FORM: **7 - PARTICIPATION STATUS**

Version: 3 – February 14, 2000

Description: Completed by Clinical Center (CC) staff; 4-page form; key-entered at CC.

When used: At any contact after randomization to Clinical Trial (CT) or enrollment in Observational Study (OS) in which the participant's follow-up status, intervention status, or newsletter status changes.

Purpose: To document a change in participant's status and the reason for a change in the status.

GENERAL INSTRUCTIONS

1. WHILMA initially sets the Intervention Status for each intervention, for each participant to "9 - Not randomized." When the participant is randomized, WHILMA automatically sets the participant's follow-up status to "1 - Full follow-up," her intervention status to "1 - Resume (Receive)" for Hormone Replacement Therapy (HRT), Dietary Modification (DM) Intervention, or Calcium/Vitamin D (CaD) as appropriate, and newsletter status to "1 - Receive newsletter." When a participant is enrolled in OS, WHILMA automatically sets her follow-up status to "1 - Full follow-up" and newsletter status to "1 - Receive newsletter".

2. Use this form as needed to change the follow-up, intervention, or newsletter status of randomized or enrolled participants. See *Vol. 2 - Procedures, Section 17.4 - Changes in Participation Status* for more details of follow-up options and changing participation status.

3. Deceased and lost-to-follow-up participants: Do not complete *Form 7 – Participation Status* for a participant identified as deceased or lost-to-follow-up. Complete *Form 120 – Initial Notification of Death* (for deceased participants) or *Form 23 – Search to Locate Participant* (for lost-to-follow-up participants), as appropriate. With data entry of *Form 120* and/or *23*, WHILMA will automatically update a participant's follow-up and/or intervention status on the member status screen and will stop newsletter mailings. (See also *Vol. 2, Section 17.3.4 – Procedures for Study Wide Vital Status Ascertainment.)*

4. Complete Items 1 - 3 identifying the date, staff person completing the form, and source of information.

5. Complete Items 4 - 6 as indicated by type of change in status.
   Note: Completion of Item 4 – Change in follow-up status is required when a participant who was previously marked as lost-to-follow-up on the *Vital Status Investigation Report* (*WHIP 9752*) is located.

6. Complete Items 7-8 as the reason(s) for decreasing follow-up or stopping intervention for Items 4-5.

7. Review the form for completeness and forward to Data Entry.

8. Data Entry: Key-enter the form into the Participation Status screen (not the Encounter screen). See *Vol. 5 - Data System, Section 7.1 - Key-Entry* for specific instructions on how to key-enter this form. Initial the first page after key-entry.

9. File the key-entered form in the participant's file.

Item Instructions

1. Date of contact

Record the date on which:

- A participant tells the CC she wants to change her status to resume intervention or follow-up activities that had previously stopped.
- A CC staff member changes the participant's status when she becomes unwilling to participate in intervention or follow-up activities and retention activities have failed, or as directed by symptom management procedures.

2. Completed by

Standard 3-digit WHI employee ID of staff person completing the form.

3. Source of information

The source of the information about the change in the participant's status. Mark one only.

1 - Participant: The woman on whom the form is being completed.
2 - Family member or friend: Include household members, even if not related.
3 - Physician: This is a physician outside of WHI.
4 - CC staff member: Use this only if you are inactivating a participant and you are not in voice contact with any of the above.
8 - Other: Mark if the above categories do not apply.
5 - CCC database update: for CCC use only. Do not mark. CCs cannot data enter this code.

4. Change in follow-up status

The new follow-up status to which the participant is changing (this may be an increase or decrease in follow-up activities). See *Vol. 2 - Procedures, Section 17.4 - Changes in Participation Status* for guidelines on when to change status.

1 - Full follow-up: Mark if the participant indicates that she is willing to follow the regular contact schedule including coming to and completing all routine activities at visits, phone calls, or mail contacts as determined by the CT component to which she was randomized or by enrollment into the OS. See *Vol. 2, Section 16 - Follow-Up* for more details of regular follow-up.

2 - Proxy follow-up: Mark if the participant is unable to respond to forms (both interview- and self-administered) because she can no longer communicate orally or in writing (e.g., due to a stroke or dementia). Fill in the proxy name, relationship to participant (e.g., if proxy and participant are brother and sister, record brother), address, and phone number, as well as the reason why the participant is no longer able to complete the forms personally. Complete item 4.1 (type of follow-up) only if applicable.

Data Entry: Proxy information is not key-entered.

