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<b>FORM:</b>	<b>2 - ELIGIBILITY SCREEN</b>
<b>Version:</b>	3 - July 8, 1994
<b>Description:</b>	Self-administered; 12-page form; data entered and scanned at Clinical Center (CC).
<b>When used:</b>	Administered to potential participants before Screening Visit 1 (SV1).
<b>Purpose:</b>	To determine eligibility for Clinical Trial (CT) or Observational Study (OS).

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## GENERAL INSTRUCTIONS

### A. Form Description

1. This form is printed in both English (*Form 2*) and Spanish (*Form 2S*) versions. The English version is in a mark-sense format and the Spanish version is in a key-enter format. Items 1 - 6 (participant name, address, etc.) on both formats are key-entered and not scanned.
2. Shaded Office Use boxes on the form signify ineligibility or further action to take.
  - A shaded Office Use box with "\_\_ FE" (Future Eligibility) checked indicates the woman may be eligible at a future date. (See Items 26.1., 27.1., and 28.2., 30.)
  - A shaded Office Use box with "\_\_ CP" checked requires follow-up review for eligibility by the Clinic Practitioner (CP) (see Items 29 and 32) on *Form 6 - Final Eligibility Review*.

See the eligibility summary in *Table 1 - Form 2/3 Phone Screen Eligibility Guidelines* as a guide for determining eligibility.

3. Eligibility for diabetes and menopause is based on an algorithm and therefore these are not shaded. See *Figure 1 - HRT Menopause Algorithm* for the Hormone Replacement Therapy (HRT) menopause eligibility and *Figure 2 - DM/OS Menopause Algorithm* for the Dietary Modification (DM)/OS menopause eligibility. The algorithm for diabetes is programmed in WHILMA.

### B. Administer and Process the Form

1. After initial interest is established and before SV1, mail or give the appropriate version of the form (English or Spanish) to the participant.
2. If you have a participant barcode label, affix it to the form in the indicated space. If you do not have a participant barcode label, print and affix as described in Step 6 below.
3. Complete Office Use Only Items 1 - 5, identifying the date, staff person completing the form, contact type, visit type and visit number, and type of form administration.
4. Review the form for completeness and consistency. Fill in appropriate ovals or boxes if the woman has not filled them in. If the number has a "0," you do not fill in an oval or box for the "0." For example, for WHI employee ID code of "105" in item 2, "Reviewed by," fill in the "100" oval or box and the "5" oval or box; there is no oval or box representing the middle "0."

For the key-entered format, mark the appropriate oval or box.

5. Review the form completely for eligibility issues using *Table 1*. Follow the HRT and DM/OS menopause algorithms in *Figures 1* and *2* to determine if a woman is eligible for DM, HRT, or OS based on her menopausal status. Discuss unclear responses with the participant. Refer appropriate items to the CP to evaluate the participant's health condition and determine eligibility.

6. Data Entry: Review the form for completeness and consistency. Return to the interviewer with any problems noted. Key-enter/scan the form when problems have been resolved.

Key-enter Items 1 - 6 into the Member Entry Screen. Generate a participant ID number and print out the participant barcode labels if not already done. Attach a barcode label to the front page of the form in the space indicated. Place the label vertically between the lines indicated. Orient the label so the top of the label (with the barcode) is to the left and the participant's name is to the right (and doesn't cover timing marks).

Burst and scan the English version of the form. Key-enter the Spanish version, initialing the first page of the questionnaire after key-entry. Do not key-enter the "Other (Specify)" items.

7. File scanned or key-entered form in the participant's file.

### C. Reviewing and Updating Form 2 - Eligibility Screen

This review procedure is to check that a woman has not become ineligible during the screening process.

#### 1. During Screening

If a participant reports any change in the information she previously provided on *Form 2 - Eligibility Screen* regarding her health or circumstances that now make her ineligible (e.g., subsequent heart attack, cancer diagnosis, intention to move away from the area, had a hysterectomy), update her *Form 2* responses as follows:

- Write the new answer in the margin of the original form in colored ink. Do not cover the timing tracks on the mark-sense form or write too close to the ovals. It is not necessary to erase the old, marked answer on the scannable form and fill in the oval or box for the new answer because you will not re-scan the form.
- Initial and date the new answer in the margin.
- Indicate that it is an update and not a correction by writing "(update)" next to the new response.
- Key-enter the updated *Form 2* response(s) on the original encounter in the database (see *Vol. 5 - Data System, Section 7 - Data Entry*).
- Run an eligibility determination.

