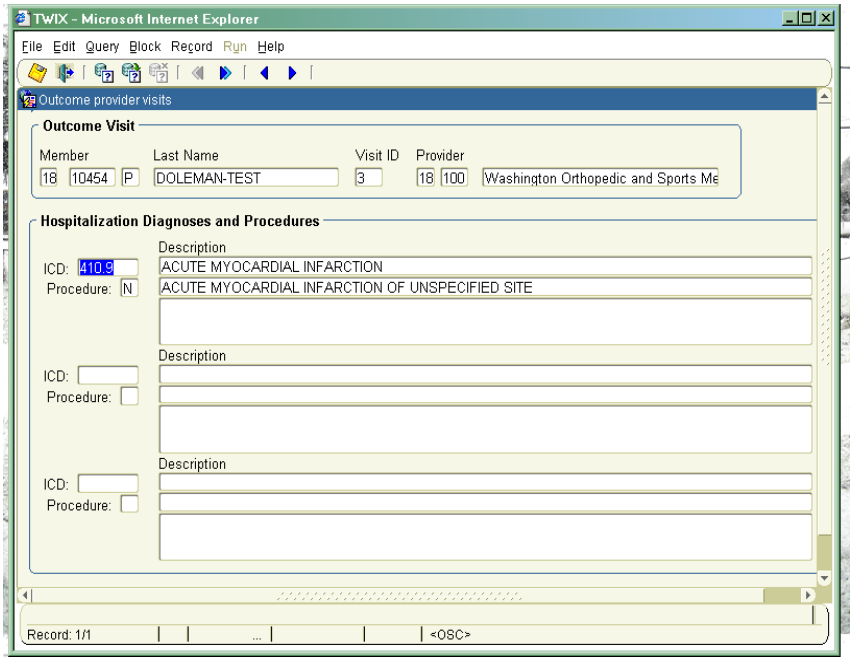
3. Select **Add Visit Documents** from the *Run* menu. This inserts, in the *Visit Documents Reviewed* block, all documents associated with the visit that have a "received" date entered (*Figure 10.32 – Documents Reviewed*). Click the **Save** button.
4. If there is more than one visit in the case, you must add the documents for each visit separately by repeating steps 2-5 for each visit. Disregard the "Forwarded" field as it is no longer used.
5. To enter the *Form 125 – Summary of Hospitalization Diagnosis*, click the **Previous Block** button to reach the *Visits Adjudicated* block.

10.6.2.4 Entering *Form 125* – *Summary of Hospitalization Diagnosis*

The FC Outcomes Coordinator is responsible for entering any *Form 125 – Summary of Hospitalization Diagnosis* that is associated with a case. A *Form 125* may be entered in either of the following locations:

- From the *Outcomes Adjudications* screen under the *Visits Adjudicated* block, select **Hospital Diagnosis** from the *Run* menu.
- From the *Provider Visits* screen under the *Provider Visits* block, select **Hospital Diagnosis** from the *Run* menu.

Figure 10.33
Hospitalization Diagnosis and Procedures



To enter a *Form 125 – Summary of Hospitalization Diagnosis*:

- From either of the *Outcomes Adjudications* screen or the *Provider Visits* screen, select **Hospital Diagnosis** from the *Run* menu.
- Enter the first ICD-9 or ICD-10 code (when available) from the form, press **Tab.** WHIX will fill in a description of the code. Press the down arrow key or select **Next** from the *Record* menu to reach the next field.
- Repeat the previous step until all ICD-9 and ICD-10 codes are entered.
- Click the **Next Block** button to reach the *Hospital Diagnosis and Procedures* text block.
- Enter the responses to questions 3.1 (*Diagnosis Text Present?*) and 4.1 (*Procedure Text Present?*) from the form.
- Click the **Save** button.
- If there is more than one inpatient visit associated with the adjudication, enter the *Form 125* for each visit.
- Close the *Hospital Diagnosis* screen.

10.6.2.5 Closing an Adjudication Case

Data entry of a closure code (e.g., code 9 – "Forward to the CCC") is the final outcomes step indicating disposition of a case. To close a case, use the following steps:

From the *Adjudications* block in the *Outcomes Adjudications* screen:

1. Enter your Employee ID in the "Case Assigned To" field.
2. Enter the current date in the "Closed" field, if all your documents have been received and *Form 125 – Summary of Hospitalizations* has been completed, if appropriate.
3. Enter the closure code in the "Closure Reasons" field. Press **F9** for FC closure codes for Extension outcomes (See *Section 8, Table 8.5* for a complete description of Outcome Closure codes):
4. If desired, enter a comment about the case in the "Comment" field.
5. Click the **Save** button to save the information and close the adjudication case. Refer to *Sections 10.6.2.5* and *10.6.2.7* for more information about closing WHI Extension "Outcomes" and "Non-Outcomes".

Field Center Closure Codes

10 – Extension case, not adjudicated, not forwarded to CCC.
11 – Extension case, duplicate visit, not forwarded to CCC.
12 – Extension case, cannot get docs, not forwarded to CCC.*
13 – Extension case, cannot get release, not forwarded to CCC.*
14 – Extension, admin problems, not forwarded to CCC (detail in comments).*

* Codes 12, 13 and 14 are reserved for non-death cases that are more than a year old.

10.6.2.6 Cases Forwarded to the CCC

Use the following steps, when closing a case that will be sent to the CCC:

1. Use a FC closure code of 9 – "Extension case forwarded to the CCC".
2. Click **Save** button and print the *WHIX1215 – Member Outcomes Status* (MOSR) report. To run this report, select **Member Status** from the *Run* menu.
3. Print the WHIX0988 – *Investigation Documentation Summary* (IDS) report. To run this report, select **IDS** from the *Run* menu. For cases forwarded to the CCC, complete the following information on the IDS:
   - Under "Adjudication Status: Mark only one", check the line entitled: Outcomes Found.
   - If the case contains a *Form 125 – Summary of Hospital Diagnosis*, indicate the number of *Form 125*s in the case. (*Note:* If there is more than one *Form 125* used for a single hospitalization, indicate that the *Form 125* is "1 of 2").
4. Include the *WHIX1215 (MOSR)* and the *WHIX0988 (IDS)* in the adjudication case packet forwarded to the CCC.

10.6.2.7 Closing a "Non-WHI Extension Outcome"

There may be times when the analyzer finds a condition that you are not required to investigate as a WHI Extension outcome. For example, the participant reports a hospitalization that is for a minor condition not requiring review by the CCC (e.g., appendectomy). In these cases, you can "close out" the case in WHIX without taking any further action on it (e.g., requesting documents or forwarding documents to the CCC).

To close an adjudication case as a "non-WHI Extension outcome":

1. Use a FC closure code 10 – "Extension case, not adjudicated, not forwarded to the CCC" or a FC closure code 11 – "Extension case, duplicate, not forwarded to the CCC" in the "Closure Reason" field.
   - Closure Code '10': For a list of selected hospitalized procedures that can be closed with a FC closure code '10', see *Table 8.1 – WHI Extension Study Outcomes* — "Investigation and Adjudication NOT required".
   - Closure Code '11': To close a case as a "duplicate", designate the visit as a duplicate in the *Provider Visits* screen by entering the Visit ID for the visit already reported in the "Dup of" field. Then close the flagged duplicate visit in the *Outcome Adjudication* screen.
2. Click the **Save** button and print the *WHIX0988 – Investigation Documentation Summary (IDS)* report for the case.
3. File the IDS in the participant's outcome chart. You do not need to print a *WHIX1215 – Member Outcomes Status* report.

Note: Cases closed with FC closure codes 10 or 11 will appear on the participant's *Member Outcome Status* report (*WHIX1215*) as "Ext Not Adj" and "Ext Duplicate", respectively.

10.6.2.8 Deleting an Adjudication Case

Occasionally, you may need to delete an adjudication case in WHIX. If the case is closed, send an e-mail to your CCC Data Liaison requesting that it be opened. To delete an adjudication case once the case is opened:

1. Choose *Adjudications* from the WHIX *Outcomes* menu.
2. Click the **Enter Query** button**.**
3. Enter the ID of the participant whose adjudication case you are deleting. Press **Tab**. Enter the adjudication case number.
4. Click the **Execute Query** button.
5. Select **Delete** from the *Record* menu to delete the adjudication case.

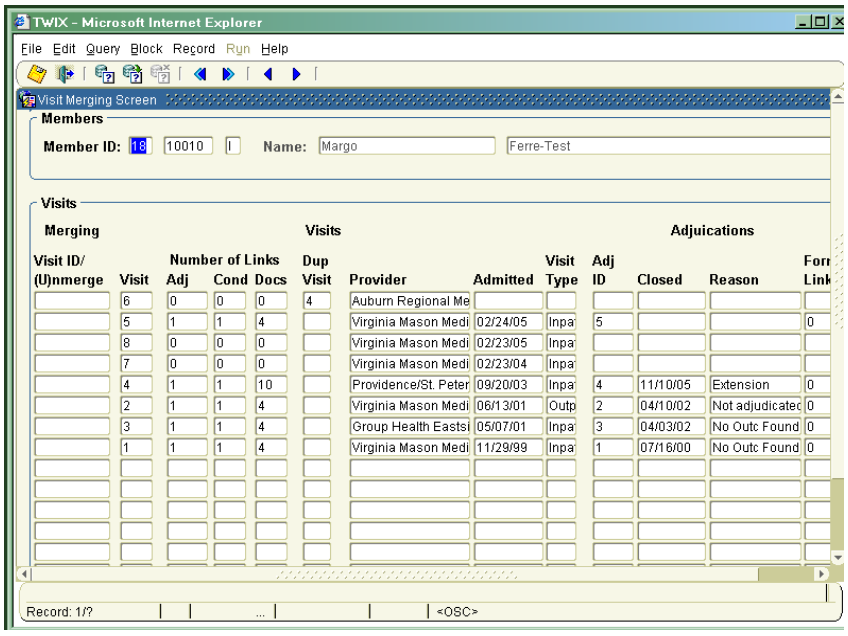
Note: If the case contains a visit, you will need to first delete the visit and any documents requested, the received dates and forwarded dates from the case. You must also delete the assigned, received, or completed dates for the case, if they have been entered and the *Form 125*, if entered.

10.6.2.9 Visit Merging

The *Visit Merging* screen (*Figure 10.34*) allows you to merge two or more provider visits into the same adjudication case.

When a *Form 33D – Medical History Update* is analyzed in WHIX, the analyzer automatically creates a separate adjudication case for each provider visit indicated on the form. Sometimes, it is appropriate for related visits to be merged into one adjudication case. The *Visit Merging* screen gives you a way to automatically merge two or more visits into a single case. You can also use this screen to "unmerge" two or more visits that have been entered into a single case.

Figure 10.34
Visit Merging



To merge two visits through the *Visit Merging* screen:

1. From the *Outcomes* menu, choose *Visit Merging*.
2. The screen opens in query mode, with the cursor in the "Member ID" field. Enter the Member ID of the participant whose provider visits you wish to merge. Click the **Execute Query** button to retrieve the record.
3. All provider visits indicated for the participant are retrieved (*Figure 10.34*). Click the **Next Block** button on the toolbar to reach the *Visits* block.

    - Information about each visit, including the Visit ID number, the provider, the number of adjudication cases associated with the visit, the admit date and the visit type, are displayed in this block.
    - Information about the adjudication case associated with the visit (if any) is displayed under "Adjudications" and includes the adjudication case number, the closed date and closure reason (if applicable).
    - Use the **Up-** and **Down-arrow** keys to move to the record for the visit you wish to merge with another.

4. With the cursor in the "Visit ID/(Un)merge" field, enter the Visit ID for the provider visit with which you wish to merge the currently selected visit.
5. Select **Merge Visits** from the *Run* menu. WHIX moves the selected visit to the adjudication case associated with the provider visit with which it has just been merged.