3 - Partial follow-up: Mark if the participant is unable or unwilling to continue one or two of: CC visits, phone contact, and mail contact. Indicate which one or two of these contact types are to be discontinued by completing item 4.1 (type of follow-up). For further details on the procedures to be carried out for women changing to partial follow-up status see *Vol. 2, Section 17.4.2 - Changing Follow-Up Status*.

4 - Custom follow-up: Mark if the woman asks to have a contact that is different from that described in #3 above. For example, coming to regular visits, but not completing specified forms or tasks, having contacts at other than specified times, and/or attending annual but not semi-annual visits. The content and timing of the contacts must fall within the parameters given in *Vol. 2, Section 16 - Follow-Up*. Specify the change from the routine contact schedule. Complete item 4.1 (type of follow-up) only if applicable.

Data Entry: Specify text is not key-entered.

5 - No follow-up: Mark if the participant wants no follow-up (no CC visits, no phone and no mail contact), and retention activities have failed. Women in this category should be contacted periodically to ask them to reconsider participation. However, if a woman is hostile towards WHI and unlikely to change and indicates that she wishes no further contact ever, select the "8 – Absolutely no contact" option instead. For further details on other forms and procedures to be carried out in women changing to no follow-up status, see *Vol. 2, Section 17.4.2 - Changing Follow-Up Status*.

8 - Absolutely no contact: Judiciously select only if the participant has become hostile to WHI and is unlikely to change and should never be contacted to ask her to reconsider participation in the WHI Study. Ideally, the participant has put her request in writing. Proxy and personal contacts should not be contacted.

6 - Deceased. Do not mark this item. (CCs cannot data enter this code.) This category will remain on the form for continuity with earlier versions of the form and to provide a link between the form and the various reports that use this data item. WHILMA automatically updates this category based on data entry of *Form 120 – Initial Notification of Death*.

7 - Lost-to-follow-up. Do not mark this item. (CCs cannot data enter this code.) Lost-to-follow-up status is based on data entry of specific forms (e.g., *Form 23 – Search to Locate Participant [Vital Status Investigation]*) and can no longer be selected at the clinic's discretion. WHILMA automatically updates this category when appropriate. This category remains on this version of the form for continuity with earlier versions of the form and link to relevant reports.

4.1. Type of follow-up (For codes 2, 3, and 4)

For participants indicating "3 – Partial follow-up" to item 4, indicate type of follow-up. Mark all that apply.

1 - No CC visits: Mark if the participant indicates that she is unwilling or unable to come to the CC for visits.

2 - No phone: Mark if the participant requests no telephone contact from CC staff.

3 - No mail: Mark if the participant requests no mail contact from the CC.

Note: Type of follow-up may also be applicable for participant's indicating "2 - Proxy follow-up" or "4 - Custom follow-up" to item 4. Only complete type of follow-up for the participants if they specifically request no CC visits, no phone, or no mail follow-up. It is unnecessary to mark "1 - No CC visits" for participants on Proxy follow-up, since proxies do not have CC visits. However, "2 - No phone" or "3 - Mail" may be indicated if requested by proxy.

5. Change in intervention status

Indicate if the participant is stopping or resuming the intervention component(s) to which she was randomized. If the participant is not changing her participation in the intervention(s), leave blank. The items apply to an active intervention (in HRT, DM intervention group [not DM comparison group], and CaD); it does not apply to OS participants. *See Vol. 2, Section 17.4.1 – Changing Intervention Status* for guidelines on changing intervention status.

For HRT and CaD participants, if you marked "5 - No follow-up" or "8 - Absolutely no contact" in item 4 above, WHILMA will automatically set the intervention for HRT and/or CaD participants (as appropriate) to "0 - Stop Intervention."

For DM Intervention participants, marking "5 - No follow-up" or "8 – Absolutely no contact" will not automatically change the DM Intervention status. However, you can update the DM Intervention status to "Stop Intervention" if that applies.

For HRT, CaD, and DM participants, if you mark "Lost-to-follow-up" on *Form 23* following a vital status investigation, WHILMA will automatically change the corresponding Intervention status to "Stop Intervention."

5.1. HRT intervention

This does not include temporarily going off or on HRT pills while you are trying to resolve symptoms (use *Form 54 – Change of Medications* if there are CC-initiated changes in HRT study pills schedules or dosages). Low adherence (not taking the appropriate number of HRT pills in the time between follow-up contacts) is not a reason to change this item.

1 - Resume intervention: Mark if the participant indicates she is willing to resume taking study pills after having previously requested to not participate. Mark this item even if the CC is having her resume at a reduced dosage regimen (complete *Form 54 – Change of Medications* to record a CC-initiated reduced regimen).