#### 2. At SV3

Review the key eligibility criteria on *Form 2* with the woman to verify that she has not experienced any changes in her health or circumstances that would make her ineligible since she completed *Form 2*.

- Use the "Script to Review and Update *Form 2*" in item D below.
- If the woman answers "Yes" to any of the questions from the script, correct the original *Form 2* and key-enter the corrections as described in Step 1 above.
- Run an eligibility determination to check if the woman is still eligible before proceeding with SV3 activities.

#### D. Script to Review and Update Form 2

**"I need to check some of the information that you have given us earlier. The purpose of these questions is to make sure that your health has not changed since you filled out the Eligibility Screen Questionnaire."**

*Note:* The following script applies to HRT and DM. For OS, refer to *Table 1 - Form 2/3 Phone Screen Eligibility Guidelines* for *Form 2* items that must be reviewed before enrollment.

1. **"Have you seen a doctor or other health care professional since you filled out that questionnaire?"**

If "Yes" ask Questions 2 - 7.

If "No" ask Questions 4 - 7.

2. **"Since you filled out that questionnaire, has your doctor or other health professional told you that you have any of the following health problems?"** (Read list.)

Ver. 3 Qx.

<b>Cancer</b>	<b>10, 11, 12, 13, 14</b>
<b>Sugar diabetes</b>	<b>23</b>
<b>A blood clot in your leg</b>	<b>24</b>
<b>A blood clot in your lung</b>	<b>25</b>
<b>Sickle-cell anemia</b>	<b>29.1.</b>
<b>Liver disease or yellow jaundice</b>	<b>29.3.</b>
<b>A bleeding problem</b>	<b>29.4.</b>
<b>Any other long-term or chronic illness</b>	<b>32</b>

3. **"Have you had any of the following?"** (Read list.)

<b>A fracture or broken bone</b>	<b>17.3.</b>
<b>A hysterectomy</b>	<b>18</b>
<b>A stroke</b>	<b>26</b>
<b>A small stroke called a TIA or transient ischemic attack</b>	<b>27</b>
<b>A heart attack</b>	<b>28</b>
<b>Heart failure</b>	<b>29.2.</b>
<b>Kidney dialysis</b>	<b>31</b>

4. **"Have you had any menstrual bleeding or spotting?"** **19**

5. **"Have you . . . "**

<b>Joined another research study?</b>	<b>9</b>
<b>Started taking female hormones?</b>	<b>17.1.</b>
<b>Started following any type of special diet?</b>	<b>21, 22</b>
<b>Lost more than 15 pounds without trying?</b>	<b>30</b>

