

FORM:	11 - CONSENT STATUS
Version:	4 - June 1, 1995
Description:	Completed by Clinical Center (CC) staff; 2-page form; scanned at CC (Spanish versions are key-entered).
When used:	<p>At Screening Visit for Initial Consent (usually SV1).</p> <p>At Screening Visit for Hormone Replacement Therapy (HRT) and/or Dietary Modification (DM) Consent(s) (usually SV2).</p> <p>At first annual visit for Calcium/Vitamin D (CaD) Consent.</p> <p>At follow-up contacts when revised consent is signed.</p> <p>Screening Visit as needed for Observational Study (OS) Consent.</p> <p>At contacts after completing a <i>Form 2/3 - Eligibility Screen</i> at which the participant declines further screening or resumes screening, but before being randomized into Clinical Trial (CT) or enrolled into the OS.</p>
Purpose:	To document the signing of the consent form or a participant's decision to stop or resume the screening process.

GENERAL INSTRUCTIONS

1. Use to indicate the relevant consent form(s) signed or refused at this contact. Use at SV0 or SV1 for the Initial Consent, at SV1 or SV2 for the HRT and/or DM Consent, and at the first annual visit for the CaD component. Use as needed during screening contacts for the OS Consent. If a woman is not eligible for one of the components, do not present the corresponding consent form to her and do not complete *Form 11* for that consent form.

Also use at follow-up contacts after randomization into CT or enrollment into OS to indicate the participant has signed an updated consent form.

Also use to indicate if the participant decides to stop the screening process any time after indicating interest on *Form 2/3*.

Do not use *Form 11* to indicate a participant has become ineligible due to questions or criteria on other forms.

Do not use *Form 11* for participants already enrolled in OS or randomized to CT to indicate they decline further participation.

2. *Form 11* must be completed and key-entered, showing that the participant signed the appropriate consent form(s), before you can randomize the participant into the CT or enroll her into the OS.
3. If the participant refuses to sign or declines further screening for the indicated consent form, complete the remainder of the form (i.e., reasons not signed or declined further screening).
4. Data Entry: Review the form for completeness and consistency. Return to interviewer with any problems noted. Data enter the form when problems have been resolved: scan the English version and key-enter the Spanish version. For the Spanish version, key-enter each consent form marked in Item 1 as a separate task. Initial the first page after data entry.
5. File the key-entered form in the participant's file.

Item Instructions

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| 1. | Consent form | The consent form(s) the participant signed, refused to sign, or declined further screening for this contact. Mark as many as apply for the contact date. Do not include consent forms for different contact dates. |
| 2. | Date of contact | Date the participant signs, refuses to sign, or declines further screening. |
| 3. | Completed by | Standard 3-digit WHI employee ID. (See common data items.) |
| 4. | Contact type | Mark appropriate oval. (See common data items.) |
| 5. | Visit type | Contact at which the participant signs, refuses to sign, or declines or resumes further screening. Mark appropriate oval and enter visit number. (See common data items.) |
| 6. | Signature | <p>Complete Item 6, marking the appropriate consent form column(s).</p> <p>Signed/Refused/Declined/Resume further screening.</p> <p>Mark "1 - Signed" if the participant signed the indicated consent form(s) marked in Item 1.</p> <p>Mark "0 - Refused" if the participant decides not to sign the consent form presented to her. If the participant initially completed <i>Form 2/3</i> indicating interest but then decides she is no longer interested in continuing the screening process for all study components (HRT, DM, <u>and</u> OS), mark "0 - Refused" for the Initial Consent.</p> <p>Mark "2 - Declined further screening" for the appropriate HRT, DM, or OS if the participant initially signed the Initial, DM, HRT, or OS Consent Forms but then decides she is no longer interested in continuing in the screening process for that study component.</p> <p>Mark "3 - Resume screening" if the participant decides she wants to resume screening after previously saying she wanted to stop screening for the particular study component.</p> <p>Examples:</p> <ul style="list-style-type: none"> • If the participant decides not to schedule an SV1 or calls to cancel her scheduled SV1 because she is no longer interested in any study component, mark "0 - Refused" for the Initial Consent. • If the participant signs the Initial Consent, but calls to stop the screening process and cancel her SV2, mark "Declined further screening" for HRT and DM. If she also does not want to be in the OS, mark declined further screening for OS. • If the participant signs the HRT and/or DM Consent forms, but later calls to stop the screening process and cancel her SV3, mark "Declined further screening" for the HRT and/or DM Consent forms, and for the OS Consent Form if she also does want to be in the OS. |
| 6.1. | Consent for genetic studies | Mark the oval only if the participant says she does <u>not</u> give her consent to use her blood for genetic studies. Answer only if the participant signed the Initial Consent form. |

6.2. Reasons not signed or declined further screening

If the participant refuses to sign the consent or declines further screening, ask her why. Mark each of the reasons the participant mentions. Do not read the list. Ask, "Is there any other reason?" until the participant answers "No."