    - For example, if you selected Visit #2 to be merged with Visit #1, WHIX moves the visit information, and associated documentation information for Visit #2 into the adjudication case for Visit #1. *Note:* The Adjudication ID associated with Visit #2 is updated to reflect this move.

    Note: You cannot merge visits linked to closed cases, visits that have been flagged as duplicate or visits that are not linked to any conditions.

    Note: If a visit is associated with more than one adjudication case, an asterisk (*) appears in the record for that visit in the left-most column (under "Visit ID/(U)nmerge"). A warning message appears at the bottom of the screen indicating the visit is associated with more than one adjudication and displays the number of the first two cases associated with the visit. No adjudication case information will be displayed for the visit.

WHIX allows you to "unmerge" provider visits should you decide after merging that the visits should actually be reviewed in separate adjudication cases.

To unmerge provider visits:

1. Follow steps 1-4 above.
2. Select **Unmerge Visits** from the *Run* menu.

WHIX moves each of the "unmerged" visits to a separate adjudication case.

10.6.2.10 Sending Packets for Central Adjudication

Completed adjudication case packets must be forwarded to the CCC for central adjudication. These cases must be closed with a code 9 – "Extension case forwarded to the CCC".

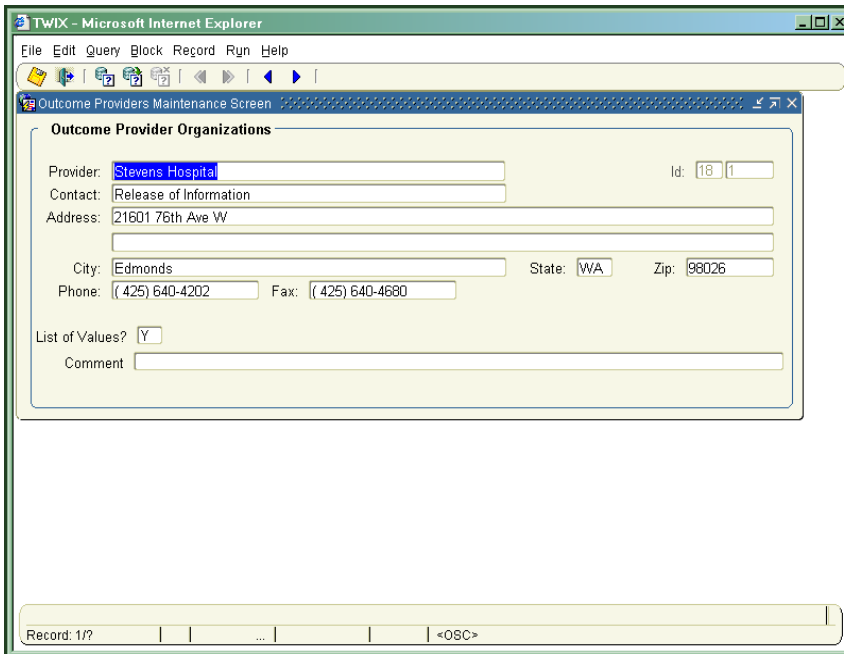
When an adjudication case packet is forwarded to the CCC, the *WHIX1215 – Member Outcomes Status* report and *WHIX0988 – Investigation Documentation Summary* should accompany the packet. The *Outcome Adjudication* screen allows you to run both reports. Print these reports and send them to the CCC along with the case packet. Send case packets to:

Outcomes Program Assistant
Women's Health Initiative
Fred Hutchinson Cancer Research Center M3-A410
1100 Fairview Ave N.
P.O. Box 19024
Seattle WA 98109-9926

10.6.3 Provider Maintenance

The outcomes system in WHIX requires that you maintain a list of medical providers (e.g., physician's office, outpatient clinic, hospital, vital statistics office) with whom reported conditions are associated. You enter the institution name and address information in the *Outcome Provider Organizations* screen, shown in *Figure 10.35*. WHIX uses this information for the *WHIX0980 – Request for Medical Records Report* to request documents from the provider (see *Section 10.7 – Queries and Reports*).

Figure 10.35
Outcome Provider Maintenance Screen



When you enter and save provider information, WHIX assigns the provider a unique (sequential) Provider ID. Conditions are then linked to the provider through this Provider ID.

You can enter the names of common providers (such as major hospitals in your area) before a participant reports a condition associated with that provider. You can also wait to enter that provider's information into WHIX until you review a participant's *Medical History Update* and she has associated a condition with a provider. In either case, you only need to add the provider information once. Then, any time any participant reports a condition to be associated with the provider, you can link the condition to provider via the Provider ID.

The "List of Values?" field allows you to designate which providers will be displayed when you are entering provider information from *Form 33D*. You should give this designation only to those providers that are likely to be used more than once by participants (e.g., major hospitals and other diagnostic facilities in the area). This will prevent the list-of-values in the *Form 33D Questionnaire Responses* screen from becoming too long.

It is up to the OC to determine which providers should be designated as "commonly-used". When you enter the *Outcome Provider Maintenance* screen from the main WHIX menu, the default for the "List of Values?" field is "yes" (provider should appear in list-of-values). This designation can only be changed through the *Outcome Provider Maintenance* screen of the *Outcomes* menu. It cannot be changed when accessing the *Outcome Provider Maintenance* screen through the *Form 33D Data Entry* screen, and providers added when the screen is accessed through the *Data Entry* screen do not appear on the list-of-values.

To enter provider information:

1. From the *Outcome* menu, choose *Outcome Provider Maintenance*.
2. If provider information has already been entered, the first provider record is displayed. Select **Insert** from the *Record* menu to create a new, blank record.
3. Enter the name of the provider institution. Press **Tab**.
4. Enter the name of the contact person or department at the institution. Press **Tab**.
5. Enter the institution address and phone and fax numbers. This information will be used in the provider labels and document request sheet. Press **Tab**.
6. If desired, change the "List of Values?" designation to "No" typing by *N*. Press **Tab**.
7. Enter a comment, if desired. Comments that you enter here print out on the *Provider Details* report (*WHIX 0992*).

    - Click the **Save** button to save the provider information. WHIX generates the Provider ID.

Select **Provider Labels** from the *Run* menu to print a sheet of address labels for the provider whose record is currently displayed on the screen.

10.6.4 Outcomes Reports

Outcomes-related reports are discussed in *Section 10.7.4 – Outcomes Reports*.

10.6.5 Processing Fatal Events in WHIX – Death Condition

10.6.5.1 Analyzing *Form 120 – Initial Notification of Death*

CCC or FC staff document an initial report of a death on *Form 120 – Initial Notification of Death*, which is analyzed by the CCC in the WHIX analyzer. WHIX only creates one death condition and links it to a maximum of one provider, regardless of how many provider IDs are documented on *Form 120*. The WHIX analyzer uses the algorithm shown in the following table to determine the appropriate condition/visit link on *Form 120, Ver. 8*.

Table 10.2
***Form 120 – Initial Notification of Death (Ver. 8)* Analyzer Algorithm**

Questions marked on *Form 120, v. 8*	**Analyzer Result**	**Manual Action Necessary** (see *Section 10.6.5.2 – Linking a Death Condition to a Provider Visit, Section. 10.6.5.4 – Adjudication of Fatal Events* and *Section 8.5 – Fatal Events).*
• Question 3 is marked *yes* and • Question 3.1 has a provider ID.	• "Death" condition is created and linked to the inpatient provider in Question 3.1. • "Inpatient death" document set is created. • Adjudication case is created.	None
• Question 3 is marked *no* or *unknown,* and • Question 4 is yes, and • Question 4.1 has a provider ID.	• "Death" condition is created and linked to provider in 4.1. • Visit is flagged as an "other" type. • Adjudication case is created.	• Determine whether the visit was an inpatient or an outpatient visit and change the *Visit Type* flag in WHIX to create the document set or • Manually create the document set
• Questions 3 and 4 are marked *no* or *unknown,* and • Question 5 is any response except *unknown,* and • Question 5.1 has a provider ID.	• "Death" condition is created and linked to provider in 5.1. • Visit is flagged as an "other" type. • Adjudication case is created.	• Determine whether the visit was an inpatient or an outpatient visit and change the *Visit Type* flag to create the document set in WHIX or • Manually create the document set.
• Questions 3, 4, and 5 are all marked *no* or *unknown,* and • Question 2 is answered with *any* of the possible responses.	• "Death" condition is created. • No provider visit is created and linked to the condition. • No adjudication case is created. • *(The comments section of the analyzer screen will display the message "Death condition created but no visit information exists".)*	• Manually create the provider visit and assign the appropriate visit type (inpatient, outpatient, other) • Link the provider visit to the death condition. • Create the document set (if the visit type is "other". • Create the adjudication case for the visit.

10.6.5.2 Linking a Death Condition to a Provider Visit

As documented in *Section 10.6.5.1 – Analyzing Form 120*, the analyzer will always create a death condition (even if info errors exist on *Form 120)*, but it won't always create and link it with the provider visit. In such cases, you must manually create the provider visit and link it to the condition that WHIX has created. If the death occurred in a health care institution, or there was an autopsy, you must first obtain the name of the institution where the death occurred or the provider who performed the autopsy.

Once you enter the provider in the *Provider Maintenance* screen (see *Section 10.6.3 – Provider Maintenance*), you can manually create the provider "visit" in the participant's *Provider Visit* screen (See *Section 10.6.1.2.1 – Manually Creating a Provider Visit* for instructions on manually creating a provider visit). You must flag the visit as "inpatient", "outpatient" or "other" (see *Section 10.6.1.2 – Provider Visits Screen* for instructions on entering the *Visit Type* flag). (*Note:* the "other" *Visit Type* flag should *only* be used for visits that are linked to a death condition in WHIX. The "other" *Visit Type* should not be linked to conditions other than death).

Remember to *link* the death condition to the provider visit that you have manually created (see *Section 10.6.1.5 – Link Provider Visits to Existing Conditions* for instructions on linking the condition to the visit).

Note: The "provider" in a death case is not always a health care provider, especially if the death occurred outside of a health care setting. Instead, the "provider" may be the provider of information about the death, such as a county records office or other state or local vital statistics bureau where you obtain a copy of a death certificate. The provider should not be a family member. Any death that occurred outside of a hospital should be flagged as an "outpatient" visit. If documents are obtained from a non-health care provider, such as a coroner's office or county/state vital statistics office, flag the visit as O*ther*.

10.6.5.3 Requesting and Receiving Medical Record Documentation for a Fatal Event

WHIX automatically creates a document set for a death condition that is linked to a visit flagged as an inpatient or an outpatient visit. When you change a *Visit Type* flag to inpatient or outpatient, WHIX automatically changes the document set.

The analyzer only creates a minimum document set (i.e., Death Certificate, *Form 120*) when a death condition is linked to a provider visit flagged as "other". Based on the services of the "provider", determine if you will need to request additional documents and manually insert these documents. For example, if an autopsy was performed by the coroner, you would need to request an autopsy report. You would go to the *Visit Documents* block of the *Provider Visits* screen to manually insert additional documents (see *Section 10.6.1.3 – Request the Medical Documentation* for instructions on manually inserting documents).

Enter request dates for the documents in the document set, print the *Request for Medical Record Information* report (*WHIX0980*) if appropriate and send it to the provider. Receive the documents (enter "response" codes in the *Visit Documents* block) as you would for any other visit.

10.6.5.4 Adjudication of Fatal Events

When the WHIX analyzer automatically creates a provider visit and links it to a death condition, it will also create an adjudication case for the visit. When the analyzer creates a death condition but does not link it to a visit, the adjudication case will *not* be automatically created. Instead, after you have manually created the visit and linked it to the death condition, you must manually create an adjudication case and enter the visit into the case. (See *Section 10.6.2 – Adjudication* for instructions on manually creating a case for a visit.)

Once the case has been created, you may process and close the case in the usual manner and forward the documents to the CCC.

