Section 6
Enrollment

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Section 6

Enrollment

Introduction

This section describes procedures used to enroll participants into the Women's Health Initiative (WHI) Extension Study 2010 to 2015 (ES 2). Consenting participants to the ES 2 received a CCC mailed newsletter, WHI Matters, introducing participants to the ES, a CCC mailing of a consent packet, a second mailing of the consent packet to non-responders, a reminder phone call to non-responders by FC or CCC staff, and a final follow-up to non-responders to offer consent over the phone.

6.1 Spring 2010 WHI Matters

In April and May of 2010, the CCC sent all Extension Study 2005-2010 (ES 1) participants a special edition of the participant newsletter, WHI Matters. The newsletter included articles about the successes of the past WHI results and findings and an introduction to the next Extension. See copy in *Appendix F – Printed Materials Templates*, WHI Matters 2010.

6.2 Mailed Consent Packets

From May through July 2010, the CCC mailed a consent packet to all Extension Study 2005-2010 (ES 1) participants eligible for the consent mailings. Only those participants with a follow-up status of 'absolutely no contact' and deceased were excluded from the mailing. The consent packet included the following materials:

- Introductory cover memo (see *Figure 6.1- Cover Letter for Mailed Consent Packet*)
- List of new Regional Centers (see *Figure 6.2- List of Regional Centers for Mailed Consent Packet*)
- 2 copies of the consent form, one for the participant to sign and return to the CCC and one to keep (see *Section 2 – Consent Forms* for copies of the consent)
- Printed copy of participant's Personal Information Update (PIU) with current information from WHIX
- Postage paid return envelope addressed to the CCC.

The CCC mailed the consent form packets using the following guidelines:

- The CCC received local IRB approval from each RC site before the mailing was done.
- Mailed to all Extension Study 2005-2010 (ES 1) participants, excluding those with a follow-up status of 'absolutely no contact' and deceased; that is, mailed to participants with Full, Custom, Proxy, Lost, and No follow-up status. This followed the procedures used in previous consent mailings, giving all participants the opportunity join ES 2.
- Mailed to all participants assigned to a FC at the same time, starting with the FCs furthest from Seattle, including Hawaii, to allow for additional mail and return times.
- Used first class postage for faster delivery and so zip code sorting was not needed.
- Mailed approximately 110,000 packets over an 8-week period from May-June.

The CCC sent a second packet, identical to the first, to non-responders 4-6 weeks after the first packet was mailed using the same mailing procedures. The order of mailing to FCs was the same as the first mailing to allow for return and data entry of the consents, with the time shortened to 4 weeks between mailings near the end of the mailing cycle.

Upon receipt of the consent form and PIU from the participant, CCC staff reviewed the consent form for completeness and for any additional comments participants may have written on the form. If necessary, participants were contacted by the CCC to discuss their comments, particularly if comments needed to be addressed to help them determine their future participation.

A list of Frequently Asked Questions (FAQs) was developed as a resource for FC staff should a participant call and have questions about the mailed packet. See *Figure 6.3- FAQs for participant questions about the consent for the WHI Extension 2010-2015*.

6.3 Reminder Phone Follow-up to Non-responders of the Second Mailing

A reminder phone call was made to all participants who did not respond to either of the two consent mailings. The purpose of the phone call was to encourage the participant to review and respond to the previous consent mailing packets. See *Figure 6.4 - Guide for Non-Responder Phone Contacts* for content of the phone call.

All FCs were encouraged to make the reminder phone calls to their own participants. The amount of effort that went into locating and obtaining consents from non-responders was at the FC's discretion. FCs that did not continue into the current ES2 had to obtain local IRB approval to do these phone consents through March 31, 2010. For those FCs that no longer had funds or staff to do the reminder phone calls, the CCC made arrangements for a shared resource, Custom Data Services(CDS), at FHCRC to do the phone calls. The FCs continuing into ES 2 had agreements for FHCRC to be their IRB of record and had FHCRC IRB approval to do the phone contacts to their original participants.

If the participant requested another consent packet when contacted, the CCC sent a third mailing to those participants.