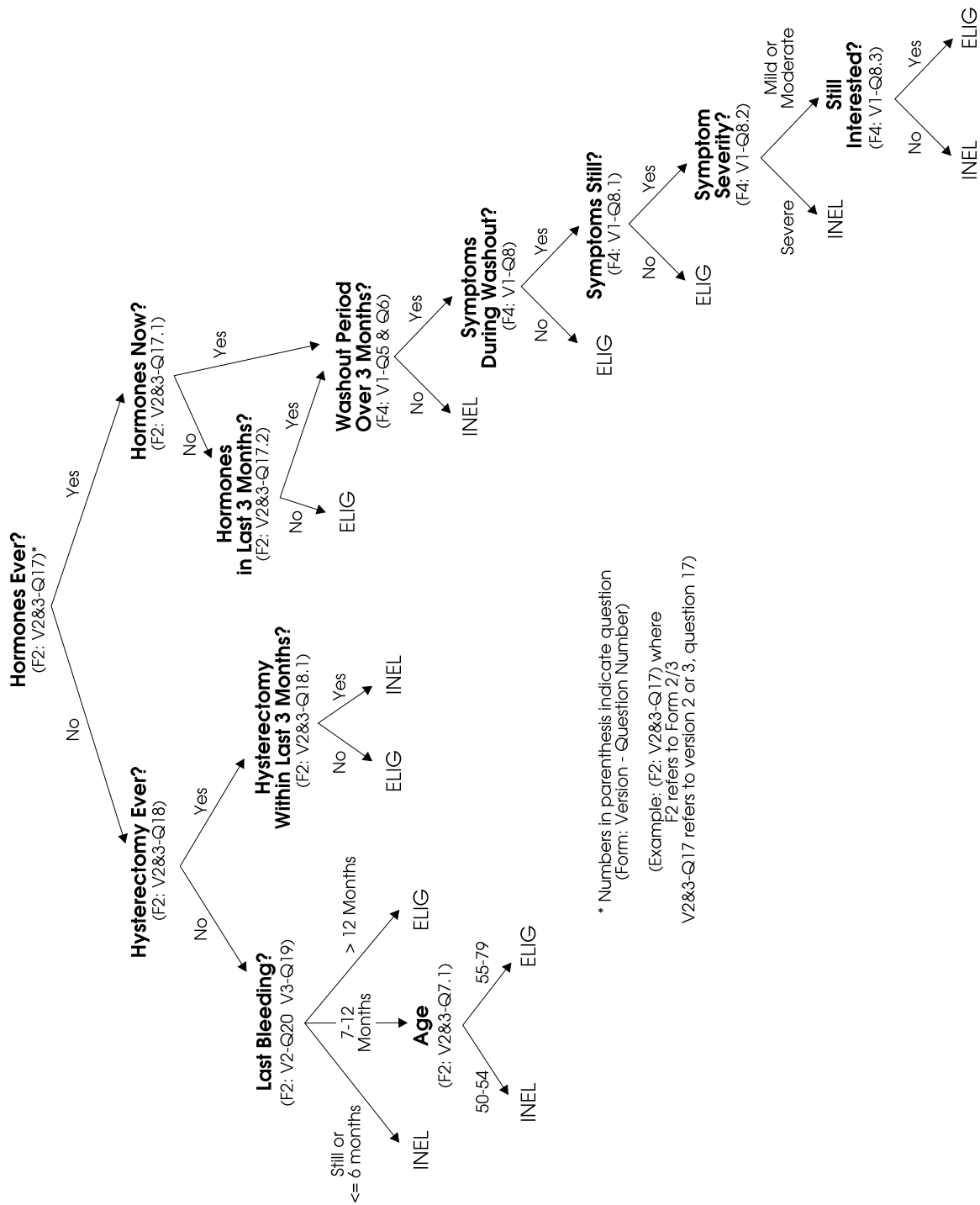
6. **"Do you plan to move away from the area in the next three years?"** **8**

7. **"And, finally, has there been a change in your mailing address, home phone number, or work phone number?"**

**"Those are all of my questions. Thank you very much for letting me go over this information with you again."**

(If participant answered "Yes" to any item, update the information on *Form 2* as described in Step C.2., "Reviewing and Updating *Form 2* at SV3" above, and run an eligibility determination.)

**Figure 1**  
**HRT Menopause Algorithm**

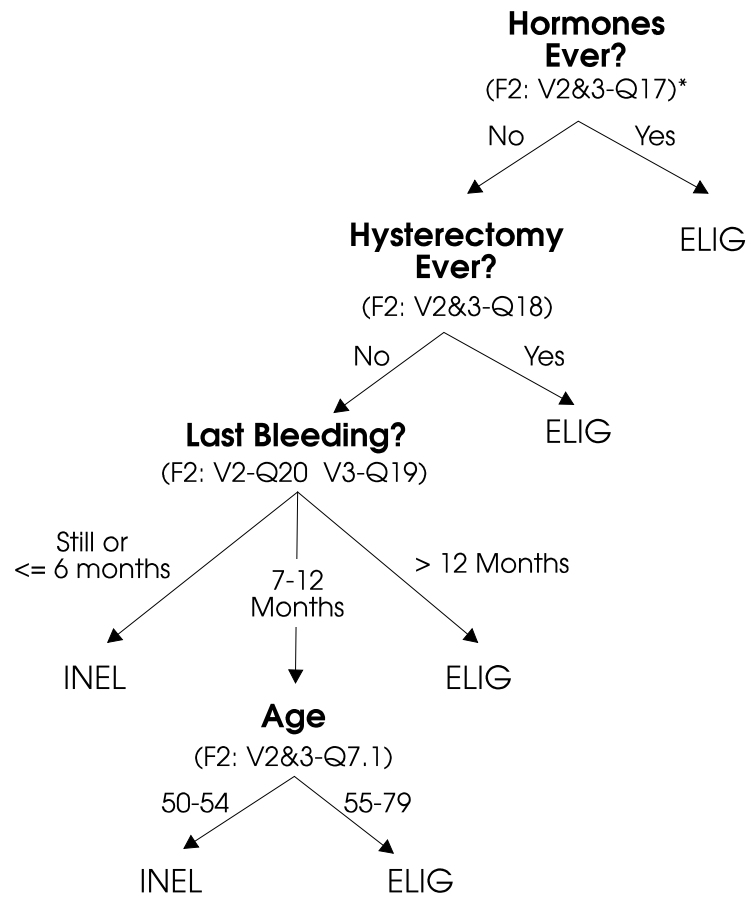


\* Numbers in parenthesis indicate question (Form: Version - Question Number)