10.6.5.5 Completing Data Collection for Fatal Events

For each reported death, you must collect and key-enter the following three forms in WHIX:

1. *Form 120 – Initial Notification of Death*, entered immediately upon notification of the death.
2. *Form 33 – Medical History Update by Proxy (*and *Form 33D – Medical History Update Detail* if necessary.*)*

When you enter a *Form 120* for a participant, her follow-up status is automatically changed to 6 – Deceased.

If the CCC receives notification of a participant's death via response to a central packet mailing, CCC staff will complete as much of a *Form 120* as possible with the information received. The CCC staff will enter the *Form 120* in WHIX and send the original copy to the FC in the weekly mailing. CCC staff will also notify the OC at the participant's FC of the death via e-mail.

10.7 Queries and Reports

There are three primary ways to retrieve information from WHIX: *Queries, Reports* and the *Custom Data Extract System* (CDE). When you query data, you select and display records on the screen one by one. When you run reports, you select and display a pre-formatted table to view on the screen or to print out. The CDE allows you to select WHIX data to create and run your own reports.

This section explains the basics of queries, reports and the CDE. It explains how to query and how to run reports, and describes the components and types of WHIX reports.

10.7.1 Queries

Querying is the process by which you retrieve records from WHIX. A query can be very simple. For example, a query can retrieve the record of every participant who has a particular last name. A query can also be more complex. For example, a query can retrieve the record of every participant that lives in a particular zip code and has a Member ID that starts with the same few digits.

10.7.1.1 Basic Query Procedures

This section explains some common query procedures.

You can include query data in any number of fields, but these fields must all be in the same block.

The three basic query commands are *Enter Query*, *Execute Query*, and *Cancel Query*. The command to Enter Query puts you into "Enter Query mode" (*Note:* If you have unsaved changes to your database, WHIX will prompt you to save changes before going into Enter Query mode.) *Figure 10.36 – Enter Query Mode* shows a screen in Enter Query mode. Once in Enter Query mode, you can enter the data on which you wish to query.

The command to Execute Query retrieves all records that satisfy the query criteria you have specified. If you have not specified any query data, all records in that block will be retrieved.

The command to Cancel Query takes you out of Enter Query mode and returns the screen to "edit mode," where data can be entered or modified. A query can be cancelled after the "Enter Query" command is invoked, but before the "execute query" command is invoked.

The commands for entering, executing, and canceling a query are found as buttons on the toolbar in all WHIX screens where querying is allowed (see *Section 10.3.2.2 – Basic Screen Actions and Toolbar Buttons*.)

10.7.1.2 Retrieving All Records

To retrieve all records for a particular block (excluding the *Members* block, see note below):

1. Move to the block you want to query.
2. Click the **Execute Query** button on the toolbar.

WHIX displays the first record in the table on the screen. You can use the **Previous Record** and **Next Record** buttons on the toolbar to move through the records. When you are at the last record, WHIX displays a message indicating that you have reached the last row of the query.

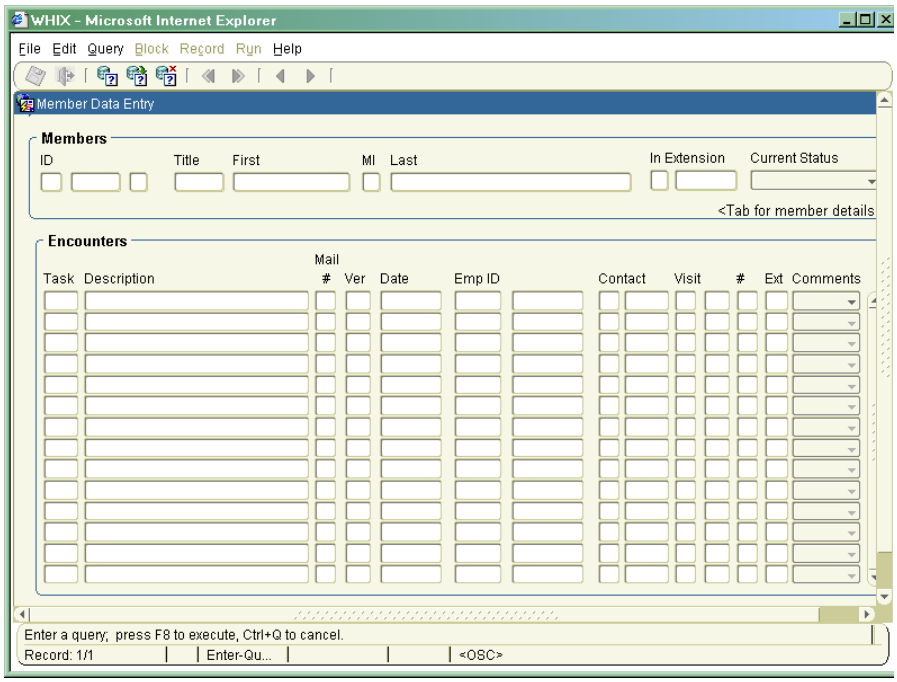
10.7.1.3 Retrieving Selected Records

The WHIX database contains a large number of data items and it would be time-consuming to retrieve all records in block. Generally, you would retrieve a selected record or records for a specific reason. For example, you might want to look at a particular participant's record to see if she has had a certain task performed. You also may want to look at several records for a demographic purpose, such as determining which participants live within a particular zip code.

Suppose you want to look at the record of a participant. You could do the general query described above. However, that could involve looking through hundreds of records until hers is retrieved. Another approach would be to query on a particular field, so that you limit the number of records retrieved.

To do this, go to the *Member Data Entry* screen. Click **Enter Query**. This puts you into Enter Query mode.

Figure 10.36
Enter Query Mode

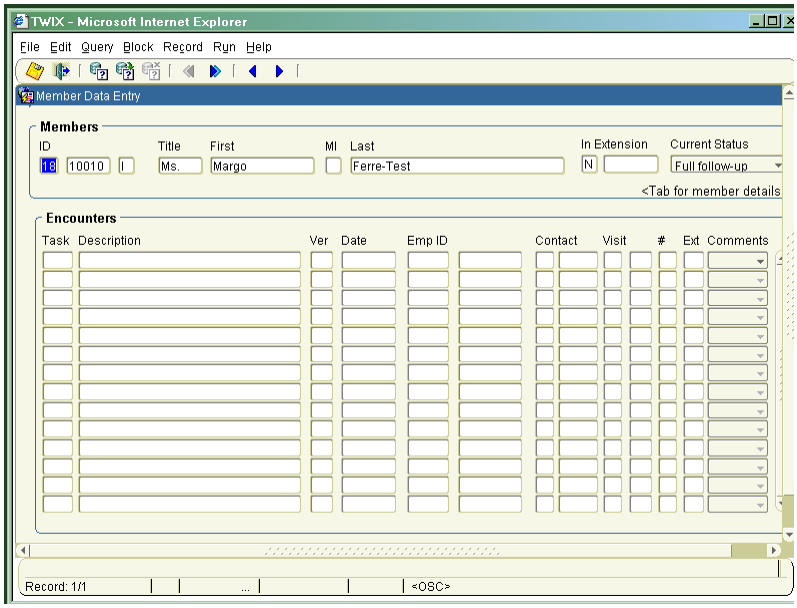


Notice your cursor is at the "ID" field of the Member ID. When you first go into Enter Query mode, the cursor automatically goes to the first field in the block in which you are querying. This sometimes brings you to fields that you cannot reach while in normal edit mode. When in edit mode, the cursor can only reach fields into which you can key-enter data. When in Enter Query mode, however, you can often reach non-enterable fields.

Tab to the field on which you wish to query. In our example, **tab** to the "Last Name" field and enter Ferre-Test. Click **Execute Query**. This brings up the record of Margo Ferre-Test, as well as those of any other participants with the same last name. The retrieved record of Margo Ferre-Test is shown in *Figure 10.37 – Query Retrieval.*

Note: Never query on participant name when entering data in WHIX. To avoid the error of entering data into the wrong participants record when you have two participants with the same name, always query on member ID number when doing data entry.

Figure 10.37
Query Retrieval



You can fill in as many fields in the block as you want before executing the query. A good general guideline is to keep the query specific enough to limit the number of records retrieved, while not limiting it so much that you exclude the record you are seeking.

10.7.1.4 Wildcards

WHIX allows you to use wildcards when formulating your queries. You use a wildcard to represent an unspecified character or combination of characters. You may find it helpful to use a wildcard if, for example, you are unsure of the spelling of a participant's name or if you need to retrieve a group of records that fall into a particular range.

You can include the following wildcards in your query criteria:

_ represents any character
% represents any combination of characters

See the examples below that show the records that would be retrieved with the given query criteria:

Query Criteria	**Possible Records Retrieved**
JON_S	JONES, JONAS, JONOS
S_AR_	SMART, SNARE, SHARP, SHARD
ENTER%	ENTER, ENTERS, ENTERED, ENTERTAIN
_IN%S	BINS, FINES, WINNERS, WINEMAKERS

10.7.1.5 Counting Query Rows

Because of the large number of records in the database, you may find it helpful to know how many records a particular query will retrieve. If too many records will be retrieved, you have the option of refining your query before executing it. WHIX provides a way to count "query rows," the number of records that a query will retrieve, before you execute it.

To use the Count Query Rows command:

1. Click **Enter Query** to go into Enter Query mode.
2. Enter values into the fields on which you wish to query.
3. Select **Count Query rows** from the *Query* menu.

The message line will display the message, "Query will retrieve ## records".

If the number is acceptable, click **Execute Query** to execute the query. If the number is too high, you can redefine the query criteria to make it more specific.

This section provides an overview of the various types of reports that can be run within WHIX, explains the components of the *Reports Parameters* screen, and gives information on printing reports and viewing them on the screen.

Section 10.7.3 – WHIX Reports lists, sorted by type/menu, each report available in WHIX, how it is accessed, and a brief description of when it might be used.

10.7.2 Running WHIX Reports

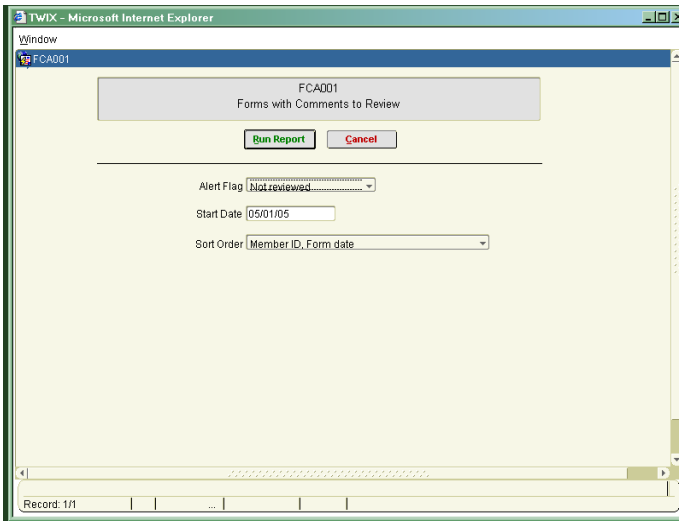
There are three main report categories in WHIX: *Member Reports*, *Outcomes Reports* and *Summary Reports*.

- The *Member Reports* menu contains reports used to track non-outcome activities such as *Form 33* collection and mammogram completion, retention and Extension mailings. Labels are also found in Member Reports.
- The *Outcome Reports* menu contains reports used in processing and tracking outcomes cases.
- The *Summary Reports* menu contains eight Extension Consent tracking summary reports carried over from WHILMA.

10.7.2.1 Report Parameters

When you select a report from the WHIX menu, the *Report Parameters* screen is displayed. Report parameters define what information appears in a report and how the report is displayed. The *Report Parameters* screen for the *Forms with Comments to Review (FCA001)* is shown in *Figure 10.38.*

Figure 10.38
WHIX Report Parameter Screen



In the example in *Figure 10.38*, the parameters are *Alert Flag, Start Date* and *Sort Order*. The *Alert Flag* text box shows all of the allowable values for that parameter in a drop-down list. To select a parameter from a drop-down list, click on the arrow to the right of the box to display the choices and click on your choice to select it. In this case, your choices are *Not Reviewed, Reviewed* and *All*. The *Alert Flag* parameter can be specified by choosing the option that you want. For example if you want to see only forms with comments that have not been reviewed, choose that option from the study parameter text box.

