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<b>FORM:</b>	<b>3 - ELIGIBILITY PHONE SCREEN</b>
<b>Version:</b>	3.1 - June 1, 1995
<b>Description:</b>	Interviewer-administered; 12-page form; key-entered or scanned at Clinical Center (CC).
<b>When used:</b>	Administered to potential participants by phone before Screening Visit 1 (SV1) or as interview at 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 3*) and Spanish (*Form 3S*) 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. The form is divided into the following three parts:
  - Part 1: Initial participant information and screening questions
  - Part 2: Hormone Health Status
  - Part 3: Health Status and Study Interest
3. Shaded areas on the form signify ineligibility or further action to take.
  - A shaded box covering the question response means the woman is ineligible for Hormone Replacement Therapy (HRT), Dietary Modification (DM) and Observational Study (OS). Do not bring her to an SV1.
  - A shaded box to the right of the response with a study notation means the woman is ineligible for the component listed in the box (e.g., DM, HRT, or OS).
  - A shaded box with the phrase "...may be eligible at a later date" means the woman is temporarily ineligible for that criterion. If DM, HRT, or OS is listed inside the box, she is temporarily ineligible for DM, HRT, or OS, as listed.
  - A shaded Office Use box with "\_\_ CP" checked requires a follow-up review for eligibility by the CC Clinic Practitioner (CP) on *Form 6 - Final Eligibility Review*.
  - CT interest questions with the phrase "May be eligible if signs ... consent" means the woman may renew her interest in a study by signing the appropriate consent (e.g., DM, HRT) at a later date. It is not necessary to change her original "No" response to interest on this form.

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

4. Eligibility for diabetes and menopause is based on an algorithm and therefore these are not shaded. See *Figure 1 - HRT Menopause Algorithm* for HRT menopause eligibility and *Figure 2 - DM/OS Menopause Algorithm* for 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, administer 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 8 below.

3. Complete Office Use Only Items 1 - 4, identifying the date, staff person completing the form, contact type, and visit type and visit number. (Note that form administration is already filled in as an interview.)

For the mark-sense formatted form, record the responses in the spaces provided and fill in the corresponding ovals or boxes. If the number has a "0," you do not fill in an oval or box for the "0." For example, for a WHI employee ID code of "105" in Item 2 "Contacted 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.

4. Read the introductory script on the form and record the responses. Follow the instructions in Item 3 above for filling in the ovals or boxes.
5. After Part One - Initial Participant Information and Screening Questions, determine if the participant is eligible for either HRT, DM, or OS.

If eligible, go to the next part.

If not eligible, read the appropriate script below in Section C - Scripts.

6. Follow the HRT, 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.
7. Review the form completely for eligibility issues using *Table 1*. Discuss unclear responses with the participant. Refer appropriate items to the CP to evaluate the participant's health condition and determine eligibility.
8. 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.

To scan, 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 "Other (Specify)" items.

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

### **C. Reviewing and Updating Form 3 - Eligibility Phone 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 3 - Eligibility Phone 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 3* 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 ovals or boxes 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 3* 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 3* with the woman to verify that she has not experienced any changes in her health or circumstances that would make her ineligible since you last administered *Form 3*.

- Use the "Script to Review and Update *Form 3*" in Step D.2. below.
- If the woman answers "Yes" to any of the questions from the script, correct the original *Form 3* 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. Scripts

### 1. Script for Administering Form 3

#### 1.1. Script 1

If the woman is eligible (no shaded answers) at the end of Part I, proceed to Part II. Otherwise, follow the script in bold below. Read the script for the questions (in parentheses) making the participant ineligible.