(Example: (F2: V2&3-Q17) where F2 refers to Form 2/3

V2&3-Q17 refers to version 2 or 3, question 17)

**Figure 2**  
**DM/OS Menopause Algorithm**



\* Numbers in parenthesis indicate question (Form: Version - Question Number)

(Example: (F2: V2&3-Q17) where F2 refers to Form 2/3 V2&3-Q17 refers to version 2 or 3, question 17)

**Table 1**  
**Form 2/3 (Ver. 3) - Phone Screen Eligibility Guidelines**

ITEM	CRITERION	ANSWER	CT	HRT	DM	OS
7.2.	Age 47 to 49	Yes	Temp			Temp
7.4.	Age less than 47, 80 or greater	Yes	INEL			INEL
8.0.	Living in area for the next three years	No	INEL*			INEL*
9.2.	Other interventional research studies	Yes	INEL*			INEL*
10.0.	Breast cancer	Yes (anytime)	INEL			
11.0.	Colon/rectal cancer	Yes (anytime)			INEL	
11.1.	Colon/rectal cancer in last ten years	Yes (< 10 years)		Temp		
12.0.	Endometrial cancer	Yes (anytime)		INEL		
12.1.	Endometrial cancer in last ten years	Yes (< 10 years)			Temp	
13.1.	Melanoma	Yes (anytime)		INEL		
13.2.	Melanoma in last ten years	Yes (< 10 years)			Temp	
14.0.	Other cancers in last ten years	Yes (< 10 years)	Temp			
17.1./17.2.	Last HRT use	Yes (< 3 months ago)		Temp		
17.4.	Hormones to treat osteoporosis-related fractures	Yes		INEL		
18.1.	Hysterectomy in last three months	Yes		Temp		
20.0.	Ten or more meals each week prepared away from home	Yes			INEL*	
21.0.	Following a special diet for malabsorption	Yes			INEL*	
22.0.	Low-fiber, low-residue diet	Yes			INEL*	
23.1./23.4.	Diabetes at age less than 21 and current insulin use	Yes			INEL	
23.2.	Hospitalized for a diabetic coma	Yes			INEL	
24.1.	Deep vein thrombosis (DVT) in last six months	Yes		Temp		
24.2.	DVT non-traumatic	No		INEL		
25.1.	Pulmonary embolus (PE) in last six months	Yes		Temp		
25.2.	PE non-traumatic	No		INEL		
26.1.	Stroke in last six months	Yes	Temp			
27.1.	Transient ischemic attack (TIA) in last six months	Yes	Temp			
28.2.	Heart attack in last six months	Yes	Temp			
29.1.	Sickle cell anemia	Yes	INEL			INEL
30.0.	Lost 15 or more pounds in last six months	Yes	Temp			
31.0.	Kidney or renal failure	Yes	INEL			INEL
33.0.	Emotional problems, etc.	Yes	INEL			INEL
34.0.	Able to come to CC	No	INEL*	INEL*		INEL*
35.0.	Interest in DM	No			INEL*	
36.0.	Interest in HRT	No		INEL*		
36.1.	Consider going off HRT	No		INEL*		

**INEL = Ineligible and cannot rescreen at later date.**

**INEL\* = Ineligible and can rescreen at a later time.**

**Temp = May be eligible later after appropriate time has passed.**

**Office Use Only Instructions**

- |    |                     |  |
|----|---------------------|--|
| 1. | Date received       | The date the form was received at the CC.  |
| 2. | Completed by        | Standard 3-digit WHI employee ID.  |
| 3. | Contact type        | Mark the appropriate oval or box. (See common data items.)   |
| 4. | Visit type          | Mark "Screening" and "0" (SV0) if completed before SV1. Mark "Screening" and "1" only if completed at SV1. |
| 5. | Form administration | Mark appropriate oval or box.  |