Other parameters may be presented as a blank text box where you type in your parameter value. In the example in *Figure 10.38* you fill in the start date of the forms. The *Sort Order* parameter in *Figure 10.38* also appears as a drop-down list.

After you enter each parameter, press **Tab** to move to the next parameter. Note that pressing the **Enter** key at any time in a *Report Parameters* screen activates the Run Report command. Use the **Tab** key to move from one parameter to the next.

The following are some general guidelines about entering report parameters in WHIX:

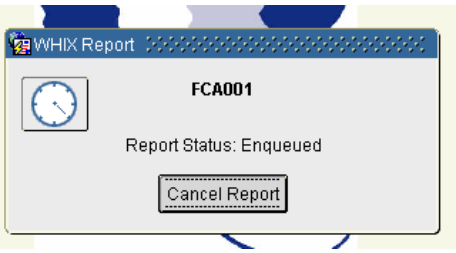
- In almost all cases, every parameter listed on the screen is required to run the report. If a parameter is left blank it will most likely result in the report running incorrectly or not at all.
- To replace a parameter value, delete the default value and enter a new one.
- For some parameters, you may enter a wildcard (%). WHIX will return an error message if you enter a wildcard in cases where it is not an acceptable value.
- Some parameters default to a particular value. If you leave such a parameter blank, WHIX will use the default value for the report.
- When asked to provide a date, the generally accepted date formats are:
  071005
  07/10/05

If a particular report does not accept the date format you have entered, WHIX displays a message showing the correct format.

10.7.2.2 Running, Viewing and Printing Reports

Once you have entered your parameters, use the **Run Report** and **Cancel** buttons *(Figure 10.38)* on the parameter screen to run a report or cancel it. A report can be canceled before or after you have clicked the **Run Report** button. The *Report Status* box *(Figure 10.39)* appear on the screen to let you know that the report is running. The report is automatically created in PDF format and displayed in Acrobat Reader® in a new window.

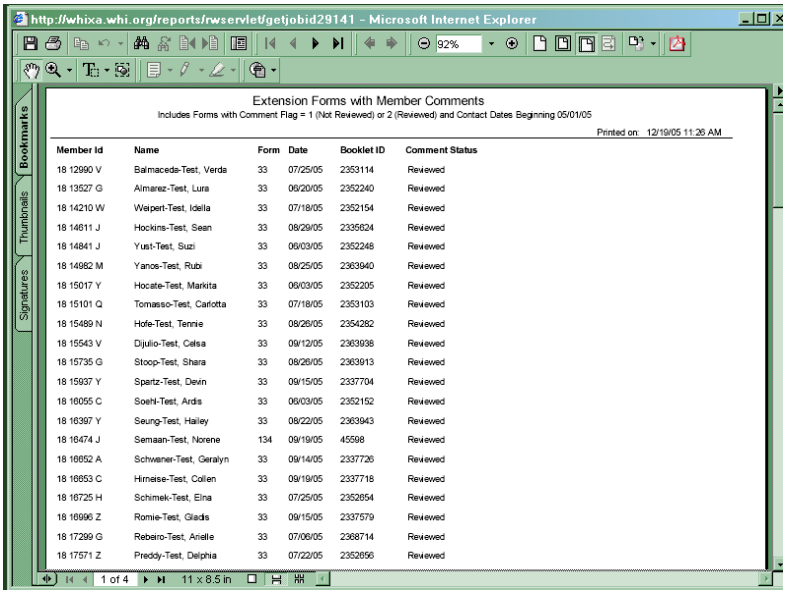
Figure 10.39
Report Status Dialog Box



Note that once you have started to run a report from the WHIX *Reports* menu, you are not able to do anything in WHIX until it finishes running or you cancel the report.

Once the report is displayed *(Figure 10.40)*, you can save it as a PDF file, or print it. Although you can run a second report or return to the menu and perform other database functions while the first report is still open in Acrobat Reader®, it is recommended that you close the current report PDF file before running another report.

Figure 10.40
Report Displayed in PDF Format

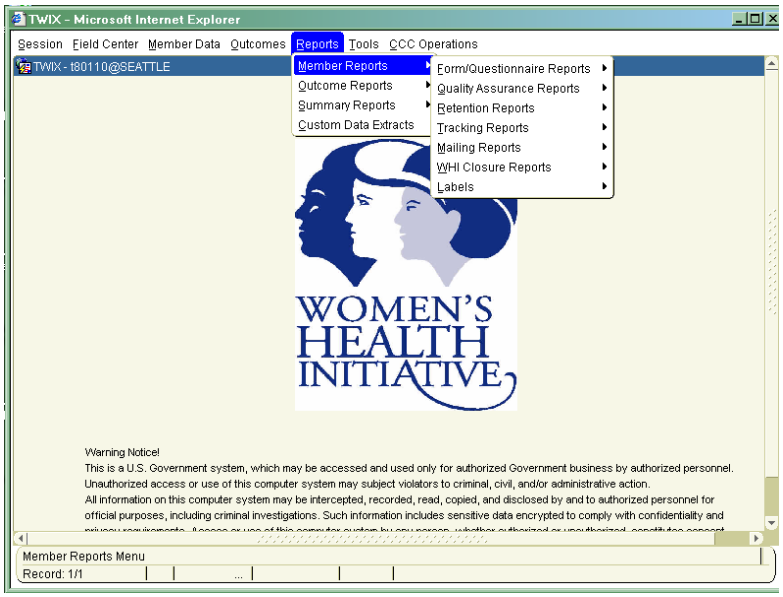


When you are ready to print the report, click the **Print** button on the toolbar. If you wish to save the PDF to a file, click the **Save** icon on the toolbar at the top of the report window. This will direct you to Windows Explorer (*Section 10.1.1.3*), where you can choose where you want to save the report.

10.7.3 WHIX Reports

To access WHIX reports, at the main menu, select **Reports** (*Figure 10.41*). This section lists the types of WHIX reports, whether they are required, and a description of each report.

Figure 10.41
WHIX Reports Menu



10.7.3.1 Member – Form/Questionnaire Reports

#	Report Name	Required	Description
FCA001	Forms With Comments to Review	Yes	Identifies *Form 33*s, *Form 134*s, *Form 150*s and *Form 151*s with participant comments that need to be reviewed.
WHIX0104	Questionnaire Responses	No	Lists, for a given participant, task and task date, the participant response to each question.
WHIX0441	Personal Information Update (PIU)	Yes	Shows, for a given participant, contact information from the *Personal Info Update* tab page of the *Member Data Entry* screen. It also shows participant's legal name, secondary contact information, proxy name and address, and healthcare provider(s) name and address. It also shows a second address for participant, the valid dates for both addresses, and participant's e-mail address. This report can be sent to a participant and the information updated if necessary. It can also be run from the *Run* menu in the *Member Data Entry* screen.

10.7.3.2 Member – Quality Assurance Reports

#	Report Name	Required	Description
QA001	Unresolved Alerts	Yes	Identifies missing or discrepant information on forms scanned into WHIX.
QA002	Extension Participants Needing Follow-up Change	Yes	Shows participants who currently have one of the following follow-up statuses and have had the status since before the date their Extension consent was signed: • No follow-up • Lost to Follow-up • Absolutely no follow-up • Custom follow-up with both "no mail" and "no phone" checked

10.7.3.3 Member – Retention Reports

#	Report Name	Required	Description
RET001	Call List for Retention Worksheet	No	Lists participants who need to be contacted for completion of *Form 24 – Retention Worksheet*.
WHIX1237	Call List for Search to Locate Participant	No	Lists all participants for whom a *Form 23 – Search to Locate Participant* has been initiated, but not closed.
WHIX1238	Member Retention Activity Tracking	No	Shows *Form 24 – Retention Worksheet* information entered for a specific participant, or group of participants. Participants appear on the report if they have: • At least one *Form 24* where the most recent 'continue contacts' question for a study problem is answered 'yes' and • The re-contact date falls into the date range specified by the user, but is not after the end date of the date range.
WHIX1591	Participants Who are Lost to Follow-up	Yes	Lists all CT and OS participants who have a status of "Lost to Follow-up".
WHIX0478	Current Participation Status	No	Shows current follow-up status of WHI Extension Study participants.

10.7.3.4 Member – Tracking Reports

#	Report Name	Required	Description
MAMM001	Mammograms Due	No	Shows HT participants who have a mammogram due within a specified time frame. Provides contact information, date of last mammogram and date that the mammogram is due. Shows the last *Form 150 – Hormone Use Update* encounter date and Question 9--Had mammogram (yes or no). Shows whether a *Form 85 – Mammogram* due for the Extension Study has been entered in the Missed Encounters Screen (*Section 10.4.2.2*) and the reason it was not completed. Parameters allow you to select for both mammograms completed, one mammogram completed and no mammograms completed. You can sort by mammogram due date, first mammogram date, second mammogram date, member ID and member name.
MAMM002	Mammograms Not Completed	Yes	Lists HT participants who have a *Form 85* entered in WHIX with no review date.
XCON001	Extension Consent Tracking	No	Lists all Extension Study participants and the status of their Extension and Supplemental consents. You can sort by last name, ID number and study assignment. You can select parameters for signed, refused, no response and not approached. A call log format is available.

10.7.3.5 Member – Mailing Reports

#	Report Name	Required	Description
ADR001	Addresses for Members with >1 Address	No	Identifies participants who have more than one address or have one address with a date entered in the "Valid Address" field. Provides a way to track and change the *Current Address* flag. It should be run using dates in the "Date Parameter" field.
MAIL003	Members Needing FC Follow-up	Yes	Shows participants who have not responded to up to 3 mailings from the CCC or who are missing one or more forms from their annual packet, and need to be contacted by the FC. This report shows the months that packets were mailed to the participants and also the month and year the next packet will be mailed. The Follow-up Status column displays both their follow-up status and the forms that are missing for the participant. The default for participants appearing on the report is 60 days (after their 3rd mailing). Participants with a status of "No Mail" will not appear on the report until 7 months after their original mailing month. The CCC will continue to attempt mailings during that time, in case the participant's mail status changes. FCs should not attempt to contact participants until they appear on the report.
WHIX0611	Address Problems	Yes	Identifies participants who have problems with their address as entered in WHIX and what the specific problem is.

10.7.3.6 Member – WHI Closure Reports

WHIX9758	CaD Treatment Assignment	Yes	Allows you to run and print unblinding letters for CaD participants

10.7.3.7 Labels

#	Report	Required	Report Description
XLABELS	Address, Form, *Form 33* Labels	Yes	Allows you to run address, form (barcode) and *Form 33* date labels in one report for specified participants. Can also be run from the *Member Data Entry* screen.
-----	Ancillary Study Address/ Form Labels	No	Allows you to run address and/or form labels for participants in an ancillary study.