0 - Stop intervention: Mark if the participant indicates she stopped taking her HRT study pills and retention activities have failed or you removed her from the intervention due to unresolved symptoms, serious health effects, or other protocol-mandated reasons for stopping study pills.

9 - Not randomized: Initially set by WHILMA and changed when the participant is randomized to HRT.

HRT pill stop/resume date

For participant who stopped or resumed the HRT intervention (even if she is resuming at a reduced dosage regimen), fill in the date (if known) that the participant stopped or resumed taking her study pills. If exact stop/resume date is not known, fill in the contact date. This item is for CC use only and is not data-entered.

5.1.1. Protocol-mandated reason for HRT

1-Yes: Mark if the participant is stopping HRT due to a protocol-mandated reason: she refuses to have a mammogram or complete gynecologic procedures or other required safety procedures or forms at the required intervals; develops breast cancer, complex or atypical hyperplasia, endometrial cancer, deep vein thrombosis, pulmonary embolism, high triglycerides (>1000 mg/dl), malignant melanoma, or meningioma; or decides to go on HRT, SERMs, or testosterone.

0-No: Mark if the participant is stopping for reasons that are not protocol-mandated.

5.2. DM intervention

Applies to participants in the intervention group only and does not include DM comparison group participants. Exceeding a fat gram goal is not a reason to change DM Intervention using this item.

1 - Resume intervention: Mark if the woman says she will participate in DM Intervention sessions, after having previously requested to not participate in DM Intervention. Assign the participant to her previous or a new DM Intervention group (see *Vol. 5, Section 8.1.3. – Assigning and Removing Participants from a DM Intervention Group*).

0 - Stop intervention: Mark if the participant refuses all participation with DM Intervention staff (sessions via visits, phone, or mail) and retention activities have failed, or if you remove her from the intervention due to unresolved symptoms or serious adverse effects. Close the participant out of her current DM Intervention group assignment (see *Vol. 5, Section 8.1.3. - Assigning and Removing Participants from a DM Intervention Group*).

8 - DM comparison: Set by WHILMA when the participant is randomized to DM Comparison group.

9 - Not randomized: Initially set by WHILMA and changed when the participant is randomized to DM.

5.3.	CaD intervention	This does not include temporarily going off or on CaD pills while you are trying to resolve symptoms (use *Form 54 – Change of Medications* if there are CC-initiated changes in CaD study pills schedules or dosages). Low adherence (not taking the appropriate number of CaD pills in the time follow-up contacts) is not a reason to change this item. 1 - Resume intervention: Mark if the participant indicates she is willing to resume taking CaD study pills after having previously requested not to participate. Mark this item even if the CC is having her resume at a reduced dosage regimen (complete *Form 54 – Change of Medications* to record a CC-initiated reduced regimen). 0 - Stop intervention: Mark if the participant indicates she stopped taking her CaD study pills and retention activities have failed or you removed her from the intervention due to unresolved symptoms, serious health effects, or other protocol-mandated reasons for stopping study pills. 9 - Not randomized: Initially set by WHILMA and changed when the participant is randomized to CaD.
	CaD pill stop/resume date	For participant who stopped or resumed the CaD intervention (even if she is resuming at a reduced dosage regimen), fill in the date (if known) that the participant stopped or resumed taking her study pills. If exact stop/resume date is not known, fill in the contact date. This item is for CC use only and is not data entered.
5.3.1.	Protocol-mandated reason for CaD	1-Yes: Mark if the participant is stopping CaD due to a protocol-mandated reason: she refuses to complete required safety forms; develops hypercalcemia, kidney failure/dialysis, or renal calculi; is taking more than the maximum allowable IU of Vit D; or is taking calcitriol (e.g., Calcijex, Rocaltrol). 0-No: Mark if the participant is stopping for reasons that are not protocol-mandated.
6.	Change in newsletter status	Change in newsletter status. All participants (CT and OS) receive an annual newsletter, unless she requests otherwise. 0 - Refuse newsletter: Mark if the participant requests that she not receive the WHI newsletter. 1 - Receive newsletter: Mark if the participant requests that she receive the WHI newsletter after having previously requested that it be stopped.
7.	Reasons for decreasing or stopping follow-up	For participants who have reduced the extent of their follow-up (codes 2-5 or 8 on Item 4), ask "Why do you want to change your participation in the study?" After each item volunteered, ask, "Are there any other reasons?" until the participant say, "No." Probe when necessary to get clear and specific reasons. See *Vol. 2., Section 2.11 – Interviewer Guidelines* for probing guidelines. Indicate at least the "primary reason" and any others mentioned. Review the list of reason codes on pages 3-4 and select the code that best matches her reasons. If there is no reduction in follow-up activities, leave this item blank.
8.	Reasons for stopping intervention	For participants who have stopped intervention (code 0 on Items 5.1-5.3), ask "Why do you want to change your participation in the study?" After each item volunteered, ask, "Are there any other reasons?" until the participant say, "No." Probe when necessary to get clear and specific reasons. See *Vol. 2., Section 2.11 – Interviewer Guidelines* for probing guidelines.