**"Thank you for answering my questions. Your answers are very important to us. However, you are not able to join the Women's Health Initiative at this time because you . . . ."**

Choose appropriate reason and then go to closing:

- (Qx. 7.1.) **" . . . are not 50 years old yet. We will contact you . . ." or "Please contact us . . . after your fiftieth birthday."**  
**" . . . are over 79 years of age, and we are only enrolling women aged 50-79."**
- (Qx. 8) **" . . . will not be living in the area for three years. If your plans change and you will be staying in the area for the next three years, please contact us."**
- (Qx. 9.2.) **" . . . are in another research study. If the study you are in is over before 1996 we will contact you." or " . . . please contact us."**

**"Thank you for your participation today. Even though you are not able to join the study at this time, all of the answers you have given will help us learn more about women's health. Good-bye."**

- (Qx. 10) **" . . . have had breast cancer." "However, you may be eligible for another part of the study. I will continue with the questionnaire and then we can talk more about a part of the study you may be able to join."**
- (Qx. 11.1., 12.1., 13.2., 14) Yes to colorectal, endometrial, melanoma, or other cancer in past ten years.)
  - CA within 0-7 years: **" . . . have had cancer within the past ten years. However, you may be eligible for another part of the study. I will continue with the questionnaire and then we can talk more about a part of the study you may be able to join."**
  - CA within 8-10 years (for CT): **" . . . have had cancer within the past ten years. However, enrollment will continue for three years, and you may be able to join at a later time. May we put your name on a list to be contacted later?"**  
or
  - CA within 8-10 years (for OS): **" . . . have had cancer within the past ten years. However, you may be eligible for another part of the study. I will continue with the questionnaire and then we can talk more about a part of the study you may be able to join."**

## 1.2. Script 2

If the woman is eligible (no shaded parts) and appears eligible by menopause algorithms shown in *Figures 1* and *2* at the end of Part III, schedule an SV1. If she is ineligible, follow the script below:

**"I want to thank you for answering my questions. Because you . . ."** (select appropriate response):

- Qx. (17.1.) **"... are currently taking hormones, you would need to stop taking the hormones for three months before joining the Hormone Program."**
- Qx. (17.2.) **"... have used female hormones recently, you would need to stop using the hormones for three months before joining the Hormone Program."**

**"To be able to join the Hormone Program, you cannot be currently using hormones, and you must be willing to be placed, by chance, into one of two groups. Women in one group will take hormones, while women in the other group will take inactive, or "placebo," pills."**

- Qx. (17.4.) **"... are taking hormones to treat an osteoporosis-related fracture . . ."**  
**"... you are not eligible to join the Hormone Program, but you may be eligible for other parts of the study."**
- (Qx. 18.1.) **"... had a hysterectomy in the past three months . . ."**  
**"... you are not eligible to join the Hormone Program until 3 months after your surgery. However, you may be eligible to join other parts of the study before that time."**

## MENOPAUSE

- (Qx. 17 and Qx. 18) **"... has never used or has not used any HRT since she was 50" and "... has not had a hysterectomy" then,**
- (Qx. 19) **"When was the last time you had any menstrual bleeding or spotting?"**

If a participant answers:

**"Still having menstrual bleeding"**

**"Within the last six months"**

**"... you are not eligible to join the study right now. You need to have no bleeding or spotting for . . ."**

– Age 55-79 **"... six months. You may contact our office six months after you have stopped bleeding or spotting."**

– Age 50-54 **"... 12 months. You may contact our office 12 months after you have stopped bleeding or spotting."**

If a participant answers:

**"7 to 12 months ago"**

– Age 50-54 **"... have had bleeding or spotting in the last 12 months. . ."**

**"... you are not eligible to join the Women's Health Initiative. However, you may be eligible at a future date (e.g., if she bled 11 months ago she may be eligible next month)."**

## DIET

- (Qx. 20) "... eat more than ten meals prepared away from home each week ..."
- Option A: Use when interviewer is certain about the woman's eligibility:
 

**"... you are not eligible to join the Dietary Program. However, you may be eligible for other parts of the study."**
- Option B: Used when interviewer is uncertain about the woman's eligibility:
 

**"... you may not be able to join the Dietary Program. I will need to check with the Nutritionist to see if you are eligible, and she/he may need to contact you to get a little more information."**
- (Qx. 21, 22) "... are following a special diet ..."
- (Qx. 23.2.) "... were hospitalized for a diabetic coma ..."
- (Qx. 23.4. and 23.1.) <=21 "... had sugar diabetes before the age of 21 and are currently using insulin. ..."
 