10.7.4 Outcome Reports

WHIX #	Report	Required	Report Description
0621	Outcome Screening Action Required	Yes	Lists Extension participants whose *Form 33* v.8 contains incomplete or inconsistent information that must be clarified for WHIX. You choose which participants to include on the report based on the *Form 33* encounter date. The report output includes the *Form 33* version number. Question number with missing data and a brief description are given. Participants with a follow-up status of 5 (no follow-up) or 8 (absolutely no follow-up) or who are deceased and had a status of 5 or 8 immediately before they were deceased and participants who have a status of deceased based on a National Death Index search as recorded on a *Form 120 – Report of Death* are excluded from the report. WHIX0622 (Members with Potential Outcomes) and WHIX1225 (Unresolved Deaths) also exclude these participants.
0622	Members with Potential Outcomes	Yes	Lists participants for whom a *Form 33D – Medical History Update (Detail)* is required, based on *Form 33* responses (only Extension participant's *Form 33*s show, but a participant may have an older *Form 33* with a version other than 8). This report is designed to be used as a "call list" for all participants needing a *Form 33D*. You choose which participants to include on the report based on the *Form 33* encounter date. Lists *Form 33s* that report an outcome but don't have a *Form 33D*, and/or are incomplete in some way (for example, a *Form 33* that reports a fracture, but is missing a response to the hospitalization). *Note*: *Form 33* v.8 and *Form 33D* v.8 will be matched based on date range rather than solely by visit number. The *Form 33* start and finish dates must be the same as or between the *Form 33D* start and finish dates for the forms to match. If WHIX can't match a Form *33D to* a *Form 33* using this calculation, it will match on visit year instead.
0978	Outcome Member Visit Details	No	Lists for a specified participant, all reported conditions and the status of all documents linked to the visit.
0980	Request for Medical Information	Yes	The "cover sheet" that you print and include when requesting provider documentation. It includes your FC's name and address, the provider's name and address, the participant's name and identifying information, and the documents not received.
0983	Analysis Encounters with Info/Conditions	Yes	For a given analysis batch, or all batches analyzed within *N* days, lists the details for each batch run for forms that did not analyze with 'N' results, that require follow-up, such as forms that yielded an INFO result by the analyzer, or forms in which conditions were identified.

WHIX #	Report	Required	Report Description
0984	Outcome Visit Details	No	Lists provider documents requested and/or received at your FC for a specified participant. Also lists visit type (inpatient or outpatient) and reported conditions. Excludes closed cases and visits where no documents need to be requested.
0985	Outcome Conditions Requiring Providers	Yes	Lists all conditions created manually or by the analyzer that have not been linked with a provider visit.
0987	Member Visits Requiring Adjudication	Yes	Lists all provider visits for which all information has been obtained, but have not yet been assigned to an adjudication case packet.
0988	Investigation Documentation Summary	Yes	Contains specific information about the adjudication case packet documents and should be attached to the case packet. *Note:* You can also run this report from the Outcomes subsystem. Go to Outcomes Adjudications, and select **IDS** (Investigation Document Summary) from the *Run* menu.
0992	Provider Details	No	Lists provider information, including contact name, address, fax and phone numbers, for all providers whose information has been entered into your WHIX database. Comments entered in the *Provider Maintenance* screen print out on this report.
1002	Find Outcome Encounters	No	Allows you to print information about outcome encounters and analysis batches that meet specified criteria. Parameters for the report allow you to find all outcome encounters for a specified participant, all outcome encounters included in a specific batch, all analyzed forms with a specified analysis result (i.e., Y, N, or I), and any combination of the above criteria. *Note*: You can also run this report from the *Find Outcome Encounters* screen. If you run the report from the *Find Outcome Encounters* screen, you can specify that the report use the same query as the screen.
1213	Outcomes Visits Requiring Requests Summary	Yes	Shows a summary of all provider visits for which there are documents outstanding. "Outstanding" is defined as a document that has not been requested, has been requested, but not received, or has been temporarily denied. The report can be sorted by: ID#, facility, CT/OS, date of last request, contact or admit date. Visits drop off the report when the case is assigned.
1215	Members Outcomes Status	Yes	Lists all confirmed outcomes, outstanding conditions, and pending adjudications entered in your database, for a specified participant and adjudication case. • Shows Extension Study enrollment date • Self reports of angina CHF and TIA from *Form 33* v.8 are displayed in a separate section • All participant hospitalizations [*Form 125*] from both WHI and WHIX are displayed • Confirmed outcomes are displayed in a section titled "Confirmed Outcomes". You can run this report from the *Run* menu of the *Outcomes Adjudications* screen. This report should be included in the adjudication case packet. *Note:* You should close the adjudication case before printing the report.

WHIX #	Report	Required	Report Description
2000	Local Cases to Send to CCC	Yes	Lists cases closed with a code 9 – Forward to the CCC that have not been received at the CCC.
1225	Unresolved Death	Yes	Displays participants with open cases linked to a *Form 120*, or with a missing Proxy *Form 33/33D*. Participants drop off the report if: • The adjudication has been closed for more than a year, even if no proxy forms were collected. • The death was discovered through NDI • The participant's status prior to death was 8 – Absolutely no contact and the case linked to the *Form 120* is closed.
1226	Address, Form and Date Labels for *Form 33D*	Yes	Creates a label set for members requiring a *Form 33D*. The labels created are one member form label, one address label, and one date label (using the finish date of the previous *Form 33*). Labels will not print for participants with a status of 5 – No Follow-up.

10.7.5 Summary Reports

WHIX #	Report	Required	Report Description
9763	Extension Consent Summary	No	Shows for each study (OS, CT, CaD, DM and HT), how many participants are eligible for the Extension Study and how many and what percentage have a *Form 111* or *Form 112* entered in WHIX with a response code of 1 – Consent Signed.
9764	Summary of Extension Consent form Responses	No	Shows for CT and OS, how many participants have a *Form 111* or *Form 112* entered in WHIX with each of the response codes.
9765	Extension Consent Summary by Race	No	Shows a breakdown by race of the number of participants in each study who are eligible for the Extension Study, and the number and percent who have a *Form 111* or *Form 112* entered in WHIX with a response code of 1 – Consent Signed.
9766	Extension Consent Summary by Age	No	Shows a breakdown by age of the number of participants in each study who are eligible for the Extension Study, and the number and percent who have a *Form 111* or *Form 112* entered in WHIX with a response code of 1 – Consent Signed.
9767	Supplemental Use Consent Summary	No	Shows for each study (OS, CT, CaD, DM and HT), how many participants are eligible for the Supplemental Use Consent and how many and what percentage have a *Form 113* entered in WHIX with a response code of 1 – Consent Signed.
9768	Supplemental Use Consent Responses	No	Shows for CT and OS, how many participants have a *Form 113* entered in WHIX with each of the response codes.
9769	Supplemental Use Consent Summary by Race	No	Shows a breakdown by race of the number of participants in each study who are eligible for the Supplemental Use Consent, and the number and percent who have a *Form 113* entered in WHIX with a response code of 1 – Consent Signed.
9770	Supplemental Use Consent Summary by Age	No	Shows a breakdown by age of the number of participants in each study who are eligible for the Supplemental Use Consent, and the number and percent who have a *Form 113* entered in WHIX with a response code of 1 – Consent Signed.

Table 10.3
WHIX Reports

	Purpose	Required?	Run Frequency	Action to Take
Form/Questionnaire Reports				
FCA001—Forms with Comments to Review	Identifies forms that the CCC has marked as having participant comments written on them that need to be reviewed.	Yes	Weekly	Run with *Comment Status* set to "not reviewed". Review comments and take action as necessary. Set *Comment* flag in *Encounters* screen to "2 – Reviewed" for each form reviewed.
WHIX0104—Questionnaire Responses	Lists, for a given participant, task and task date, the participant response to each question.	No	As needed	Review responses and take action as necessary.
WHIX0441—Personal Information Update (PIU)	Shows contact information from the *Personal Info Update* tab page of the *Member Data Entry* screen.	Yes	As needed	Send to a participant if necessary and update the information in WHIX. Can also be accessed from the *Run* menu in the *Member Data Entry* screen.
Quality Assurance Reports				
QA001—Unresolved Alerts	Identifies missing/discrepant information on forms entered in WHILMA.	Yes	Weekly	Run with *Security Level* parameter set to "Requiring Resolution" and *Task* parameter set to "All WHIX tasks". Review form responses, obtain missing information from participants and enter it in WHIX.
QA002—Extension Participants Needing Follow-up Change	Identifies participants who have signed an Extension consent, but have a status of: Absolutely No Contact, No F/U of Lost to F/U	Yes	As needed	Review, contact participant and change participation status as appropriate. Complete a *Form 9* and *Form 23*, as needed.
Retention Reports				
RET001—Call List for Retention Worksheet	Lists participants to recontact for completion of *Form 24 – Retention Worksheet*	No	At Least Monthly	Review list, contact participants as indicated by the "Recontact Date" on RET001.
WHIX0478—Current Participation Status	Shows current participation status, effective date of follow-up status change and follow-up restrictions (such as "no phone")	No	As needed	Review list and contact participants as necessary.
WHIX1237—Call List for Search to Locate Participant	Lists participants for whom a *Form 23 – Search to Locate Participant* has been initiated, but not closed	No	Monthly	Review and continue attempts to contact participants. Close out *Form 23* when participant is located.

	Purpose	Required?	Run Frequency	Action to Take
Retention Reports (cont.)				
WHIX1238—Member Retention Activity Tracking	Shows *Form 24 – Retention Worksheet* information entered for a participant or a group of participants.	No	As needed	Review and contact participants as appropriate.
WHIX1591—Participants Who Are Lost to Follow-up	Lists CT and OS participants who have a status of "Lost to Follow-up".	Yes	Monthly	Review and continue attempts to contact participants.
MAMM001—Mammograms Due	Provides contact information date of last mammo and date that mammo is due.	Yes	Monthly	Contact participants for information on when and where they will obtain their Extension mammogram.
MAMM002—Mammograms Not Completed	Provides a list of HT participants who have a *Form 85* entered in WHIX with no review date	Yes	Monthly	Follow-up to see if mammogram has been completed, complete and enter *Form 85*.
MAMM003—Extension Mammograms Completed	Provides a list of HT participants who have completed the two mammos required for the Extension	No	As needed	
XCON001—Extension Consent Tracking	Lists participants and their Extension Consent Status	No	As needed	Can be used to follow-up with participants who have not signed an Extension consent.
Mailing Reports				
ADR001—Addresses for Members With >1 Address	Identifies participants who have more than one address, or have only one address with "valid" dates entered and provides a way to track and change the *Current Address* flag.	No	As needed	
MAIL003—Extension Enrolled Members Needing Clinic Follow-up	Lists participants who have not responded to up to 3 mailings or who are missing one or more forms from their annual packet and who need FC follow-up.	Yes	Weekly	Do not contact participants until they appear on the report.
WHIX0611—Address Problems	Lists participants who have address problems in WHIX, such as *Undeliverable Address* flag set to "Y", missing information or address too long to fit on mailing label.	Yes	Monthly	Contact participants if necessary to resolve address problems.

	Purpose	Required?	Run Frequency	Action to Take
WHI Closure Reports				
CaD Letters	Unblinding letters for CaD participants	Yes	As needed	Print for CaD participants who did not receive their unblinding information at close-out.
Labels				
XLABELS—Address, Form, *Form 33* Labels	Allows you to run address form (barcode) and *Form 33* date labels in one report.	Yes	As needed	All WHI forms must have a participant barcode label. All *Form 33*s should have a date label on the first page.
Ancillary Study And/or Form Labels	Allows you to run address and/or form labels for a participant in an ancillary study.	No	As needed	
Outcome Reports				
WHIX0621—Outcome Screening Action Required for WHI Extension *Form 33*	Identify missing or discrepant information on *Form 33*.	Yes	Twice per month	Review forms listed, contact participant, collect information and edit form in WHIX.
WHIX0622—Members With Potential Outcomes	Lists *Form 33*s that need a *Form 33D*.	Yes	Weekly	Contact participant, collect and enter *Form 33D*.
WHIX0978—Outcome Member Visit Details	Lists for a specified member, all reported conditions and the status of all requested documents.	No	As needed	
WHIX0980—Request for Medical Information	The "cover sheet" that you print and include when requesting provider documentation.	Yes	When requesting documents	Run after entering the document request date.
WHIX0983—Analysis Encounters with Info/Conditions	For a given analysis batch, lists the analysis result for each encounter that requires follow-up, such as forms that yielded an INFO result by the analyzer, or forms in which conditions were identified.	Yes	Weekly	Resolve discrepancies on forms and correct in WHIX.
WHIX0984—Outcome Visit Details	Lists provider documents requested and/or received at your FC for a specified participant.	No		
WHIX0985—Outcome Conditions Requiring Providers (orphan conditions)	Lists all conditions created manually or by the analyzer that have not been linked with a provider visit.	Yes	Monthly	Review and correct by manually linking the condition to a provider visit.