Fill in reasons for all relevant components; e.g., if she is stopping HRT and DM intervention, indicate separately the reasons for stopping each. If she is stopping intervention in more than one study component, separately list the reasons for stopping intervention for each component, even if they are the same reasons. If she is not stopping intervention for some components, leave those blank.

Indicate at least the "primary reason" for each component she is stopping. Review the list of reason codes on pages 3-4 and select the code that best matches her reason(s).

Most reasons are applicable to all components. However, several reasons are specific to DM, HRT, and/or CaD. For these reason codes, the specific study is listed behind the reason text on the form. Do not select these reasons for components not indicated. If no particular component is specified after the reason, the reason can be selected for any component.

Note: If the reason the participant is stopping intervention is a protocol- or CC-defined reason, select the category that best represents the reason, regardless of whether or not the participant mentions it. If you mark "1-Yes" protocol-mandated reason to item 5.1.1 or 5.3.1, you will receive a data entry warning message if you do not provide a protocol-mandated reason for stopping in item 8. For example, if you indicate on item 5.1.1 that she is stopping for a protocol-mandated reason and then list "transportation" as her reason for stopping, you will get a warning message that a protocol-mandated reason was not provided.

8.1 Reasons for stopping HRT intervention

If the participant is randomized to HRT and is stopping intervention activities, indicate a primary reason for stopping. If she is stopping for a protocol-mandated reason, indicate that reason as the primary reason. List other reasons, if applicable.

If the participant is not stopping HRT intervention or is not in HRT, leave this item blank.

8.2 Reasons for stopping DM intervention

If the participant is randomized to DM and is stopping intervention activities, indicate a primary reason for stopping. List other reasons, if applicable.

If the participant is not stopping DM intervention or is not in DM, leave this item blank.

8.3 Reasons for stopping CaD intervention

If the participant is randomized to CaD and is stopping intervention activities, indicate a primary reason for stopping. If she is stopping for a protocol-mandated reason, indicate that reason as the primary reason. List other reasons, if applicable.

If the participant is not stopping CaD intervention or is not in CaD, leave this item blank.

7. Reason Codes

Two main purposes for the reason codes are to:

- classify participants who have decreased their participation status and
- provide CC staff with information they can use in attempts to reengage the participant in the study.

Some of the reason codes are identified as **protocol-mandated reasons** for removing the participant from the intervention. These are indicated on the form with a 1 for HRT and a 2 for CaD.

Other reason codes for stopping intervention **apply only to specific study components. When this is the case, the applicable component(s) (DM, HRT, CaD) is listed <u>after</u> the reason.** Do not record the reason codes for components other than those specified. WHILMA will not allow data entry of the codes for components other than those specified. If no particular component is specified after the reason, the reason can be used for any component.

Mark the reason code that best fits the reason the participant gives for decreasing her participation. For non-protocol-mandated reason codes, if unsure about which reason code(s) to select, mark the reason code(s) that most closely resembles the participant's situation (e.g., mark the reason that would most closely fit any attempts to reengage the participant).

Reason Codes – Personal/Family

10 – Demands of work. Select if the participant mentions problems such as:

- Being too busy with work
- Being too stressed by work
- Changing shifts at work
- Being on strike
- Being on overtime

66 – Death in the family or of a close friend. For example:

- Death has led to stress, depression, withdrawal
- Loss of support as a result of the death

11 – Family illness, emergency or other family demand. Examples include:

- Divorce
- Arranging home care for an elderly parent

67 – Caregiver responsibilities demanding time, effort, lifestyle change. Examples include:

- Caring for grandchildren or other children
- Caring for spouse, friend, or elderly parent

13 – Conflicting priorities other than work or family. Examples include:

- Becoming an officer in a club
- Working on a political campaign
- Too busy in general
- Too many other distractions to stick with the study
- Volunteering in a service organization like Meals on Wheels

14 – Financial problems, including unemployment. Select for any cost issues of the study, except transportation. Examples include:

- Having to take unpaid time off work
- Having to pay for a surrogate caregiver for someone at home

(Refer to reason #10 – Demands of work for being on strike or overtime at work)

15 – Lack of cooperation/support from family and/or friends. Select if participant mentions that family and/or friends are:

- Not giving her the assistance she needs to participate in the study
- Interfering with her participation

68 – Family/friends request that she withdraw. Select if a family member or friend decides that the participant must withdraw from the study.