**Item Instructions**

- |      |                            |  |
|------|----------------------------|--|
| 1.   | Name                       | The woman's name. This will be the name used on her CC records. Include title (optional), first name, middle initial, and last name.<br><br>Data Entry: Key-enter as upper/lower case.   |
| 2.   | Current mailing address    | The woman's current mailing address, not residence address. This is the address where questionnaires and informational materials will be sent. Make sure an apartment number or room number, and zip code (nine digits, if possible) are included.<br><br>Data Entry: Key-enter as upper/lower case.   |
| 3.   | Home phone number          | The woman's home phone number (if applicable). Include the area code.  |
| 4.   | Have work phone            | No/Yes.<br><br>Data Entry: Do not key-enter.   |
| 4.1  | May we call you            | No/Yes.  |
| 4.2. | Work phone number          | The participant's work phone number (if applicable). Include the area code.  |
| 5.   | Other phone number         | Another phone number where the participant can be reached. Include area code.  |
|      | Whose phone number         | The name of the person whose phone number is given in Question 5 - Other phone number.   |
| 6.   | Best time(s) to call       | The best time(s) to contact the woman by phone. Mark if these times are at home, at work or other. If phone numbers are given, at least one time should be written in. Indicate the best day of the week (e.g., Monday), and the best time of day (e.g., 1-2 PM). "Anytime" is an acceptable response. |
| 7.   | Date of birth              | The woman's date of birth.   |
| 7.1. | Age                        | The woman's current age.   |
|      | Office use                 |  |
| 7.2. | 47 - 49                    | Mark "__ 47 - 49" if the answer to Question 7.1. indicates this choice. The woman may be age-eligible at a later date.   |
| 7.3. | 50 - 79                    | Mark "__ 50 - 79" if the answer to Question 7.1. indicates this choice. The woman is age-eligible.   |
| 7.4. | <47 or 80+                 | Mark "__ < 47, 80+" if the answer to Question 7.1. indicates this choice. The woman is not age-eligible.   |
| 8.   | Living in area three years | No/Yes. Women planning to move beyond commuting distance to the CC are not eligible for any component.   |

9. Participation in other research studies No/Yes.
- 9.1. Name of study Write in the name of the study.  
Data Entry: Name of study is not key-entered in Spanish version of form.
- 9.2. Office use, excluded study No/Yes.  
0 - No. The study is not a randomized intervention study.  
1 - Yes. The study is a randomized intervention study.  
Each CC should prepare a local list of excluding studies to streamline decision making. Consult first the CC's list of excluded studies to determine if the research study that the woman is participating in is excluded. Active participants in other randomized intervention trials are also not eligible for WHI.
10. Breast cancer ever No/Yes. A woman with a history of breast cancer is not eligible for CT. This includes invasive and in situ breast cancer.
11. Colon, rectal, bowel, intestinal cancer ever No/Yes. A woman with any history of colon, rectum, bowel or intestinal cancer is not eligible for DM.
- 11.1. Colon, rectal, bowel, or intestinal cancer in the last ten years No/Yes. A woman with colon, rectum, bowel, or intestinal cancer in the last ten years may be eligible for HRT at a later date. If the period since her diagnosis will exceed ten years before recruitment ends, the woman may be eligible at a later date.
12. Endometrial cancer No/Yes. A woman with a history of endometrial cancer is not eligible for HRT.
- 12.1. Endometrial cancer in the last ten years No/Yes. A woman with endometrial cancer in the last ten years may be eligible for DM at a later date, if the period since her diagnosis will exceed ten years.
13. Skin cancer ever No/Yes. A woman with a history of skin cancer (not melanoma) is eligible for all components.
- 13.1. Melanoma No/Yes. A woman with a history of melanoma is not eligible for HRT.
- 13.2. Melanoma in the last ten years No/Yes. A woman who has had melanoma in the last ten years may be eligible for DM at a later date. If the period since her diagnosis will exceed ten years before recruitment ends, the woman may be eligible at a later date.
14. Other cancer in the past ten years No/Yes. A woman with any other cancer in the past ten years may be eligible for all components at a later date. If the period since her diagnosis will exceed ten years before recruitment ends, the woman may be eligible at a later date.  
The intent is to capture only invasive cancers and to accept the woman's self-report of cancer. The participant's report may not be accurate and may capture non-invasive cancers. This strategy is conservative. Clinical Centers have the option to more accurately determine if the cancer was truly invasive or in situ, but this is not required.  
For example, a history of cervical carcinoma in situ (a non-invasive cancer) does not make a participant ineligible. If the woman marked "Yes" to other cancer and you find that it was an in situ cancer, you can correct the woman's answer from "Yes" to "No." If carcinoma in situ is picked up on the baseline Pap smear, this would make the participant temporarily ineligible until cleared by her primary provider (see *Vol. 2 - Procedures, Section 5.1.1.3. - Exclusions Based on Baseline Pap Smear*).  
Although thyroid cancer is often curable and may be called "localized," it is classified as an invasive cancer. A woman with a history of thyroidectomy for thyroid cancer, therefore, would be ineligible for all clinical trial components.