	Purpose	Required?	Run Frequency	Action to Take
Outcome Reports (cont.)				
WHIX0987—Member Visits Requiring Adjudication (orphan visits)	Lists all provider visits that have not yet been assigned to an adjudication case packet.	Yes	Monthly	Review and correct as needed by manually creating an adjudication case and linking the provider visit to it.
WHIX0988—Investigation Documentation Summary	Contains specific information about the adjudication case packet documuments and should be attached to the case packet.	Yes	As needed	Print for each case and include with case packet.
WHIX0992—Provider Details	Lists contact name, address, and fax and phone numbers, for all providers whose infor-mation has been entered into WHIX for your FC.	No	As needed	
WHIX1213—Outcomes Visits Requiring Requests Summary	Summary of all provider visits needing document requests.	Yes	1-2 times a month.	Shows a summary of all provider visits for which there are documents outstanding. Send document requests as needed. Visits drop off the report when the case is closed.
Unresolved WHI Extension Participant Deaths (WHIX1225)	Identifies participant deaths that need to be investigated. Identifies missing proxy *Form 33*s.	Yes	Monthly	Collect and assemble the death documentation. Collect and enter the proxy *Form 33*.
WHIX1226—Address, Form and Date Labels for *Form 33D*	Creates a label set for members requiring a *Form 33D.* Generates one member form label, one address label, and one date label (using the date of the previous *Form 33*).	Yes	As needed when collecting *Form 33D*	Use of *Form 33D* labels is strongly encouraged to avoid start date data entry errors.
WHIX2000—Local Cases to Send to CCC	Shows cases closed with code 9 that have not been received at the CCC.	Yes	Monthly	Prepare case packets and send to CCC as described in *Section 10.6.2.10.*
Summary Reports				
WHIX9763—Extension Consent Summary	Shows for each study (OS, CT, CaD, DM and HT), how many participants are eligible for the Extension Study and how many and what percentage have a *Form 111* or *Form 112* entered in WHIX with a response code of 1 – Consent Signed.	No	As needed.	

	Purpose	Required?	Run Frequency	Action to Take
Summary Reports (cont.)				
WHIX9764—Summary of Extension Consent form Responses	Shows for CT and OS, how many participants have a *Form 111* or *Form 112* entered in WHIX with each of the response codes.	No		
WHIX9765—Extension Consent Summary by Race	Shows a breakdown by race of the number of participants in each study who are eligible for the Extension Study, and the number and percent who have a *Form 111* or *Form 112* entered in WHIX with a response code of 1 – Consent Signed.	No		
WHIX9766—Extension Consent Summary by Age	Shows a breakdown by age of the number of participants in each study who are eligible for the Extension Study, and the number and percent who have a *Form 111* or *Form 112* entered in WHIX with a response code of 1 – Consent Signed.	No		
WHIX9767—Supplemental Use Consent Summary	Shows for each study (OS, CT, CaD, DM and HT), how many participants are eligible for the Supplemental Use Consent and how many and what percentage have a *Form 113* entered in WHIX with a response code of 1 – Consent Signed.	No	Monthly	
WHIX9768—Supplemental Use Consent Responses	Shows for CT and OS, how many participants have a *Form 113* entered in WHIX with each of the response codes.	No	Monthly	

	Purpose	Required?	Run Frequency	Action to Take
Summary Reports (cont.)				
WHIX9769— Supplemental Use Consent Summary by Race	Shows a breakdown by race of the number of participants in each study who are eligible for the Supplemental Use Consent, and the number and percent who have a *Form 113* entered in WHIX with a response code of 1 – Consent Signed.	No	Monthly	
WHIX9770— Supplemental Use Consent Summary by Age	Shows a breakdown by age of the number of participants in each study who are eligible for the Supplemental Use Consent, and the number and percent who have a *Form 113* entered in WHIX with a response code of 1 – Consent Signed.	No	Monthly	

10.7.6 WHIX Custom Data Extract System

The WHIX Custom Data Extract system allows you to:

- Define a subset of participants and run selected WHIX reports on those participants.
- Extract selected data from WHIX into an Excel spreadsheet.

Using the CDE system involves three basic steps:

1. Create a blank query screen for entering a query.
2. Enter and execute a query to retrieve the data you want.
3. Extract the data into a file and open the file in another software package such as Excel *or* run WHIX reports based on the participants identified in your query.

10.7.7 Creating a Query Screen

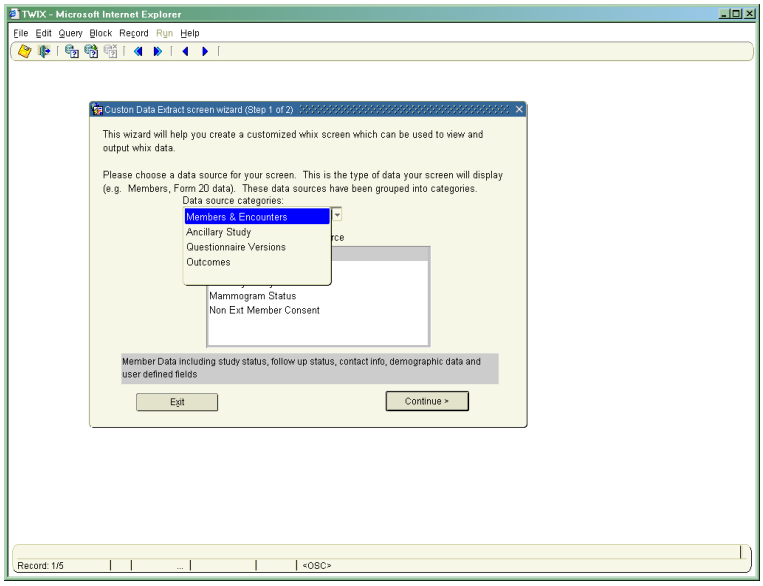
10.7.7.1 Choosing a Data Source

The first step in using the CDE system is to create a query screen where you can retrieve the data you are interested in. The CDE system allows you to build a "custom" query screen containing just those columns that are relevant to your query. The screen you create will look something like a blank spreadsheet with rows and columns. Each column represents a data item such as participant age or Extension consent status. Each row is a "record" or a group of related fields.

Begin by opening the CDE system:

1. Select **Reports** from the WHIX main menu.
2. Select **Custom Data Extracts** from the *Reports* menu. This brings up the *Build WHIX Screen Wizard Step 1* dialog (*Figure 10.42*).

Figure 10.42
Build WHIX Screen Wizard Step 1 of 2



The data sources are grouped into four categories as shown in *Figure 10.42*:

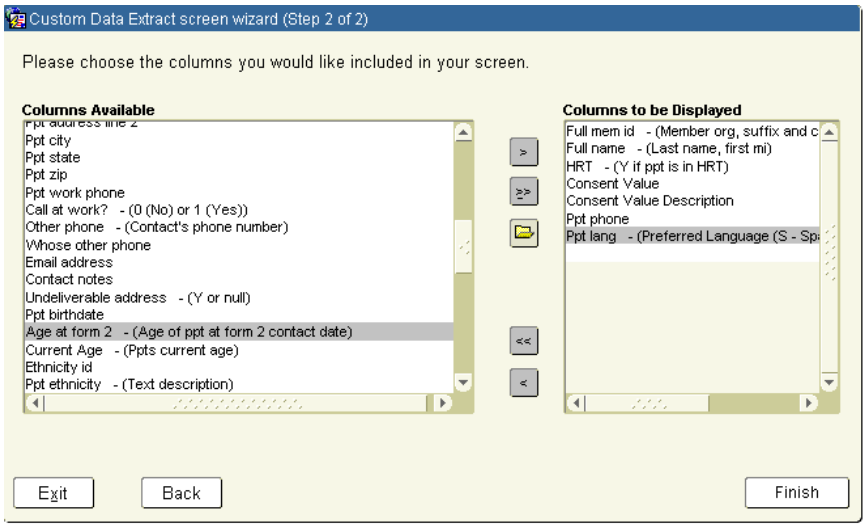
- Members and Encounters
- Ancillary Study
- Questionnaire Versions
- Outcomes

Each data source category contains one or more data source(s). Click on a data source category to view the associated data sources. To create a query screen from a data source:

1. Click on a data source to select it.
2. Click the **Continue** button on the dialog box to move to the next screen where you select individual columns from the data source to create your query screen.

10.7.7.2 Selecting Columns for Your Query Screen

Figure 10.43
Build WHIX Screen Wizard Step 2 of 2



The *Build WHIX Screen Wizard Step 2* dialog box (*Figure 10.43*) is where you select columns to create your own query screen. On the left-hand side of the dialog box is the list of **Columns Available** for you to use in creating your query screen. **Help text** in parentheses next to the column name provides additional information about the column, but will not appear as part of the column heading in your query screen. Some columns, such as member ID, study status (HRT, DM, CaD, OS), intervention status (HRT status, DM status) are common to many of the data sources. Columns that contain numeric codes often have the term **ID** as part of the column name. For example, the column **Follow-up status ID** contains the follow-up status codes from *Form 9 – Participation Status*. The column called **Follow-up Status**, on the other hand, contains the text description of the follow-up status from *Form 9*—for example, "Full follow-up".

You select a column from the **Columns Available** list by double-clicking on it or by highlighting it and clicking the **single right-arrow** button at the top of the column of buttons in the center of the dialog box (*Figure 10.43*). When you select a column, it will move to the right-hand side of the dialog box under **Columns to be Displayed**. If you select a column and then decide that you don't want it in your query, highlight it under **Columns to be Displayed** and click the **single left-arrow** at the bottom of the column of buttons in the center of the dialog box to move it back into the **Columns Available** list. You can select up to a maximum of 40 columns for a query.

The **double right-arrow** button will move all of the items in the **Columns Available** list to the **Columns to be Displayed** list. The **double left-arrow** button will move all of the items in the **Columns to be Displayed** list back to the **Columns Available** list. The **file folder** button allows you to access a set of "saved" column selections that you define. If you find yourself often using the same set of columns for a query, you can save it and re-create it later from a **Saved column list**. See *Section 10.7.7.3* for instructions on saving a column list.

The **Back** button at the bottom of the dialog box will move you back to the *Build WHIX Screen Wizard Step 1* dialog box (*Figure 10.42*), where the data source categories and subcategories are displayed.

If you are extracting data in order to create a report using Excel, the columns you select for your query screen should include the items that you wish to query on as well as those that you want to display on the report.

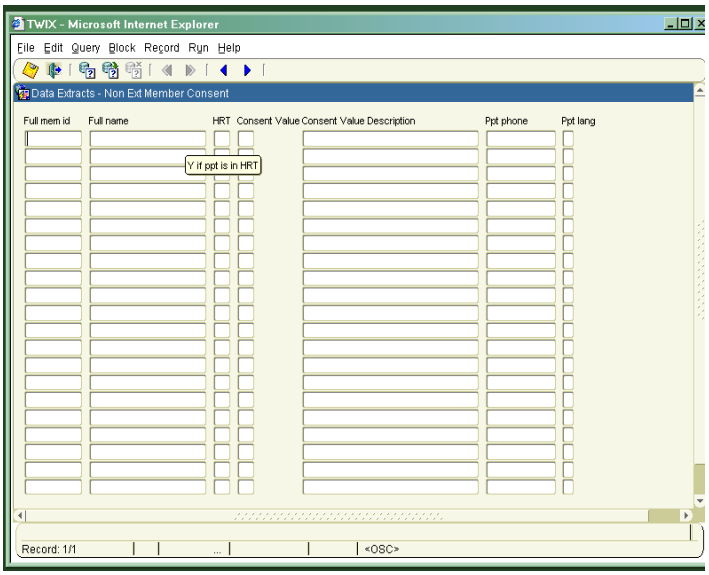
For example, say that you are interested in obtaining list of HT participants who have an Extension Consent status of 3—"No response to contact attempts". You want each participant's ID number, name, phone

number, consent value (from *Form 112*) and preferred language on the list, since you plan to call them. These items—ID, name, phone number, consent value, consent value description and preferred language—must be included as columns in your query screen since you want them to appear on the final report. In addition, you must include HT intervention status as a column in your query screen, since you want to select (query) only those HT participants who have not responded to contact attempts. Remember that numeric as well as text fields for the same data item are often available as column choices. When querying, it is often easier to query on a numeric field, but if you are creating a report that will be reviewed by someone who may not be familiar with the codes, you may want to include the text description column as well to make the report easier to read. In our example, we will include both the numeric and text columns for consent value.