16 – Living in a nursing home/sheltered care setting. Select if the participant resides in a congregate housing facility that might preclude CC visits or her ability to participate for other reasons.

(If she cannot participate in the DM intervention because she is not in charge of meal preparation, select reason #155.)

69 – Feels discouraged regarding participation overall. Select if the participant feels discouraged or embarrassed regarding her ability to fully participate in the study in general.

(Refer to reason #59 if she is discouraged specifically about her inability to follow intervention requirements, for example, the pill regimen or the eating pattern.

70 – Loss of interest, boredom.

71 – Feels it is not an important study. (Select #139 if participant wants to take her own calcium and feels she should stop CaD study pills.)

72 – In another study in conflict with WHI intervention.

Reason Codes – Travel

20 – Too far to CC. Select if:

- The participant has not changed her residence but has decided it is too far to come to the CC
- The participant has changed her residence and still lives in the area, but considers her new location to be too far from the CC

21 – Transportation problems (other than distance). Examples include:

- Difficulty in making arrangements
- Cost of such items such as fares, gas, or tolls
- No longer comfortable driving and cannot/does not want to make other arrangements
- Cannot get to visits/meeting on own and does not want to depend on others to provide transportation
- Difficult to take a cab or make special arrangements

22 – Traffic. For example, traffic problems connected with getting to the CC.

23 – Parking at CC. Examples include:

- Cost
- Difficulty finding space

24 – CC neighborhood/safety. Examples include:

- The nature of the surrounding neighborhood is dangerous or depressing.
- The CC moves to a new neighborhood that the participant does not like
- The participant's perception of the neighborhood changes.

73 – Moved out of area and/or refuses to be followed at another CC. Examples include:

- Has moved to an area without another CC
- Is unwilling to be transferred to another CC

Reason Codes – Visits and Procedures

30 – Doesn't like visits, calls: Select if the participant mentions problems about visits, such as:

- Visits or calls are too long
- Visits or calls are boring
- Visits or calls are unpleasant
- Contact with the CC serves no purpose
- Not liking the questions at the phone calls
- There are too many phone calls

(Select reason #150 if she does not like attending DM sessions.)

31 – Doesn't like having blood drawn. For example, it is too painful.

32 – Doesn't like ECG (DM or HRT only). For example, she doesn't like that it requires her to undress.

74 – Doesn't like mammograms (DM or HRT only). Examples include:

- refuses to have mammograms
- doesn't like to undress for mammogram
- mammogram is painful

If she is worried about health effects of having a mammogram see reason #41 – Worried about health effects of medical tests/procedures.

Note: This is a protocol-mandated reason for stopping HRT intervention.

75 – Cost of mammograms (DM or HRT only). Select if the participant mentions that she:

- is unable to get reimbursed (i.e., either by the clinic or by her insurance) for the cost of mammograms
- cannot afford mammograms
- feels they are too expensive

Note: This is a protocol-mandated reason for stopping HRT intervention.

33 – Doesn't like gynecologic procedures (HRT only). Select if participant refuses gynecologic procedures (i.e., pelvic exam, Pap smear, or endometrial aspiration) or mentions dislike or fear of any gynecologic procedures.

Specify the procedures on the form.

If she is worried about health effects of gynecologic procedures, see reason #41.

This is a protocol-mandated reason for stopping HRT intervention.

Data Entry: Key-enter the specify text.

58 – Doesn't like required safety forms and/or procedures (HRT or CaD only). Select if the participant mentions that she does not like or is not willing to:

- complete required safety forms: Form 10 for HRT participants and Form 17 for CaD participants.
- have the minimum safety procedures done as outlined in *Vol. 2 - Procedures, Section 16 – Follow-Up.*

This is a protocol-mandated reason for stopping HRT or CaD intervention.

34 – Doesn't like filling out forms (other than forms required for safety). Examples include:

- There are too many forms
- The forms are too hard to fill out
- The forms are too long
- The forms are too personal

35 – Doesn't like other procedures (other than procedures required for safety). Select if participant mentions disliking or fearing any procedures other than the ones mentioned above.

