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

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

WOMEN'S HEALTH INITIATIVE

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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