15. Ethnicity Participant's race or ethnic group. If the woman is more than one group, mark the one she identifies with most. If "8 - Other" is marked, write in the ethnic group.  
Data Entry: do not key-enter "Other (Specify)" text.
16. Heard about WHI How the participant heard about the study. Mark only one. If she heard in more than one way, mark the one that made her decide to contact WHI. If "8 - Other" is marked, write in the medium.  
Data Entry: do not key-enter "Other (Specify)" text.
- 16.1. Office use, referral source code The referral source code (RSC) for the source given in Question 16. See *Vol. 2 - Procedures, Section 3.2.1. - Targeted Mass Mailings* for a description of referral source codes.
17. Hormones ever No/Yes. This question refers to the use of female hormones such as estrogen (Premarin) or progesterone (Provera), skin patches, implants, creams, suppositories, shots. This includes estrogen creams, regardless of site of use (e.g., even if used on the skin). In the case of birth control pills, answer "Yes" only if the pills were used after the age of 50.
- 17.1. Hormones now No/Yes. A woman currently taking (using) hormones must complete a washout to continue screening for HRT.
- 17.2. Hormones in the last three months No/Yes. A woman who has taken hormones in the last three months must complete a washout to continue screening for HRT.
- 17.3. Osteoporosis-related fracture or broken bone No/Yes.
- 17.4. Hormones to treat osteoporosis No/Yes. Mark "Yes" only if the woman's health care provider specifically said hormones were to treat a previous osteoporosis-related fracture (not to prevent possible future fractures). A woman taking hormones to treat a fracture or broken bone is not eligible for HRT.
18. Hysterectomy ever No/Yes.
- 18.1. Hysterectomy in last three months No/Yes. A woman who has had a hysterectomy in the last three months is not eligible for HRT but may be eligible at a later date.
- 18.2. Age at hysterectomy The woman's age when she had the hysterectomy.
19. Any bleeding Any menstrual bleeding or spotting. This question includes hormone induced bleeding.
20. Meals away from home Number of meals the participant eats away from home.  
**Rationale:** The number of meals prepared away from home each week is an indicator of a woman's ability to comply with the rigorous dietary changes required by DM. For example, a woman who has ten or more meals each week prepared away from home may not have control over (the fat content of) her meals to the level needed for making the necessary dietary changes. In addition, a woman who has ten or more meals each week prepared away from home may have a lifestyle that is too complicated or busy to accommodate the time commitment required for making the required dietary changes. Women who have ten or more meals each week prepared away from home are not eligible for DM unless the CC Nutritionist overrides this exclusion on *Form 6, Ver. 3, Question 17*.  
**Definition of a meal:** A meal is the food eaten at one time or the food that constitutes 20-30% of daily food consumption. What constitutes a meal will vary from person to person. For example, a bagel with cream cheese may be a meal for one person while it may only be a portion of a meal for another person. Use the definition above to determine what constitutes a meal for each woman.

The following are considered to be prepared away from home:

- Meals prepared at a restaurant, cafe, deli, vendor stand, etc.
- Meals prepared by Meals-on-Wheels (or similar service).
- Meals prepared by congregate feeding programs (senior centers or similar).
- Meals prepared by retirement/community housing (or similar).
- Meals prepared by friends or relatives at their homes.
- Meals prepared at home but without the woman's input or control. For example, if a woman shares housing with others (family, friends, etc.) and has little control over her food choices and/or preparation because someone else does the cooking, her meals are considered to be prepared away from home.
- Meals purchased ready-to-eat that do not require assembly or preparation. For example, if a woman purchases ready-to-eat macaroni and cheese at a deli, takes it home, heats it, and then eats it, this is considered to be prepared away from home.
- Prepackaged meals supplied as part of a weight loss program.

The following are not considered to be prepared away from home:

- Meals prepared at home but eaten elsewhere. For example, if a woman prepares her lunch at home and then takes it to work, this is considered to be prepared at home.
- Foods purchased as ingredients that require assembly and preparation. For example, if a woman purchases meat, cheese and bread at a deli to make a sandwich, this is considered to be prepared at home.
- Frozen dinners. Although frozen dinners do not require preparation, they frequently have a nutrition label which allows the woman to make an informed decision about the fat content. Therefore, frozen dinners are not considered prepared away from home. Exception: frozen meals supplied as part of a weight loss program are considered to be prepared away from home.