Do not mark reasons the participant does not mention. For example, do not mark "6.1.7. - Doesn't like clinical or lab procedures" even if you only think the participant doesn't like certain procedures.

Probe when necessary to get clear and specific reasons. See *Vol. 2 - Procedures, Section 2.11. - Interview Guidelines* for probing guidelines.

Reasons not signed or declined further screening, continued

- 1 - Family problems, demands, or issues: Mark this for problems that are family related such as:
 - Divorce
 - Caring for grandchildren
 - Arranging home care for an elderly parent
 - Death in the family
- 2 - Priorities other than family (work, etc.): Mark this if the participant mentions problems such as:
 - Being too busy with work
 - Changing shifts at work
 - Being on strike
 - Being on overtime
 - Becoming an officer in a club
 - Working on a political campaign
 - Volunteering in a service organization like Meals on Wheels
 - Having to take unpaid time off work
 - Having to pay for a surrogate caregiver for someone at home while at the CC
- 3 - Too far to CC.
- 4 - Transportation problems other than too far: Mark this if the participant mentions any other transportation problem such as:
 - Difficulty to arrange transportation
 - Cost of such items as fares, gas or tolls
- 5 - Parking: Mark this if the participant mentions parking problems at the CC like:
 - Cost
 - Difficulty finding a space
- 6 - Neighborhood, traffic: Mark this if the participant mentions:
 - Traffic problems connected with getting to the CC or at the CC
 - Not wanting to come to the CC because of the nature of the surrounding neighborhood (e.g., that it is dangerous or depressing)
- 7 - Doesn't like clinical or lab procedures: Mark this if the participant mentions she:
 - Doesn't like having blood drawn
 - Doesn't like ECG
 - Doesn't like gynecologic procedures
- 8 - Doesn't want dietary intervention.

Reasons not signed or declined further screening, continued

- 9 - Doesn't like taking medications every day: Mark this if the participant mentions problems connected with not wanting to take the medications every day, such as:
- Remembering them
 - Swallowing them
 - Taking too many medications already
- 10 - Doesn't want to take hormones or CaD: Mark this if the participant states specifically that she does not want to be randomized to active medication.
- 11 - Wants to take active hormones or CaD: Mark this if the participant states specifically that:
- The reason she does not want to join HRT is because she wants to take hormones
 - The reason she does not want to join CaD is because she wants to take CaD supplements
- 12 - Doesn't want to give up hormones or CaD supplements: Mark this if a participant states specifically that she does not want to discontinue hormone replacement therapy or CaD supplements she is already taking.
- 13 - Doesn't like randomization or blinding: Mark this if the participant mentions things like:
- Not wanting to be a guinea pig
 - Disliking the uncertainty of not knowing whether her medications are active or placebo
- 14 - Doesn't like forms: Mark this if the participant mentions things like:
- There are too many forms
 - Forms take too long
 - The forms are too hard to fill out
 - Doesn't like filling out the forms
 - Doesn't like the questions on the forms
- 15 - Too much time involved (non-form related): Mark this if the participant mentions things like:
- Study is too long
 - Too many visits
 - Visits are too long
- 16 - Worried about risks from intervention: Mark this if a participant mentions she is worried about:
- Possible symptoms or side effects
 - Risk of developing health problems (e.g., cancer)
 - Current health problems getting worse
- 17 - Advised not to participate by personal physician: Mark if her personal physician has advised her not to participate for any reason. Do not mark the underlying health reason upon which the physician based the advice unless the participant mentions it as a separate reason.
- 18 - Other: Mark this only for reasons that don't fit into one of the categories above. Write the reason on the blank line.
- Data Entry: Do not key-enter the specific reason.
- 99 - Refuses to give reason: Mark this if a participant refuses to give you a reason. Probe diplomatically but don't irritate the participant.

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- 6.3. Review interest Mark "No" or "Yes" based on participant's request or CC staff judgment.
 - 6.4. Review date Date for future review of interest based on participant's request or CC staff judgment.
 - 6.5. Reason Specify reason for review at a later date.
Data Entry: Do not key-enter the reason.