6.4 Phone Consenting of Non-Responders

In February 2011, the WHI Steering Committee approved a procedure for administering the ES 2 consent over the phone. The CCC obtained FHCRC IRB approval for the phone consents that same month, which applied to all the RC sites for which FHCRC had become the IRB of record, i.e., all RC sites excluding one. The one RC site was asked to submit and obtain its own institutional IRB approval before conducting the phone consents. As with the phone call reminders, the RCs could contact their own original ES1 participants. The CCC asked CDS at FHCRC to contact the approximate 7,000 remaining non-responding participants at the 30 non-continuing FCs to conduct the phone consents. See the instructions for *Form 115 – Extension Study Consent* for the phone consent guidelines.

RCs were asked to prioritize the phone consenting as follows:

1. Medical Records Cohort (MRC) participants
2. Participants who were mailed a consent packet when previously contacted but for whom the CCC had not yet received the signed consent.
3. Remaining participants who had not responded to the consent mailings or phone calls.

A participant's proxy was not allowed to sign the WHI Extension Consent Form. The CCC contacted identified proxies who signed the consent form for the participants. The proxies were told that the participant had to sign the consent form, if she was able. Participant who were able to sign the consent were sent a new consent packet for signature.

When a phone consent was obtained, CDS and RC staff completed *Form 115 – Extension Study Consent Status*, indicating Interviewer-administered consent, and signing and dating the form. The RCs then sent the Form 115 to the CCC for data entry. The CCC data entered and archived the forms. RCs data entered Form 115 for participants refusing any consent.

Figure 6.1
Cover Letter for Mailed Consent Packet

WOMEN'S HEALTH INITIATIVE

WHI Clinical Coordinating Center

FRED HUTCHINSON CANCER RESEARCH CENTER
A LIFE OF SCIENCE

May 1, 2010

Dear <Participant Name>,

We are writing to thank you once again for participating in the Women's Health Initiative and to invite you to continue to be a part of this landmark study. With your help, the WHI has provided answers to important questions about women's health. Your partnership in WHI has created a legacy that will improve the lives of future generations.

The National Institutes of Health (NIH) has recognized the value of the WHI and your unique contributions to it. Scientists and NIH leaders realize that much remains to be learned from the WHI and therefore the NIH has renewed the program. Your ongoing participation is crucial to its success. With longer follow-up of women like you, the WHI can help us learn how women can lead healthier lives into their 80s, 90s and beyond.

With your permission, the WHI Clinical Coordinating Center will continue to contact you for an annual health update. We will ask you to sign a medical release form to permit us to obtain more details from your health care providers, if needed. This renewal of the WHI brings some changes in study procedures. In the future, clinical center responsibilities for obtaining medical records will be consolidated into either the WHI Clinical Coordinating Center or one of the WHI Regional Centers or their affiliates.

If you are willing to continue in the study, please sign one copy of the consent form, update the Personal Information pages and return both documents in the enclosed envelope. A second copy of the consent, signed and dated by the Principal Investigator, is included for your records.

If you have questions about information in the consent form or the change in WHI procedures, please leave a message on the WHI toll-free number at 1-800-218-8415.

On behalf of the entire WHI, we thank you for your partnership over these many years and we look forward to your continued involvement.

Warmest regards,

Garnet Anderson, PhD
CCC Principal Investigator (Current) Field Center PI

Figure 6.2
List of Regional Centers for Mailed Consent Packet

REGIONAL CENTERS

To locate your Regional Center, find the name of your WHI clinical center on the list below. The Regional Center and phone number for each center is shown in the right-hand column.

Clinical Centers	Western Regional Centers
Kaiser Permanente/Bay Area Clinic, Oakland CA	Stanford University Toll free (888) 729-8442 (650) 725-5307
South Bay WHI Program, Torrance CA	
Stanford University/San Jose Clinical Center, Palo Alto, CA	
UCLA Center for Health Sciences, Los Angeles, CA	
University of California, Davis CA	
WHI-UC Irvine Clinical Center, Orange, CA	
Center for Health Research, Portland, OR	
University of Arizona, Phoenix, AZ	University of Arizona Toll free (800) 341-7672 (520) 321-7440
University of Arizona, Tucson, AZ	
University of Hawaii School of Medicine, Honolulu, HI	
University of Nevada, Reno, NV	
UC San Diego Clinical Center, Seattle, WA	Fred Hutchinson Cancer Research Center Toll free (800) 514-0325
Seattle, Clinical Center Seattle, WA	