21.	Gluten-free diet	No/Yes. These diets are prescribed for health conditions that might preclude the DM Intervention diet. If the woman answers "Yes," she is not eligible for DM. Diabetic or low-salt diets <u>do not</u> exclude the woman.
22.	Low-fiber diet	No/Yes. A woman who answers "Yes" should not be on the DM Intervention diet and is therefore not eligible for DM.
23.	Diabetes	No/Yes. Do not include diabetes when pregnant. Mark "No" if the woman says she has not had diabetes or if she says she has had hypoglycemia or <u>low</u> blood sugar.
23.1.	Age at onset	The age the woman was told she had sugar diabetes other than during pregnancy. If the age at onset is less than 21, and if the participant has been taking insulin shots, she is ineligible.
23.2.	Diabetic coma ever	No/Yes. This includes <u>only</u> a coma due to diabetes (e.g., diabetic ketoacidosis). A woman ever hospitalized for a diabetic coma is not eligible for DM.
23.3.	Special diet	No/Yes. Mark "Yes" if a doctor told the woman to cut down on certain foods because of the woman's diabetes.
23.4.	Insulin shots	No/Yes. Mark "Yes" regardless of who administers the shots.
23.5.	Insulin now	No/Yes. Mark "Yes" regardless of who administers the shots.
23.6.	Pills for diabetes	No/Yes. Mark "No" if the woman has not taken oral medication for diabetes or if she took sugar pills to raise her blood sugar.
23.7.	Diabetes now	No/Yes. Mark "Yes" even if blood sugar is controlled with medication.
24.	Deep vein thrombosis (DVT)	No/Yes.

24.1.	DVT in the last six months	No/Yes. A woman with DVT in the last six months is not eligible for HRT but may be eligible at a later date.
24.2.	Traumatic DVT	No/Yes. A woman with DVT within one month of a serious accident, fracture, injury, or operation is eligible for HRT. Women with non-traumatic DVT are not eligible for HRT.
25.	Pulmonary embolus (PE)	No/Yes.
25.1.	PE in the last six months	No/Yes. A woman who answers "1 - Yes" to PE in the last six months is not eligible for HRT but may be eligible at a later date.
25.2.	Traumatic PE	No/Yes. A woman with PE within one month of a serious accident, fracture, injury, or operation is eligible for HRT. Women with non-traumatic DVT are not eligible for HRT.
26.	Stroke	No/Yes.
26.1.	Stroke in the last six months	No/Yes. A woman with a stroke, cerebrovascular accident (CVA) in the last six months is not eligible for DM or HRT but may be eligible at a later date.
	Office use	Mark "__ FE" (Future Eligible) if Question 26.1. is "1 - Yes." The woman is not eligible for the CT, but may be eligible in the future.
27.	Transient ischemic attack (TIA)	No/Yes. Mark "Yes" if the woman had a small stroke that lasted less than 24 hours TIA, reversible stroke, or mini-stroke.
27.1.	TIA in the last six months	No/Yes. A woman with TIA in the last six months is not eligible for DM or HRT but may be eligible at a later date.
	Office use	Mark "__ FE" (Future Eligible) if Question 27.1. is "1 - Yes." The woman is not eligible for the CT, but may be eligible in the future.
28.	Heart attack	No/Yes. Mark "Yes" if the woman had a heart attack, coronary, MI, or myocardial infarction. Mark "No" if the woman says she has had angina, chest pain without a heart attack, or sudden cardiac arrest without a heart attack.
28.1.	Age at first heart attack	The woman's age when she had her first heart attack (her best guess).
28.2.	Heart attack in the last six months	No/Yes. A woman with a heart attack in the last six months is not eligible for DM or HRT but may be eligible at a later date.
	Office use	Mark "__ FE" (Future Eligible) if Question 28.2. is "1 - Yes." The woman is not eligible for CT, but may be eligible in the future.
29.1.	Sickle cell anemia	No/Yes. A woman with sickle cell anemia is not eligible for DM, HRT or OS.
29.2.	Heart failure	No/Yes. If the woman answers "1 - Yes," refer to the Clinic Practitioner by marking the "2. __ CP" line in the "Office Use 29." shaded box. The CP must determine the woman's eligibility for this criterion by marking the corresponding question on <i>Form 6</i> , based on survivability.
29.3.	Liver disease	No/Yes. If the woman answers "1 - Yes," refer to the Clinic Practitioner by marking the "3. __ CP" line in the "Office Use 29." shaded box. The CP must determine the woman's eligibility for this criterion by marking the corresponding question on <i>Form 6</i> , based on survivability.
29.4.	Bleeding problem	No/Yes. If the woman answers "1 - Yes," refer to the Clinic Practitioner by marking the "4. __ CP" line in the "Office Use 29." shaded box. The CP must determine the woman's eligibility for this criterion by marking the corresponding question on <i>Form 6</i> , based on survivability.

