OMB # 0925-0414 Exp: 4/06

COMMENTS:	**- Affix label here-** Clinical Center/ID: __ __ __ __ - ___ ___ ___ - ___ First Name _____M.I._____ Last Name _____

1. Date of Contact: ___-___-___ (M/D/Y)

2. Completed By: ___

3. Source of Information:
   - ☐ 1 Participant
   - ☐ 2 Family Member or Friend
   - ☐ 3 Physician
   - ☐ 4 CC Staff
   - ☐ 8 Other
   - 5 CCC Database Update

4. Change in Follow-Up Status. If participant is changing her follow-up status at this contact, mark the new follow-up status. (*Mark only one. If you mark code 2-5 or 8, also complete Question 7.*)

☐ 1 Full follow-up

☐ 2 Proxy follow-up (*Complete 4.1* ***only*** *if applicable.*)

Proxy Name: _____

Relationship: _____

Address: _____

_____

Phone Number(s):_____

Reason:_____

☐ 3 Partial follow-up (*Complete 4.1.*)
(Does not participate in one or two contacts listed under 4.1)

☐ 4 Custom follow-up (*Complete 4.1* ***only*** *if applicable)*
(Contacts customized to meet specific participant needs) (Specify:_____)

4.1. Type of follow-up (for codes 2, 3, and 4). (*Mark all that apply.*):
- ☐ 1 No CC visits
- ☐ 2 No phone
- ☐ 3 No mail

☐ 5 No follow-up *(OK to have periodic contact with participant)*

☐ 8 **Absolutely** no contact *(No contact with participant)*

6 Deceased → Complete *Form 120 – Initial Notification of Death* (do not complete *Form 7*).

7 Lost-to-follow-up → Complete *Form 23 – Search to Locate Participant (Vital Status Investigation)*. (do not complete *Form 7*.)

5. Change in Intervention Status: If the participant is stopping or resuming intervention(s), mark only those that the participant is changing at this contact. (*Mark all that apply. If you mark "0 - Stop," also complete Question 8.*)

	Resume Intervention	Stop Intervention	Pill Stop or Resume Date	Protocol Mandated Reason?
5.1. HRT Intervention	☐ 1	☐ 0 →	__ __ - __ __ - __ __ (M D Y) →	5.1.1. ☐ 1 Yes ☐ 0 No
5.2. DM Intervention	☐ 1	☐ 0		
5.3. CaD Intervention	☐ 1	☐ 0 →	__ __ - __ __ - __ __ (M D Y) →	5.3.1. ☐ 1 Yes ☐ 0 No

K _____ V_____

6. Change in Newsletter Status.

Refuse Newsletter	Receive Newsletter
☐ 0	☐ 1

7. Reasons for decreasing or stopping follow-up. Ask the participant, "Why do you want to change your participation in the study?" After each reason is given, prompt with "Are there any other reasons?" until the participant says "No." Indicate the primary and other reasons (as appropriate) that the participant gives for decreasing or stopping follow-up (Q4). Refer to pages 3-4 for a list of reason codes. Do not read the list to the participant. If she is not decreasing or stopping her follow-up activities, leave this item blank.

   Reasons for decreasing or stopping follow-up:

   Primary reason: ⌊__⌋

   Other reasons (if provided): ⌊__⌋ ⌊__⌋ ⌊__⌋ ⌊__⌋

8. Reasons for stopping intervention. Ask the participant, "Why do you want to change your participation in the study?" After each reason is given, prompt with "Are there any other reasons?" until the participant says "No." Indicate the primary and other reasons (as appropriate) that the participant gives for stopping intervention in the study component(s) indicated in Q5. If she is stopping intervention in more than one component, provide the reasons for each component. If she is not stopping intervention in the component, leave the item blank.

   Refer to pages 3-4 for a list of reason codes. Do not read the list to the participant. The reasons for stopping intervention that apply to specific components have the applicable study (HRT, DM, CaD) listed after the reason. If the reason provided is a protocol- or CC-defined reason, select the code that best represents that reason, regardless of whether or not the participant mentions it.

   8.1 Reasons for stopping HRT intervention:

   Primary reason: ⌊__⌋

   Other reasons (if provided): ⌊__⌋ ⌊__⌋ ⌊__⌋ ⌊__⌋

   8.2 Reasons for stopping DM intervention:

   Primary reason: ⌊__⌋

   Other reasons (if provided): ⌊__⌋ ⌊__⌋ ⌊__⌋ ⌊__⌋

   8.3 Reasons for stopping CaD intervention:

   Primary reason: ⌊__⌋

   Other reasons (if provided): ⌊__⌋ ⌊__⌋ ⌊__⌋ ⌊__⌋

Reason Codes: Select and indicate on Items 7-8 the appropriate codes for all the reasons the participant gives for decreasing or stopping follow-up or intervention activities as indicated in Items 4-5. The reasons for stopping intervention that apply to specific components have the applicable study (HRT, DM, CaD) listed after the reason. Protocol-mandated reasons for stopping intervention are indicated with [1] for HRT and [2] for CaD.