**"... you are not eligible to join the Dietary Program, but you may be eligible for other parts of the study."**

## SIX-MONTH EXCLUSIONS

- (Qx. 24.1.) "... had a blood clot in your leg in the last six months ..."
- (Qx. 25.1.) "... had a blood clot in your lung in the last six months ..."
- "... you are not eligible to join the Hormone Program right now, but you may be eligible for other parts of the study."**
- (Qx. 26.1.) "... had a stroke in the last six months ..."
- (Qx. 27.1.) "... had a TIA in the last six months ..."
- (Qx. 28.2.) "... had a heart attack in the last six months ..."
- "... you are not eligible to come to the clinic right now, but you may be eligible later. Please call us." or**  
**"May we call you back in \_\_\_\_\_ months to continue with the screening process for the study?"**

## CLINIC PRACTITIONER

- (Qx. 29.2.) "... have had heart failure ..."
- (Qx. 29.3.) "... have had liver disease ( or chronic active hepatitis, cirrhosis or yellow jaundice) ..."
- (Qx. 29.4.) "... have had a bleeding problem ..."
- (Qx. 32) "... have \_\_\_\_\_ (other long term or chronic illness) ..."
- "... I will need to check with the nurse in our clinic to see if you are eligible to come in to the clinic for the first visit. May I call you back as soon as I have an answer for you?"**
- (Qx. 29.1.) "... have sickle cell anemia ..."
- (Qx. 30) "... have lost more than 15 pounds in the last six months without trying ..."
- "... you are not able to join the Women's Health Initiative right now. May we call you back in one year to continue the screening process for the study?"**
- (Qx. 31) "... are on a kidney dialysis or kidney machine for kidney or renal failure ..."
- "... you are not able to join the Women's Health Initiative."**

- (Qx. 35 and 36) = "No," Participant is Not Interested in Either Arm of the Clinical Trial:

**"These are all the questions that I have for you. I understand your concerns about \_\_\_\_\_. I appreciate the information you have given me today. All of your answers will help us learn more about women's health."**

If CC decides to schedule SV1s for CT ineligible but OS eligible women:

**"There is another part of the study that you may be interested in joining called the Observation Study. Many important women's health issues will be studied in this part of the WHI. We are interested in learning about what causes disease in women. We'd also like to see what health habits affect a woman's risk for getting heart disease, cancer, or broken bones."**

**"Women in the Observational Study will all be asked to fill out several questionnaires and forms at the start of the study. Then, every year for the next 8 to 12 years, you will be mailed forms. These forms will ask questions about your health and any medical problems that may have developed in the last year. You will be given a stamped envelope to mail the forms back to the CC after you finish them."**

**"In three years you will come back to the CC for a follow-up visit. At this visit, measurements and lab tests will be done. Your height, weight, waist, and hips will be measured, and your pulse and blood pressure will be taken. We will also draw a small amount of your blood for testing."**

**"Every year you will be sent a newsletter. This newsletter will give you information about the progress of the study and will help us know that we still have your correct address."**

**"Do you think you would be interested in the Observational Study?"**

- (Qx. 35) = "Yes," Participant is Interested and Eligible for DM Only:

**"Now let me tell you about the Dietary Program. If you are interested in joining the Dietary Program, you will need to come into the clinic for a few screening visits that will help decide if you're able to join the program. If you are able to join the study, our computer will place you, by chance, into one of two groups. One group is contacted by the Clinical Center every six months and continues with their usual eating patterns. Women in the other group are also contacted by the Clinical Center every six months and, in addition, come to a series of group sessions with a Nutritionist to learn how to lower fat and increase fruits, vegetables, and grains in their diet. If you are placed in this group, you will attend 18 of these sessions the first year, and then about four sessions per year for the rest of the study. Your participation would be for eight to twelve years."**

**"Some of the screening tests for this part of the study include a mammogram, clinical breast exam, and an electrocardiogram."**

**"In order to continue your screening process, I'll mail you a questionnaire about your diet. When you receive it, complete the form with the enclosed pencil. After you have finished, please return it in the stamped envelope provided or bring it with you to your clinic appointment. After we receive your completed questionnaire, we'll call you back to discuss your joining the study. Is this all right with you?"**

- Qx. (35.1.) If Participant Asks When and How Often the DM Sessions are Held:

**"We offer classes mornings, afternoons, and evenings. Women attend 18 of these sessions the first year, and then about four sessions per year for the rest of the study."**

- (Qx. 36) = "Yes," Participant is Interested and Eligible for HRT Only:

**"Good! I want to take a moment to describe the parts of the study in more detail for you. Your participation would be for eight to 12 years."**

(This information may be used differently at each CC at CC discretion.)