We can use the *Non-Extension Member Consents* data source to build our query screen. We need to select the following columns:

- Full member ID
- Full name
- Phone number
- Consent value
- Consent value description
- Preferred language
- HT (Y if participant is in HRT)

Figure 10.44
Query Screen



Once you have selected the desired columns in the *Build WHIX Screen Wizard Step 2* dialog box, click the **Finish** button on the dialog box. This brings up the query screen showing the columns you have selected (*Figure 10.44*). If you have selected more columns than can fit on the screen, use the horizontal scroll bar at the bottom of the screen to view additional columns. Note that the Help Text does not appear in the column headings. However, if you place the mouse pointer over a field in a column, WHIX displays the help text as a "screen tip". In the example in *Figure 10.44*, the Help Text for the HRT field is displayed as a screen tip.

If after reviewing your column selections, you decide that you want to add or delete columns before proceeding with your query, you can do so easily without starting the column selection process over again:

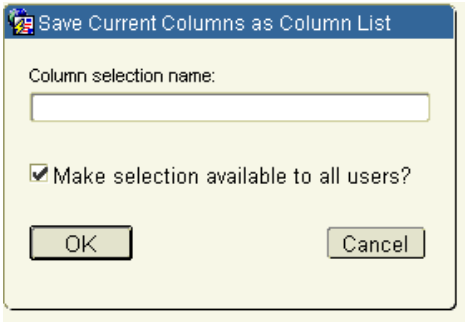
1. Select **Run** from the menu.
2. Select **Add/Remove Columns**.

This brings up the *Build WHIX Screen Wizard Step 2* dialog box again (*Figure 10.43*). Use the arrows as before to add or delete columns. Click the **Finish** button on the dialog box when you have completed your column selection.

10.7.7.3 Saving a Column List

If your list of columns is one that that you will need to use frequently, you can save the list for future use. With the query screen displayed as in *Figure 10.44.*

Figure 10.45
Save Current Columns as Column List

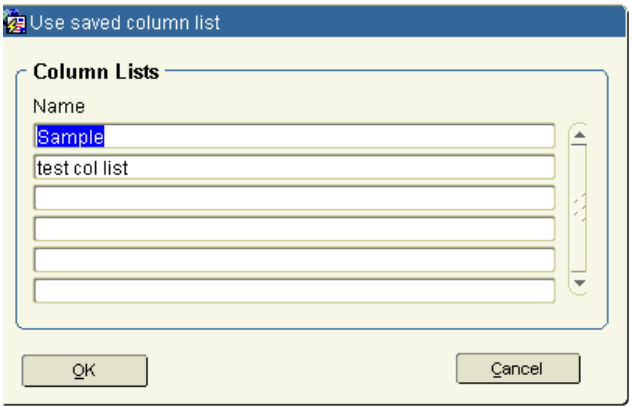


1. Select **Run** from the main menu.
2. Select **Save Current Columns** as Column List.

The dialog box in *Figure 10.45* appears. Type a name for the column list in the text box. If you don't want the saved list to be available to other WHIX users in your FC, click on the **checkbox** next to the *Make selection available to all users?* text to delete the checkmark. When you do this, the column list that you have saved will appear only in your list and not in the saved column list of other WHIX users at your FC. If you would like your saved column list to be available to all WHIX users at your FC, leave the checkmark in the box next to *Make selection available to all users?* Click the **OK** button to close the Save Current Columns as Column List dialog box.

From now on, when you are in the *Build WHIX Screen Wizard Step 2* dialog box (*Figure 10.43*), if you click on the **file folder** button in the middle of the dialog box, a dialog box displaying the column lists that you have created and saved is displayed (*Figure 10.46*). Select a column list and click the **OK** button or double-click on the name of a saved column list to create the query screen using those saved columns.

Figure 10.46
Saved Column List

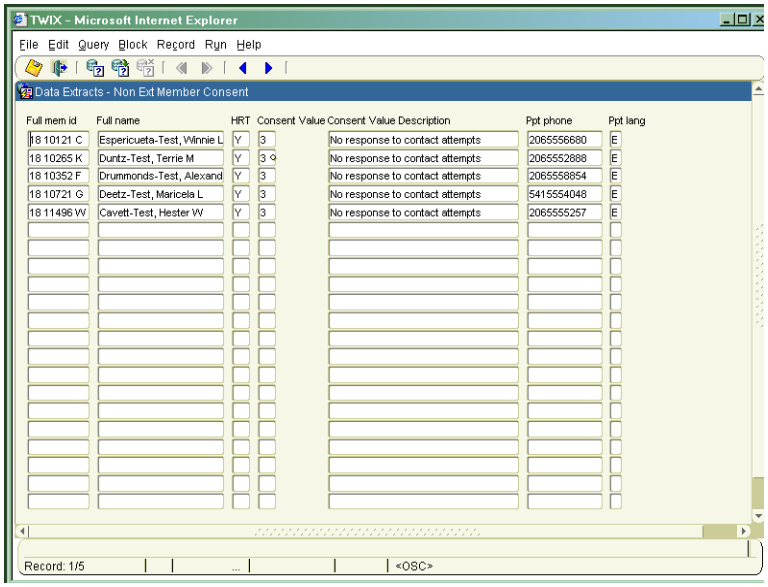


10.7.8 Entering and Executing a Query

10.7.8.1 Entering Search Criteria

The next step is to enter the search criteria for your query. In our example, we want only HT participants who have a status of "No response to contact attempts". Click the **Enter Query** button. **Tab** to the *HRT* column and enter a "Y" to query for participants who are in the HT study. Next **tab** to the *Consent Value* column and enter "3"—the code for "No response to contact attempts". In this simple example, these are the only search criteria you need to enter. Click the **Execute Query** button on the toolbar. The results of your query will be displayed in the columns of the query screen (*Figure 10.47*). You can use the **Page-down** key to view all of the results of your query if necessary. To create an Excel file from your query result, select **Write Data File** from the *Run* menu. WHIX automatically opens Excel and loads the results of your query into a spreadsheet which you can save. (See *Section 10.7.8.5* for information on creating the Excel file from your query.)

Figure 10.47
Results of a Query



10.7.8.2 Using Data Filters

If you routinely create queries involving a subset of participants, such as HT participants who due for their Extension mammogram, you may want to create a ***data filter*** that you can re-use every time you create a query involving that subset of participants. A data filter will limit your query to pre-defined criteria, so that you don't need to enter those criteria every time you create a query on your subset of participants.

For instance, say that each month you need reports of all participants who have a consent status of 3 – "No response to contact attempts", you could always enter the "No response" code in the Consent Value every time you create a query to obtain information on those participants. However, it is faster and more efficient to create a re-usable data filter that will automatically screen out all participants except those who have a Code 3 – "No response to contact attempts".

The steps to create a data filter are as follows:

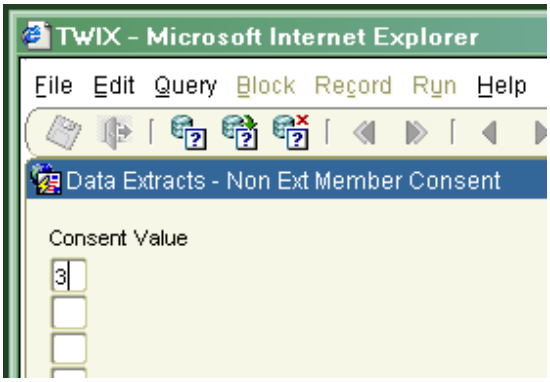
1. Create a query screen in the CDE system as described in *Section 10.7.6.*
2. Enter the search criteria that you want to save as a filter.
3. Enter and Execute your query.
4. Save the query as a filter.

The filter can then be selected from a list of saved filters and re-used in future queries.

As an example, to create a data filter for HT participants who have a consent status of 3 – "No response to contact attempts":

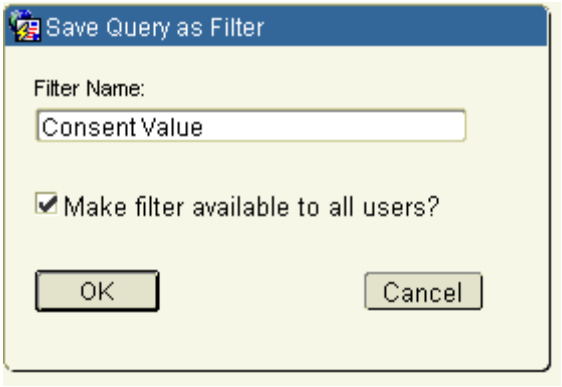
1. Select **Custom Data Extracts** from the *Reports* menu. This brings up the *Build WHIX Screen Wizard Step 1* dialog box.
2. Select the **Non-Extension Member Consent** data source.
3. Click the **Continue** button on the dialog box to bring up the *Building WHIX Screen Wizard Step 2* dialog box.
4. Select **Consent Value** from the "Columns Available" list.
5. Click the **Finish** button on the dialog box. The Consent Value column is displayed as the only column in your query screen.
6. Click the **Enter Query** button on the toolbar.
7. Enter the code for **No Response to Contact Attempts** (3) into the Consent Value column (*Figure 10.48*).

Figure 10.48
Entering Search Criteria



8. Click the **Execute Query** button on the toolbar. WHIX displays the data from your query.
9. Select the **Run** menu.
10. Select **Save current Query as Filter.** The Save Current Query as Filter dialog box is displayed (*Figure 10.49*).
11. Type a name for your filter into the text box.
12. Indicate whether you want the filter to be available to other WHIX users at your FC.
13. Click the **OK** button on the dialog box.

Figure 10.49
Save Query as Filter Dialog Box

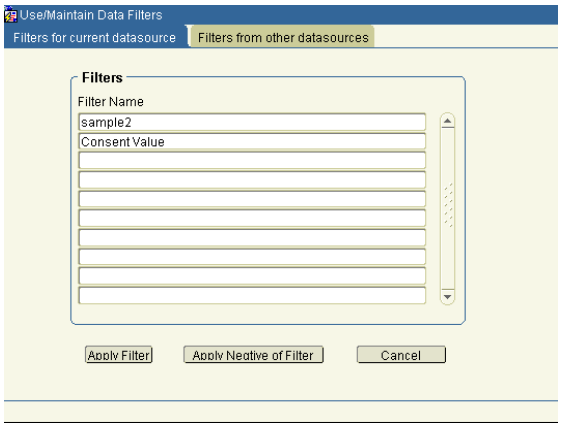


From now on, after you have selected columns to create a query screen in the *Build WHIX Screen Wizard Step 2* dialog box (*Figure 10.43*), you can use your saved filter. Note that only the query itself, and not the results of the query (the data) are saved when you save a filter.

To use a saved filter:

1. Select **Custom Data Extracts** from the *Reports* menu. This brings up the *Build WHIX Screen Wizard Step 1* dialog box.
2. Select a **Data Source**.
3. Click the **Continue** button on the dialog box to bring up the *Building WHIX Screen Wizard Step 2* dialog box.
4. Select your columns and click the **Finish** button.
5. Select **Use Data Filter** from the *Run* menu. The **Pick Data Filter** dialog box (*Figure 10.50*) is displayed. Note that there are two tab pages to this dialog box. The first tab page displays the filters that you have created in the data source in which you are currently working. The other tab page is described below.