Specify which procedures.

Data Entry: Key-enter the specify text.

41 – Worried about health effects of medical tests/procedures. Select if participant is worried about or afraid of physical or mental injury (past, present, or future) from any medical procedure, like:

- Mammography
- Gynecologic exam
- Bone density measures

76 – Wants results of blood analyses.

77 – Wants results of bone mineral density measurement (BD sites only).

36 – Problem with the CC. Select if a participant mentions a problem specific to the CC (other than traffic or safety), such as:

- The examination rooms are not comfortable, private, or clean enough
- The waiting room is too small or crowded
- The rooms are too spread out or difficult to find within the building

Specify the problem briefly on the blank line.

Data Entry: Key-enter the specify text.

51 – Problem with CC staff person (other than DM Group Nutritionist). Examples include:

- An unpleasant or unsatisfactory interaction with staff member
- Dislike or discomfort with a particular staff member

(If the problem is with the group nutritionist, see reason #54.)

78 – Staff change/turnover. Examples include:

- DM group nutritionist has left and she is not comfortable with the new leader
- CP has changed and she is not comfortable with the new practitioner

Reason Codes – Symptoms

47 – Vaginal bleeding (HRT only). For example, does not want any more spotting or bleeding.

48 – Breast tenderness (HRT only). For example, pressure causes breast pain.

80 – Other breast changes (HRT only). Select if participant reports that she is stopping due to breast changes, other than tenderness, such as:

- Change in breast size, shape, or density
- Bra does not fit or is uncomfortable
- Breast fullness

81 – Bloating/Gas. Examples include:

- Burning or flatulence
- Abdominal fullness or increased size

82 – Constipation. Select if the participant reports that she is stopping due to:

- Constipation or irregularity
- Being "bound up"

83 – Other gastrointestinal problems. Select if the participant reports that she is stopping due to GI problems other than bloating, gas, or constipation. These would include: indigestion, nausea, heartburn, diarrhea, stomach or intestinal cramps.

84 – Headaches. For example:

- Migraines
- Tension headaches

85 – Vaginal changes (HRT only). Select if the participant reports that she is stopping due to vaginal changes, such as dryness, painful intercourse, or unpleasant or increased vaginal discharge. (See reason #47 for vaginal bleeding.)

86 – Hair/skin changes. Select if the participant reports that she is stopping due to hair or skin changes, such as hair loss or dry hair or skin.

87 – Hot flashes/night sweats (HRT only).

89 – Weight loss/gain. Select if the participant reports that she is stopping due to an unexpected weight loss or gain.

(If the participant is in DM intervention and reports that she is stopping because she is unhappy that she did not lose weight, use reason #154.)

90 – Low energy/too tired. For example, increased fatigue.

91 – Possible allergic reaction. Examples:

- Skin sensitivities
- Other allergic reactions (see reason #84 for headaches).

92 – Other symptoms. Select if the participant reports that she is stopping due to other symptoms not listed above.

If there are other health issues not related to a specific symptom or condition, see reason #171 – Study conflicts with other health care issues.

Specify the symptom <u>briefly</u> on the blank line.

Data Entry: Key-enter the specify text.

Reason Codes – Health Conditions

Select from the following list of health problems if the participant says that she is unable to meet the requirements of the study due to the problem. Note that some of these problems are protocol-mandated reasons for removing the participant from the intervention.

100 – Breast cancer. Select if the participant reports breast cancer, carcinoma in-situ, or ductal carcinoma.

This is a protocol-mandated reason for stopping HRT intervention.

101 – Complex or atypical hyperplasia. Select if endometrial aspiration report or participant's health care providers says she has either of these diagnoses.

This is a protocol-mandated reason for stopping HRT intervention.

102 – Endometrial cancer. Select in endometrial aspiration report or participant's health care provider says she has endometrial or uterine cancer (or cancer of the womb).

This is a protocol-mandated reason for stopping HRT intervention.

103 – Deep vein thrombosis. Select if the participant says she has DVT or blood clots in the deep veins of either leg.

This is a protocol-mandated reason for stopping HRT intervention.

104 – Pulmonary embolism. Select if the participant says she has had a PE or a blood clot in her lung.

This is a protocol-mandated reason for stopping HRT intervention.

105 – Gallbladder disease. Select if participant says she is stopping because she has had gall bladder disease (cholecystitis; cholelithiasis) or surgery (cholecystectomy).

106 – Hypercalcemia. Select if participant's health care provider reports high blood calcium.

This is a protocol-mandated reason for stopping CaD intervention.