Clinical Centers	Midwestern Regional Centers
Evanston Hospital (Northwestern University), Evanston, IL	Ohio State University Toll free (800) 251-1175 (614) 688-3563
Northwestern University, Chicago, IL	
Medical College of Wisconsin, Milwaukee, WI	
Rush-Presbyterian – St. Luke's Medical Center, Chicago, IL	
Ohio State University, Columbus, OH	
University of Cincinnati College of Medicine, Cincinnati, OH	
Berman Center for Outcomes & Clinical Research, Minneapolis, MN	University of Iowa Toll free (800) 347-8164 (515) 241-8989
University of Iowa, Davenport, IA	
University of Iowa, Des Moines, IA	
University of Iowa, Iowa City, IA	
University of Wisconsin, Madison, WI	
Detroit Clinical Center, Detroit, MI	University of Pittsburgh Toll free (800) 552-8140 (412) 624-3579
University of Pittsburgh Pittsburgh, PA	

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Figure 6.2 (continued)
List of Regional Centers for Mailed Consent Packet

Clinical Centers	Northeastern Regional Centers
New Jersey Medical School, Newark, NJ	University of Buffalo Toll free (855) 944-2255 (716) 829-3128
UMDMJ – Robert Wood Johnson Medical School, New Brunswick, NJ	
Albert Einstein College of Medicine, Bronx, NY	
School of Medicine, SUNY, Stony Brook, NY	
University of Buffalo, Buffalo, NY	
Brigham and Women's Hospital, Chestnut Hill, MA	Brigham and Women's Hospital Toll free (800) 510-4858 (617) 732-9860
Charlton Memorial Hospital, Fall River, MA	
Memorial Hospital of Rhode Island, Pawtucket, RI	
UMASS/FALLON Women's Health, Worcester, MA	
George Washington University, Washington, DC	WHI of the Nation's Capital - Medstar (301) 560-2924
WHI of the Nation's Capital – Medstar Hyattsville, MD	

Clinical Centers	Southeastern Regional Centers
UNC Women's Health Initiative, Chapel Hill and Durham, NC	Wake Forest University School of Medicine Toll free (877) 736-4962 (336) 713-4221
Women's Health Initiative of the Triad, Greensboro, NC	
Women's Health Initiative, Winston-Salem, NC	
University of Tennessee, Germantown, TN	
University of Tennessee – Medical Center, Memphis, TN	
Baylor College of Medicine, Houston, TX	
University of Texas Health Science Center, San Antonio, TX	
University of Alabama, Birmingham, AL	University of Florida, Gainesville Toll free (800) 944-4594 (352) 294-5211
Emory University, Decatur, GA	
University of Florida Clinical Center, Gainesville, FL	
University of Florida Clinical Center, Jacksonville, FL	
University of Miami School of Medicine, Miami, FL	

WHI CLINICAL COORDINATING CENTER

Fred Hutchinson Cancer Research Center, Seattle, WA (message line) (800) 218-8415

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Figure 6.3
FAQs for participant questions about the consent for the WHI Extension 2020-2015

What exactly will I be doing if I continue with WHI?

- You will be filling out and mailing back health forms each year. The information we will ask for is very similar to what you have provided all along—changes to your health status, medications you take, medical procedures you might have had, and any hospitalizations. If you have had health changes, we may ask for some specific details such as dates of hospitalizations and name and address of the hospital. These forms will be mailed to you and will take less than an hour of your time to complete each year.

Will I need to travel anywhere?

- No. You do not need to come for clinic visits or travel anywhere to continue participating. However, sometimes participants may be invited to be in special studies within the WHI, and these may involve short visits. You would always have the choice to participate or not in these special studies, without any effect on your regular participation in WHI.

Can I continue participating in the WHI by only filling out the forms?

- Yes, you may continue participating by only filling out the forms.

I don't think I have anything more to contribute; nothing that you would be interested in. *OR* I am not healthy anymore, so my information is probably not of interest to you.

- Your information continues to be very valuable. You have contributed so much to women's health, and now as WHI women are getting older, there is even more to be learned. We hope to learn more from our participants about promoting healthy aging and improving quality of life. We will be studying factors related to risks for heart disease, stroke, blood clots, cancers, osteoporosis and fractures. We also expect to learn about less common health concerns that women experience.

I don't see very well any more, may I have someone help me fill out the forms?

- Yes, you may have someone, such as a friend or family member, help fill out the forms. You have been asked if there is someone who can provide information about your health if you are not able to do so. That person might also be someone you could ask to help you with your forms. If you need further assistance, you will be given a phone number to call.