Figure 10.50
Pick Data Filter Dialog Box



6. Select a filter by clicking on the **name of the filter**.
7. Click the **Apply Filter** button to use the filter in your query. Click the **Apply Negative of Filter** button to apply the negative of the filter to your query. For example, if you select the "No response to contact attempts" filter that was created in the example above, and then click the **Apply Negative of Filter** button, all HRT participants who have codes other that "3" entered as a consent value (includes "not approached") on *Form 111* or *112* will be retrieved in your query.

In any data source, you can use any filter that was created from queries using that data source. These filters are listed under the *Filters for Current Data Source* tab.

The other tab page of the *Pick Data Filter* dialog box is titled *Filters from Other Data Sources*. If two separate data sources, such as *Members* and *Ancillary Study Consents*, are linked in the WHIX table structure, you can use data filters created in one source to filter a query you are creating in the "linked" data source. Filters from linked data sources will show on the *Filters from Other Data Sources* tab page of the *Pick Data Filter* dialog box.

When a filter has been applied to a query, the name of the filter appears in the title bar of the query screen. To "de-activate" a filter that you have applied to a query, select **Stop Using Filter** from the *Run* menu of the query screen before you execute the query.

The *Adjudications* data source has a pre-made filter that FCs can use to query "orphaned" adjudication cases that are not linked to any provider visits. To access this filter:

1. Select *Custom Data Extract* from the *Reports* menu
2. Select the *Outcomes* data source category
3. Select the *Adjudications* data source
4. Select the columns (including case number) you wish to use in your query and click finish
5. Select "Use /Maintain Data Filter" from the *Run* menu
6. Select the "Adj not connected with Visit" filter and apply it.

Using this filter in your query will display cases that are not linked to a provider visit.

10.7.8.3 Using the Query Wizard

The *Query Wizard* is a feature of the CDE system that allows you to specify several values or a range of values in a single field in your query.

For example, if you want to retrieve:

- All HT participants with Extension consents entered between October 1, 2004 and November 30, 2005.
- All participants who were 55, 58 or 62 years old at the time they completed *Form 2*.
- All participants with a follow-up status of custom follow-up or no-follow-up.

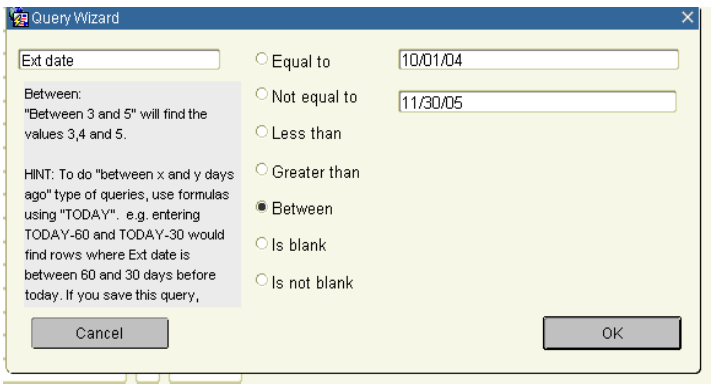
You use the query wizard in the query screen.

To use the query wizard to find all participants with Extension Consents entered between October 1, 2004 and November 30, 2005:

1. Select **Custom Data Extracts** from the *Reports* menu. This brings up the *Build WHIX Screen Wizard Step 1* dialog box.
2. Select the **Non Extension Member Consent** data source.
3. Click the **Continue** button on the dialog box to bring up the *Building WHIX Screen Wizard Step 2* dialog box.
4. Select the following columns from the available columns list: **Full member ID, Full Name, HRT (Y if participant is in HRT), Extension** and **Extension Date**
5. Click the **Finish** button on the dialog box. Your selected columns will be displayed on the screen.
6. Click the **Enter Query** button on the toolbar.
7. Position the cursor in the HT column and enter "Y".
8. Position the cursor on the **Ext date** column and right-click.
9. Select **Query Wizard** from the shortcut menu that WHIX displays.

The *Query Wizard Dialog* box (*Figure 10.51*) appears. You can select from a list of five relational operators: e*qual to, not equal to, less than, greater than,* and *between*. In addition, you can select records where the value in a particular column is null (*is blank*) or is not null (*is not blank*). Click on the round "button" in front of your choice to select it. In the example in *Figure 10.51* below, "Between" is selected.

Figure 10.51
Query Wizard Dialog Box



The number of values you can enter in the right-hand side of the dialog box depends upon the operator that you select.

- **Equal to**: Select 1 or more values in order to search for records that are equal to the individual values you have entered.
- **Not equal to**: Select 1 or more values in order to search for records that are not equal to the individual values you have entered.
- **Less than**: Select a value in order to search for records that are less than the specified value.
- **Greater than**: Select a value in order to search for records that are more than the specified value.
- **Between**: Select 2 values in order to search for records that are between the two specified values.

In our example we selected "Between" as the operator, and typed the dates that we wish to retrieve 10/01/04, and 11/30/05 into the text boxes.

Click the **OK** button on the dialog box.

Click the **Execute Query** button on the toolbar. Only those records meeting the criteria that you specified in the Query Wizard dialog box (plus any search criteria that you have entered in other fields) will be retrieved.

If you are querying on a date field and you select *less than*, *greater than* or *between* as the operator, you can type the word TODAY to represent the current date.

For example:

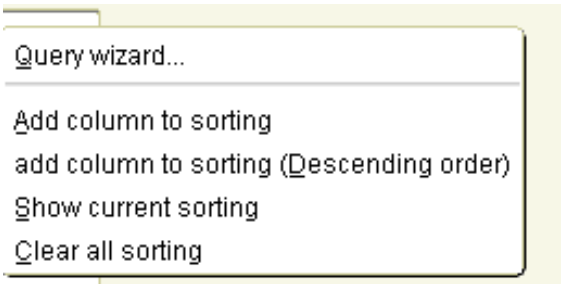
- TODAY-30 specifies a date 30 days previous to the current date
- TODAY+30 specifies a date 30 days after the current date

Using the word TODAY instead of typing the current date is especially useful in saved queries, because TODAY in a saved query will always mean the current date. It will save you the effort of typing in the current date when you have a query that you run on a regular basis. For example, you can select the "Between" operator, and enter the values TODAY and TODAY+30 to represent a date range that begins with the current date and ends 30 days into the future

10.7.8.4 Sorting Data in a Column

When you right-click on a field in a column, the *Query Wizard Shortcut* menu is displayed. In the previous section, we discussed using the Query Wizard to define a range of data in a column as part of a query. When you view the *Query Wizard* menu, you will notice there are also options for sorting data within a column (*Figure 10.52*).

Figure 10.52
Query Wizard Shortcut Menu



To sort a column once you have executed a query:

1. Position the cursor on the column you wish to sort first.
2. Right click to display the **Query Wizard** shortcut menu.
3. Select **Add column to sorting** to sort the column in ascending order or select **Add column to sorting (descending order***)* to sort the column in descending order.
4. Click the **Execute Query** button to sort the data.

To sort additional columns, repeat steps 1-4. Note that any column sorts that you have already implemented will remain in place when you sort additional columns (i.e., the original columns that you sorted will not be un-sorted by subsequent column sorting). For example, if you sort a set of records by participant age, then sort it by date of Extension consent, the records will still be sorted by age, and in addition, within each age category they will be sorted by Extension consent date.

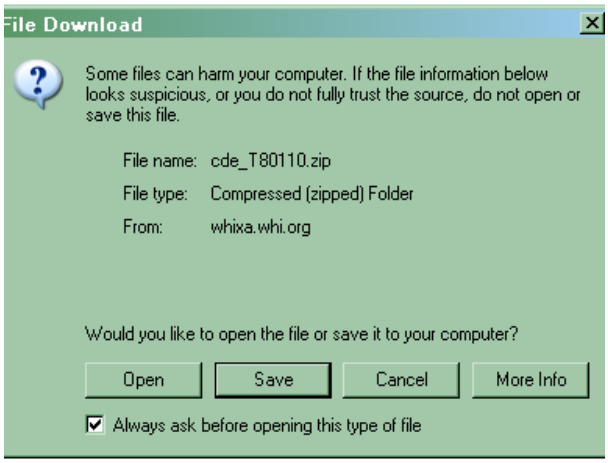
10.7.8.5 Creating a File from a Data Extract in Excel

Data files in the new CDE are written to a file on the CCC server in Seattle and are downloaded to your computer. The data file is compressed (into a zip file) to make the download faster. The zip file must be uncompressed before you can view your data in Excel.

To write a query result to a file:

- With your query results displayed on the screen, select **Write Data File** from the *Run* menu.
- When the File Download box appears, *(Figure 10.53)* you can click **Save** to save the compressed file on your computer or click **Open** to view the compressed file right now.

Figure 10.53
File Download Box



If you click **Save**, the save as dialog window will appear. The default filename is cde [your WHIX username].zip. The default directory is My Documents. You can rename the file and/or change where the file will be saved using this dialog window.

If you click the **Open** button or when you double click a zip file you previously saved, the program WinRAR will open. This program handles compressed files.

- The first time you use WinRAR, it will ask you what types of files it should try to handle. Click **OK** to accept the defaults.
- Your file will be listed in the WinRAR panel. It will be titled cde [your WHIX username].csv. Double click the file to open it in Excel.

To save the data as an Excel spreadsheet, select **Save As** from the *File* menu. In the "Save In" box, select the drive/folder to which you want to save the file.

- Type a new name for the file in the File Name box.
- Select **Microsoft Excel 97-2002 and 5.0/95 Workbook (.xls**) from the "Save as Type" box.

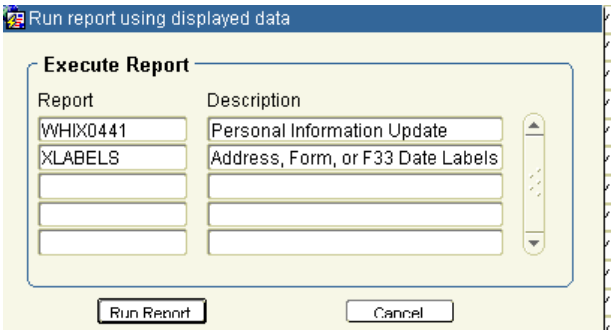
10.7.9 Run Reports Using Displayed Data

You can also run two WHIX reports, *XLABELS—Address, Form, Form 33 Labels* and *WHIX0441—Personal Information Update*, based on a query you have created and executed using the **CDE** system. First, you create and execute a query. Then you can run the reports based on the participants that were selected in your query.

To use this feature:

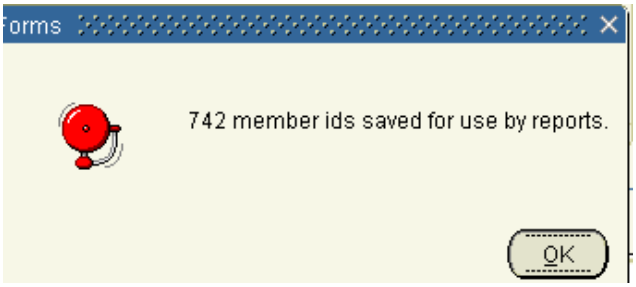
1. **Enter** and **execute** a query as described in *Section 10.7.8 – Creating a File from a Data Extract in Excel*.
2. Select **Run Report Using Displayed Data** from the *Run* menu. WHIX displays the *Execute Report* dialog box (*Figure 10.54*).

Figure 10.54
Execute Report Dialog Box



3. Highlight the report name or description.
4. Click the **Run Report** button on the dialog box.
5. A message box will appear (*Figure 10.55)* telling you how many member IDs were saved. This is the number of participants for whom the labels or report will run.
6. Click the **OK** button.

Figure 10.55
Message Box



The *Report Parameters* screen will appear. Select the parameters you want and click **Run Report**. You can then print the labels or PIU Report.

Section 10
Data Management

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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 due 4/05 – 9/06)	≥ 70% Mammogram reports collected and recorded into database (cumulative, 4/05 – 3/07)	N/A	N/A	N/A
	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

Section 11
Quality Assurance

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