107 – Kidney failure or kidney dialysis. Select also if the participant reports renal failure or dialysis, peritoneal dialysis, or hemo-dialysis.

This is a protocol-mandated reason for stopping CaD intervention.

108 – Renal calculi. Select also if the participant reports kidney stones.

This is a protocol-mandated reason for stopping CaD intervention.

109 – High triglycerides (>1000 mg/dl). Select also if WHI analysis or health care provider reports hypertriglyceridemia above 1000 mg/dl.

This is a protocol-mandated reason for stopping HRT intervention.

110 – Malignant melanoma. Select also if participant reports melanoma or skin melanoma (as distinct from other types of skin cancer).

This is a protocol-mandated reason for stopping HRT intervention.

111 – Meningioma. Select also if participant reports brain cancer that on probing or by physician report is a meningioma.

This is a protocol-mandated reason for stopping HRT intervention.

112 – Heart attack. Select also if participant reports she is stopping because of a myocardial infarction (MI) or "coronary".

113 – Stroke. Select also if participant reports she is stopping because of a transient ischemic attack (TIA) or cerebrovascular accident (CVA).

114 – Arthritis. Select if the participant reports she is stopping because of osteoarthritis or rheumatoid arthritis (see reason #118 for osteoporosis).

115 – Diabetes. Select also if the participant says she is stopping because she has high blood sugar.

116 – Depression. Select if participant is stopping because she is depressed, clinically depressed, sad all the time, or suicidal. See *Vol. 2, Section 2 – CC Guidelines*.

117 – Cholesterol (high or concern about levels). Select if participant says she is stopping because her cholesterol (or cholesterol type like HDL, LDL, VLDL) is too high.

118 – Osteoporosis. Select also if participant says she is stopping because of "brittle bones", osteopenia, or low bone density.

119 – Loss of vision and/or hearing.

65 – Communication problem.

120 – Cognitive/memory changes. Includes Alzheimer's disease, cognitive decline, senile dementia.

121 – Other health conditions. Select if the participant reports a health condition not listed above and therefore does not want to continue at current participation status.

Specify the health problem briefly on the blank line.

If there are other health issues not related to a specific symptom or condition, see reason #171 – Study conflicts with other health care issues.

Data Entry: Key-enter the specify text.

Reason Codes – Intervention - General

56 – Doesn't like randomized nature of intervention (CT only). Examples:

- Doesn't want to be a guinea pig
- Dislikes the uncertainty of not knowing whether her study pills are active or placebo
- Wants to buy or take active pills on her own
- "Knows" she is on active/placebo and wants to go off

57 – Expected some benefit from intervention (CT only).

Specific examples:

- Expected to have more energy or to feel better
- Unhappy that lipids are not improving

General examples:

- Expected more health information or advice
- If she expected more health care, see reason #46.

59 – Feels guilty, unhappy, or like a failure for not meeting goals of intervention (CT only). For example:

- Feel guilty about not following pill regimen
- Feels unhappy that she is unable to meet fat gram goals

See reason #69 if she feel discouraged about her participation overall.

Reason Codes – HRT/CaD Intervention

Codes in this category are for HRT and CaD participants only.

52 – Doesn't like taking pills (HRT or CaD only). Examples include:

- Doesn't remember to take them daily or, for CaD, twice daily
- Is tired of taking them on a daily or twice daily (for CaD) basis

130 – Doesn't like taste of study pills (HRT or CaD only). Examples include:

- Doesn't like texture
- Doesn't like the way it coats the tongue/mouth

131 – Unable to swallow pills (HRT or CaD only). For example, pills are too big to swallow.

132 – Takes too many pills (HRT or CaD only). Examples include:

- Takes more than just study pills
- CaD and HRT pills are too many

133 – Has made personal decision to go on active HRT (HRT only). Select reason #135 if health care provider has advised her to do this.

This is a protocol-mandated reason for stopping HRT intervention.

134 – Has made a personal decision that she does not want to be on HRT (HRT only). Select reason #136 if health care provider has advised her.

135 – Advised to go on active HRT by health care provider (HRT only). Select reason #133 if she has made a personal decision.

This is a protocol-mandated reason for stopping HRT intervention.

136 – Advised to not be on active HRT by health care provider (HRT only). Select reason #134 if she has made a personal decision.

137 – Has made a personal decision to go on SERMs (HRT only). This includes Evista, raloxifene, tamoxifen. Other SERMs may be released in the future. Select reason #138 if health care provider advised this.

This is a protocol-mandated reason for stopping HRT intervention.