What is the "WHI Regional Center" that is mentioned in the consent? Is this the same as my Clinical Center?

- For this next extension, we have simplified the WHI overall. Several Regional Centers will be selected from among the WHI Clinical Centers. You will be followed by the WHI Clinical Coordinating Center, primarily through mailings each year just as was done for the last few years, but if we need more information from you, someone from the coordinating center or one of the new regional centers will contact you. Your clinical center may be your new regional center, or it may be another WHI clinical centers.

Will I still receive the newsletter?

- Yes. Every year, as a WHI participant, you will still receive a *WHI Matters* newsletter.

How long will the WHI keep going?

- That is a good question. We don't know for sure how long the WHI will keep going. We can say that with every year that WHI continues, your contribution becomes even more valuable, because we learn so much more about women's health over time.

Can I still call (email or write) the person at my Clinical Center who I used to call? Who do I contact if I have questions about my participation in WHI?

- We ask that you call the toll-free 1-800 number on the consent form--1-800-218-8415. That number is for the WHI Clinical Coordinating Center. The health forms you receive in the mail lists contact information for the WHI Clinical Coordinating Center and your current WHI Regional Center.

You said something about participating in other studies related to WHI. What kinds of studies are you talking about?

- These could be related to any number of health topics. Examples of past studies included measuring calcium in the arteries around the heart in some hormone trial participants and looking at blood and urine for markers of dietary intake.

I lost my consent form. How can I get another one?

- We would be happy to mail another one to you. <<Ask for current mailing address and telephone number. Send information to the CCC. >>

Can I receive the results of the tests done on my blood?

- We cannot give you the results of your blood tests. This is because the labs are for research only and not for providing individual results.

What if I sign up now but then decide later on that I don't want to participate anymore?

- You can withdraw from the WHI at any time. Your health care will not be affected by your choice to continue in the WHI or not.

Figure 6.4
Guide for Non-Responder Phone Contacts

CALL DURING PARTICIPANT'S PREFERRED CALL TIMES. IF NONE IS LISTED, CALL BETWEEN 9:00 a.m.-5:00 p.m. during various days. Conduct the call in a location supportive of voice privacy. Make at least 3 call attempts. If voice mail is available, it is OK to leave a voice-mail message (see Q1c).

START:
Hello, my name is <<*your name*>> and I'm calling from the <<*your Field Center's name*>> Field Center for the Women's Health Initiative. I am calling for <<*name of participant*>>.

Pause to allow response.

If no response, go to Q1**.**

If participant responds affirmatively, go to Q2.

Ql. Is this <<*name of participant*>>?

Q1a. If YES, go to Q2.

Q1b. If NO, and if participant is not available,

When would be a good time for me to call again?

Q1bi. If a time is offered,

Thank you very much. I will call back on <<*day, date, time*>>. Good-bye.

NOTE DAY, DATE, TIME TO CALL AGAIN ON THE CALL RECORD WORKSHEET.

Q1bii. If no time is offered,

Thank you very much. I will call back another time. Good-bye.

NOTE ANOTHER DAY, DATE, TIME TO CALL AGAIN ON THE CALL RECORD WORKSHEET.

Q1c. IF YOU REACH VOICE MAIL OR AN ANSWERING MACHINE:

This is <<*your name*>> calling from the <<*your Field Center's name*>> Field Center of the Women's Health Initiative. I am calling for <<*name of participant*>> to talk about the next part of the Women's Health Initiative. You may reach WHI toll-free at 1-800-218-8415. We will also call you back within a few days if we don't hear from you. Thank you.

Q2. I am calling to talk with you about continuing to be part of the WHI. Is this a good time to talk?

Q2a. IF YES, go to Q3.

Q2b. IF NO,

Is there a more convenient time for me to call you?

Q2bi. If YES,

Thank you. I will call you on <<*day, date, time*>>.

NOTE DAY, DATE, AND TIME ON CALL RECORD WORKSHEET.

Q2bii. If NO,

Thank you very much. I will call again in a few weeks. Good bye.

NOTE CALLING AGAIN IN A FEW WEEKS ON THE CALL RECORD WORKSHEET.

Q2c. IF PARTICIPANT REQUESTS NOT TO BE CALLED AGAIN,

I understand that you do not want to be called again for this study. We honor your request. Thank you very much for your time. If you decide later that you would like to continue, you may call WHI toll-free at 1-800-218-8415.