Personal/Family

10 Demands of work

66 Death in the family or of a close friend

11 Family illness, emergency or other family demands

67 Caregiver responsibilities demanding time, effort, lifestyle changes

13 Conflicting priorities other than work or family

14 Financial problems, including unemployment

15 Lack of cooperation/support from family and/or friends

68 Family/friends request that she withdraw

16 Living in a nursing home or sheltered care setting

69 Feels discouraged regarding participation overall

70 Loss of interest, boredom

71 Feels it is not an important study

72 In another study in conflict with WHI intervention

Travel

20 Too far to CC

21 Transportation problems (other than distance)

22 Traffic

23 Parking at CC

24 CC neighborhood/safety

73 Moved out of area and/or refuses to be followed at another CC

Visits and Procedures

30 Doesn't like visits, calls

31 Doesn't like having blood drawn

32 Doesn't like ECG (*DM, HRT*)

74 Doesn't like mammograms (*DM, HRT*)[1]

75 Cost of mammograms (*DM, HRT*)[1]

33 Doesn't like gynecologic procedures (*HRT*)[1] (Specify _____)

58 Doesn't like required safety forms and/or procedures *(HRT, CaD)*[1, 2]

34 Doesn't like filling out forms (other than those required for safety)

35 Doesn't like other procedures (other than those required for safety) (Specify _____)

41 Worried about health effects of medical tests/procedures

76 Wants results of blood analyses

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

36 Problem with the CC (Specify_____)

51 Problem with CC staff person (other than DM Group Nutritionist)

78 Staff change/turnover

Symptoms

47 Vaginal bleeding (*HRT*)

48 Breast tenderness (*HRT*)

80 Other breast changes (*HRT*)

81 Bloating/Gas

82 Constipation

83 Other gastrointestinal problems

84 Headaches

85 Vaginal changes (e.g., dryness) (*HRT*)

86 Hair/skin changes

87 Hot flashes/night sweats (*HRT*)

89 Weight loss/gain

90 Low energy/too tired

91 Possible allergic reaction

92 Other symptoms not listed above (Specify_____)

Health Conditions

100 Breast cancer[1]

101 Complex or atypical hyperplasia[1]

102 Endometrial cancer[1]

103 Deep vein thrombosis[1]

104 Pulmonary embolism[1]

105 Gallbladder disease

106 Hypercalcemia[2]

107 Kidney failure/dialysis[2]

108 Renal calculi[2]

109 High triglycerides (> 1000 mg/dl)[1]

110 Malignant melanoma[1]

111 Meningioma[1]

112 Heart attack

113 Stroke

114 Arthritis

115 Diabetes

116 Depression

117 Cholesterol (high or concern about levels)

118 Osteoporosis

119 Loss of vision and/or hearing

65 Communication problem

120 Cognitive/memory changes

121 Other health conditions not listed above (Specify _____)

Intervention – General

56 Doesn't like randomized nature of intervention *(CT)*

57 Expected some benefit from intervention *(CT)*

59 Feels guilty, unhappy, or like a failure for not meeting study goals of intervention *(CT)*

HRT/CaD Intervention

52 Doesn't like taking pills *(HRT, CaD)*

130 Doesn't like taste of pills *(HRT, CaD)*

131 Unable to swallow pills *(HRT, CaD)*

132 Takes too many pills *(HRT, CaD)*

133 Has made a personal decision to go on active HRT *(HRT)* [1]

134 Has made a personal decision that she does not want to be on HRT *(HRT)*

135 Advised to go on active HRT by health care provider *(HRT)* [1]

136 Advised to not be on active HRT by health care provider (*HRT*)

137 Has made a personal decision to go on SERM (e.g., Evista/raloxifene, tamoxifen) (*HRT*) [1]

138 Advised to go on SERM (e.g., Evista/raloxifene, tamoxifen) by health care provider (*HRT*) [1]

139 Wants to take her own calcium (*CaD*)

140 Feels diet is already sufficient in calcium/Vitamin D (*CaD*)

141 Taking more than the maximum allowable IU of Vit D (*CaD*)[2]

142 Taking Calcitriol (*CaD*)[2]

143 Taking testosterone medications (*HRT*)[1]

DM Intervention

54 Problem with DM Group Nutritionist or group members *(DM)*

150 Doesn't like attending DM intervention classes (*DM*)

151 Doesn't like self-monitoring *(DM)*

152 Doesn't like budgeting fat grams *(DM)*

153 Has concerns regarding long-term risks/benefits of low fat diet *(DM)*

154 Unhappy that not losing weight *(DM)*

155 Not in control of meal preparation *(DM)*

156 Too difficult to meet or maintain dietary goals *(DM)*

157 Doesn't like eating low fat diet *(DM)*

158 Doesn't like eating 5 vegetables/fruits per day *(DM)*

159 Doesn't like eating 6 grains per day *(DM)*

160 Feels fat gram goal is unrealistic *(DM)*

161 Eating pattern conflicts with personal health beliefs *(DM)*

Other Health Issues

42 Worried about costs if adverse effects occur

46 Expected more health care

170 Advised not to participate by health care provider for other reason

171 Study conflicts with other health issues (Specify _____)

Other

88 Other reason not listed above (Specify_____)

99 Refuses to give a reason

1 Protocol-mandated reason to stop HRT.
2 Protocol-mandated reason to stop CaD.