138 – Advised to go on SERMs by health care provider (HRT only). This includes Evista, raloxifene, tamoxifen. Other SERMs may be released in the future. Select reason #137 if this is a personal decision.

This is a protocol-mandated reason for stopping HRT intervention.

139 – Wants to take her own calcium supplements (CaD only). Select also if health care provider advises her to take own calcium or she is concerned about getting too much calcium.

140 – Feels diet is already sufficient in calcium/Vitamin D (CaD only). (Select reason #139 if she is taking calcium supplements or #141 if she is taking Vitamin D supplements.)

141 – Taking more than the maximum allowable IU of Vitamin D (CaD only). The maximum allowable IU of Vitamin D is 600 IU.

This is a protocol-mandated reason for stopping CaD intervention.

142 – Taking calcitriol. Brand names are Calcijex or Rocaltrol (CaD only). Select if participant is currently taking calcitriol.

This is a protocol-mandated reason for stopping CaD intervention.

143 – Taking testosterone medications (HRT only).

This is a protocol-mandated reason for stopping HRT intervention.

Reason Codes – DM Intervention

Codes in this category are for DM intervention participants only.

54 – Problem with DM Group Nutritionist or group members (DM intervention only).

150 – Doesn't like attending DM intervention classes (DM intervention only).

151 – Doesn't like self-monitoring (DM intervention only).

- Doesn't like keeping food records
- Doesn't like fat gram calculating

152 – Doesn't like budgeting fat grams (DM intervention only).

153 – Has concerns regarding long-term risks/benefits of low fat diet (DM intervention only).

154 – Unhappy that not losing weight (DM intervention only).

155 – Not in control of meal preparation (DM intervention only). Select if the participant is not in control of her own meal preparation and is unable to follow the dietary pattern. For example:

- She lives with a caregiver who prepares her meal
- Roommate/spouse shares meal preparation responsibilities and is not willing to accommodate intervention
- She receives meals from "Meals on Wheels"
- She is in a nursing home or some type of assisted living situation that provides meals

156 – Too difficult to meet or maintain dietary goals (DM intervention only). Select if participant mentions that she finds it too difficult to meet the dietary goals of the intervention in general (see reasons #157-159 for reasons related to the specific dietary goals), for example:

- Too difficult to maintain on a daily basis
- Too difficult to maintain on special/social occasions
- Friends/family offer high fat foods
- Too difficult to maintain due to frequent travel

157 – Doesn't like eating low fat diet (DM intervention only). For example:

- It doesn't taste good
- She doesn't like limiting her choices
- Doesn't like to follow it daily
- Doesn't like it on special occasions
- Doesn't like it when eating out or on vacation
- Too difficult to obtain the foods

158 – Doesn't like eating 5 vegetables/fruits per day (DM intervention only). Select if participant mentions that it's too difficult or that she doesn't like eating 5 vegetables/fruits per day.

159 – Doesn't like eating 6 grains per day (DM intervention only). Select if participant mentions that it's too difficult or that she doesn't like eating 6 grains per day.

160 – Feels fat gram goal is unrealistic (DM intervention only). Select if the participant mentions that the fat gram goal is unrealistic and impossible to meet or if she doesn't accept the goal.

161 – Eating pattern conflicts with personal health beliefs (DM intervention only).

Reason Codes – Other Health Issues

42 – Worried about costs if adverse effects appear. Mark if participant is worried or afraid of any costs (past, present, or future) that could be incurred due to adverse effects of WHI.

46 – Expected more health care. Mark if a participant mentions having expected more health services from the CC, like blood work or x-rays.

170 – Advised not to participate by health care provider for other reason. Mark if the participant mentions this for reasons other than a health care provider's recommendation to go on/off HRT or on a SERM.

Always clarify this reason. Repeat the participant's statement as a question: "You want to stop participating because your doctor told you not to?"

Do not mark the underlying health reason upon which the health care provider based the advice unless the participant mentions it as a separate reason.

171 – Study conflicts with other health care issues. Mark if participant reports that study activities conflict with her health regimen, such as the need to follow a special diet.

If the health care issue is related to a specific condition or symptom not listed above, see also reasons #92 – Other symptoms and #121 – Other health conditions.

Data Entry: Key-enter the specify text.

Reason Codes - Other

88 – Other reason not listed above. Select only for reasons that don't fit into one of the categories above. Write the reason on the blank line.

Data Entry: Key-enter the specify text.

99 – Refuses to give a reason. Select if a participant refuses to give you a reason for changing her participation status.

Probe diplomatically, but don't irritate the participant.