

FORM:	115 – EXTENSION CONSENT STATUS
Version:	2.0 – Jan 2011
Description:	Completed by Field Center (FC) staff; 1-page form; key-entered at FC.
When used:	After consent mailing by CCC in May-June 2010 and anytime after that to indicate the participant contacted the FC to say she does not want to continue in the next Extension period to 2015.
Purpose:	To document that the participant contacted the FC after receiving the CCC mailed consent packet, and said she does not want to continue in the next Extension period.

GENERAL INSTRUCTIONS

1. Use to indicate that the participant contacted the Field Center to say that she did not want to continue in the next WHI Extension Study after receiving the consent form mailed by the CCC

The participant must have been mailed the consent packet mailed from the CCC before FCs can use this form. Do not use this form to indicate a participant wants to stop follow-up in the Extension Study or says she does not want to continue in the study based on receiving the WHI newsletter: the participant should receive the mailed consent packet before being able to say she refused to sign the consent form.

2. Review the form for completeness and forward to the FC data entry staff.
3. Data Entry: Key-enter the form into the WHI database. See *Data Management* section for specific instructions on how to key-enter this form. Initial form after key-entry.
4. File the key-entered form in the participant's file.

Item Instructions

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|----|--------------------------------|---|
| 1. | Date of contact | Date the FC receives information from the participant that she does not want to continue in the next Extension period. |
| 2. | Completed by | Standard 5-digit WHI employee ID. (See common data items.) |
| 3. | Contact type | Mark appropriate box. (See common data items.) |
| 4. | Status | Consent refused

Mark "2 – Consent refused after receiving Consent Mailing" if the participant contacts the FC to say she does not want to continue in the next Extension period.

Mark "3 – Not approached" if staff at the FC do not or cannot attempt to reach the participant by phone.

Mark "7" – Participant verbally consented to study by phone" if the consent was obtained over the phone. |
| 5. | Interviewer Statement and Date | Signature of interviewer and date if the consent was obtained over the phone. See phone scrip below

Not data entered. |

Phone Script for Contacting and Consenting Participants by Telephone

GENERAL INSTRUCTIONS:

Call during participant's preferred call times. If none is listed, call between 9:00 a.m.-9:00 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).

If at any time during the call the participant has questions, refer to the Consent FAQs document.

If at any time she indicates that she does not want to continue in the study, skip to Q10 and end the call.

START:

Hello, my name is <<your name>> and I'm calling from 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.

Q1. 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 Women's Health Initiative. I am calling for <<name of participant>>. 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 REFUSED”.

Q3. Recently we mailed a letter to you inviting you to continue participating with the Women’s Health Initiative. The purpose of this call is to ask if you are willing to continue your participation. To help you decide, I’d like to review the purpose and requirements of study participation.

The main purpose of the WHI Extension Study is to continue to learn more about the health of postmenopausal women, especially about risks for heart disease, stroke, blood clots, cancers, and fractures, as well as factors related to healthy aging.

If you agree to continue with the study, you will be asked to fill out health forms each year, similar to the forms you have completed in the past. If you have had health events for which we need additional information, we may ask you to sign a Release of Medication Information form. These activities will take about an hour of your time each year.

You will not receive any personal benefit from participating. The only risk for this study is a small risk of confidentiality.

You will not be paid in the study. The WHI will not pay for any health problems or conditions that might occur during the study period. The study does not replace your usual medical care.

Your study records will be kept confidential and will not be released for any reason without your written permission unless compelled by law. Information from this study may be published in scientific journals but your identity will not be revealed.

Only WHI staff at the Clinical Coordinating Center at the Fred Hutchinson Cancer Research Center in Seattle, Washington and your WHI Regional Center will have access to your identifying information to maintain contact with you and update your study records. Some other people or organizations may need to look at your records for research, such as the National Institutes of Health. These organizations are interested in study data, not your personal information.

This is not a treatment study. Your alternative is not to participate.

Your decision to continue in the study is voluntary. You may stop at any time, for any reason, without notice. If you decide to stop participating in the study, it will not affect your medical care or your medical insurance coverage.

We ask for your permission to contact your spouse, close relative, or friend for updated information about your health in case you are unable to complete the health update forms. We may also try to obtain additional information about your health status through nationally available records, such as social security or Medicare.

If you have any questions about any part of the study or your rights as a volunteer, I will try to answer them during this call. You are also welcome to call the WHI toll-free number, 1-800-218-8415, if you ever have any questions about the study or your rights as a study participant.

Q6. Okay, those are the main points I need to cover about your study participation. Do you have any other questions for me at this time?

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

When there are no further questions, continue

Q7. Now that I have reviewed the study requirements, would you be willing to continue with the WHI Extension Study?

Reflect your assessment of the participant's interest in continuing with the WHI as one of the following four possibilities:

Q7a. INTEREST in continuing with the WHI,

Go to Q8.

Q7b. DOUBT OR HESITATION in continuing with the WHI,

Go to Q9.

Q7c. WOULD LIKE ANOTHER COPY OF THE CONSENT FORM TO REVIEW BEFORE DECIDING

Indicate this on the call record sheet, mail her a consent form, and call her back approximately 2 weeks later

Q7c. NOT INTERESTED in continuing with WHI,

Go to Q10.

Q8. If the participant consents to continue

Great, I'm so glad to hear that. Sometime during the next year, you'll receive your next data collection packet, as well as a copy of the participant newsletter *WHI Matters*. Thank you so much for your time and your participation in the Women's Health Initiative over the years. Your participation is very important to the health of women everywhere. Thank you and have a good day/evening.

COMPLETE CONSENT STATUS FORM, SIGN, AND DATE

Q9. If the participant responded to Q5 by expressing

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.

Q10. If the participant is unwilling to continue

I understand that you are not interested in continuing with the WHI. Thank you very much for your time. We really appreciate all that you have already 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 REFUSED".