DATA ENTER F115 STATUS "CONSENT REFUSAL".

Q3. **Recently we mailed a letter to you inviting you to continue participating with the Women's Health Initiative. Did this letter reach you?**

Q3a. IF YES, go to Q4.

Q3b. IF NO OR UNSURE, Go to Q3c.

Q3c. **I'd like to mail the letter to you again. First, I'd like to verify your mailing address.** <<***Read mailing address.***>> Make any necessary changes. **<<*Read corrected mailing address.*>>**

The letter should arrive to you within a week. There is a consent form with the letter. If you have any questions, you are welcome to call us. Here is the toll-free WHI phone number to call: 1-800-218-8415. Your participation in the Women's Health Initiative is extremely valuable and we thank you very much. Good bye.

CONTACT THE CCC TO REQUEST MAILING THE LETTER AND CONSENT.

Q4. Good. We're glad the letter reached you! Your participation in the Women's Health Initiative is extremely valuable. With the letter was a consent form for you to read, sign, and return to us. We haven't received your consent yet, which is why we are calling.

Pause to give the participant an opportunity to comment.

Q4a. IF THE PARTICIPANT SAYS SHE HAS SIGNED THE CONSENT AND MAILED IT BACK.
Go to Q5.

Q4b. IF SILENCE, OR THE PARICIPANT ASKS QUESTIONS ABOUT THE CONSENT, OR EXPRESSES UNSUREDNESS, DOUBT OR HESITATION IN CONTINUING WITH WHI,
Go to Q6.

Q4c. IF THE PARICIPANT EXPRESSES INTEREST IN CONTINUING WITH WHI,
Go to Q7.

Q4d. IF THE PARICIPANT EXPRESSES THE WISH NOT TO CONTINUE PARTICIPATING WITH WHI,
Go to Q8.

Q5. If the participant responded to Q4 by expressing
I HAVE SIGNED THE CONSENT AND MAILED IT BACK,

Great! Thank you! Your participation continues to be very valuable. You have contributed so much to women's health, and now as WHI women are getting older, there is even more to be learned. Thank you again. Good bye.

<<MAKE NOTE ON CALL RECORD WORKSHEET.>>

Q6. If the participant responded to Q4 by expressing
SILENCE, or QUESTIONS about the consent, or UNSUREDNESS, DOUBT, OR HESITATION in continuing with WHI,

Use the consent talking points to assist responding to the participant's questions, unsuredness, doubts or hesitations.

When there are no further questions, reflect your assessment of the participant's interest in continuing with the WHI as one of the following three possibilities:

Q6a. INTEREST in continuing with the WHI,

Go to Q7.

Q6b. NOT INTERESTED in continuing with WHI,

Go to Q8.

Q6c. UNSUREDNESS, DOUBT OR HESITATION in continuing with the WHI,

Go to Q9.

Q7. If the participant responded to Q4 or Q5 by expressing
INTEREST in continuing with the WHI,

You sound interested in continuing with the WHI. That's great! Do you still have the letter and consent?

Q7a. If YES,

We ask that you sign the consent and mail it back to us in the envelope provided. We look forward to receiving your signed consent. Thank you again for your participation with the Women's Health Initiative. Good bye.

Q7b. If NO,

Go to Q3b.

Q8. If the participant responded to Q4 or Q5 by expressing
NOT INTERESTED in continuing with WHI,

I understand that you are not interested in continuing with the WHI. Thank you very much for your time. We appreciate all that you have done for the Women's Health Initiative. If you decide later that you would like to continue participating with the WHI, you may call us toll-free at 1-800-218-8415. Good-bye.

DATA ENTER F115 STATUS "CONSENT REFUSAL".

Q9. If the participant responded to Q5 by expressing UNSUREDNESS, DOUBT OR HESITATION in continuing with WHI,

We'd like to give you time to think about continuing to participate. May we call you in a few days?

Q9a. If YES,

Thank you. We will call you on <<*day, date, and time.*>>

NOTE DAY, DATE, AND TIME ON CALL RECORD WORKSHEET.

Q9b. If NO,

Thank you very much for your time. We appreciate all that you have done for the Women's Health Initiative. If you decide that you would like to contact us, you may call us toll-free at 1-800-218-8415. Good-bye.

DATA ENTER F115 STATUS "CONSENT REFUSAL".