30. Lost 15 pounds or more in the last six months No/Yes. A woman who has lost 15 or more pounds in the last six months without trying, even if due to a life crisis (e.g., death of a spouse) is not eligible for DM or HRT. A woman who loses 15 or more pounds in the last six months is ineligible even if she has regained the weight she lost.
31. Kidney dialysis No/Yes. Mark yes if a woman is having kidney dialysis, hemodialysis, or peritoneal dialysis. Women with severe kidney failure requiring dialysis are not eligible for the DM, HRT, or OS.
32. Other long-term or chronic illness No/Yes. Mark "Yes" if a woman has a long term illness other than those specified in other questions. For example, if she has hypertension, enter this information. However, if she has cancer, mark "Yes" to Question 14.
- 32.1. Specify illness Long term or chronic illness the participant has.  
Data Entry: Do not key-enter "Specify" text.
- Office use If the woman answers "1 - Yes," refer to the Clinic Practitioner by marking the "\_\_ CP" line in the "Office Use 32." shaded box. The CP must determine the woman's eligibility for this criterion by marking the corresponding question on *Form 6*.  
The most common chronic conditions given by your clinic screenees may be ones that are not eligibility items, and that will not affect their likelihood of 3-year survival. Your CC Principal Investigator (PI)/physician should list the conditions that he or she does not feel require CP review. For example, arthritis, hypertension, hypothyroidism, and high cholesterol have been found to be very prevalent in screenees, yet these are not eligibility items, should not in most cases affect the 3-year survival, and should not require clinician review.
33. Reasons for ineligibility No/Yes. If a participant answers "Yes," she is ineligible for the DM, HRT, or OS. WHILMA uses this question in its eligibility determination. In the eligibility determination, WHILMA will give an ELIG result if the answer is "No," an INEL result if the answer is "Yes," and an INFO result if there is no answer.
34. Ability to get to clinic No/Yes. Women who are not able to come to the CC are not eligible for the DM, HRT, or OS.
- 34.1. What kind of help Mark the appropriate oval or box for the kind of help needed:  
1 - Transportation  
2 - Child care  
3 - Adult care  
4 - Other (Specify)  
Data Entry: Do not key-enter "Other (Specify)" text.
35. Interest in DM No/Yes/Don't know. If the woman answers "No," she may be eligible if she subsequently signs a DM consent.

- 35.1. Able to attend regular meetings for one year No/Yes.  
 Women who are interested in DM participation must be available for the first six months of DM Intervention (e.g., DM Intervention Sessions 1 - 12). This question asks if the woman is available for one year (from the time she completes the form). The 1-year time frame was selected because it allows adequate time for the woman to go through the 3-6 month screening process, the 2-3 month (8-12 week) group formation process and six months of DM Intervention (Sessions 1 - 12).  
 During the first six months, the DM Intervention covers the basic dietary change and behavioral skills required by a woman to be able to change their eating patterns. It also provides time for both the Group Nutritionist and the group members to develop rapport and group bonding.  
 There are no provisions for "drop-ins" to DM group sessions at other CCs during the first six months of intervention. Therefore, an effort should be made to identify snowbirds (women who live elsewhere during the winter or summer months) at or before SV1.
36. Interest in HRT No/Yes/Don't know/need more information. If a woman answers "No," she may be eligible if she subsequently signs an HRT consent.
- 36.1. Take only pills given by CC staff No/Yes/Don't know. If a woman answers "0 - No," she is not willing to take only the pills given to her by the CC staff or if she wants to be specifically in hormone or placebo group (i.e., wants to choose which treatment group she will be in) she is not eligible for HRT.
- 36.2. Talk with doctor about HRT No/Yes/Don't know/Not on hormones.
- 36.3. Permission to send information on HRT to doctor No/Yes. If the woman answers "1 - Yes," write in her doctor's name, clinic name, address, city, state and zip code. HRT informational materials for primary care providers should be sent to this address.  
 Data Entry: Do not key-enter text.
37. Help needed No/Yes.
38. Date form finished Date woman completed the form.  
 Language Data Entry: English or Spanish versions of the form. (See common data items.)