**"If you are interested in joining the Hormone Program, you will need to come into the clinic for a few screening visits that will help decide if you're able to join the program. If you are able to join the Hormone Program, our computer will place you, by chance, into one of two groups. Women in one group will take hormones, while women in the other group will take inactive or 'placebo' pills.**

**"Some of the screening tests include having a pelvic exam; Pap smear; mammogram; electrocardiogram; and, if you still have your uterus or womb, an endometrial biopsy, which is a test to check the lining of your uterus or womb. You will also be contacted by the Clinical Center for follow-up visits every six months."**

Participant is Interested and Eligible for HRT and DM:

**"Good! I want to take a moment to describe the parts of the study in more detail for you. For all parts of the study, your participation would be for eight to 12 years."**

(This information may be used differently at each CC at CC discretion.)

**"If you are interested in joining the Hormone Program, you'll need to come into the clinic for a few screening visits that will help decide if you're able to join the program. If you are able to join the Hormone Program, our computer will place you, by chance, into one of two groups. Women in one group will take hormones, while women in the other group will take inactive or "placebo" pills.**

**"Some of the screening tests for the hormone part include having a pelvic exam, Pap smear, mammogram, electrocardiogram (or ECG), and an endometrial biopsy, which is a test to check the lining of your uterus or womb. These tests will help us make sure that it is safe for you to join the study. You will be contacted by the Clinical Center for follow-up every six months.**

**"These screening tests will also help decide if you are able to join the Dietary Program. If you are able to join the Dietary Program, our computer will place you, by chance, into one of two groups. One group is contacted by the Clinical Center every six months and continues with their usual eating patterns. Women in the other group also are contacted by the Clinical Center every six months and, in addition, attend a series of group sessions with a Nutritionist to learn how to lower fat and increase fruits, vegetables, and grains in their diet. If you are placed in this group, you'll attend 18 of these sessions the first year, and then about four sessions per year for the rest of the study. Your participation would be for eight to 12 years.**

**"Some of the screening procedures for this part of the study include a mammogram, clinical breast exam, and an electrocardiogram. These tests are used to insure that it is safe for you to join the study.**

**"In order to continue your screening process, I'll mail you a questionnaire about your diet. When you receive it, complete the form with the enclosed pencil. After you have finished, please return it in the stamped envelope provided or bring it with you to your clinic appointment. After we receive your completed questionnaire, we'll call you back to discuss your joining the study. Is this all right with you?"**

1.4. Script for Temporary Ineligibility

If Participant Response Requires Clinic Practitioner Consultation:

**"These are all the survey questions I have for you right now. After I've reviewed your questionnaire with a staff clinician, I'll call you back, okay?"**

If Participant has had a (Question 18.1.) Hysterectomy in Past Three Months; or (Question 26.1.) Stroke or (Question 27.1.) TIA or (Question 28.2.) Heart Attack in the Past Six Months:

**"For safety reasons, we must wait until (*three/six*) months have passed since your (hysterectomy/heart attack, stroke or TIA) to continue the screening process. May I call you back in (*three/six*) months so we can continue at that time?"**

If Washout is Required for Further Screening:

**"If you are interesting in joining the Hormone Program, you will need to stop taking your current hormones and be off them for three months before completing the screening process. You'll need to talk to your doctor about stopping your hormones before you join the study. You and your doctor can make a decision that is best for you.**

**"If you then decide to proceed with this part of the study, you'll need to come into the clinic for a few screening tests that will help decide if you're able to join the program. Some of the screening tests include having a pelvic exam, mammogram, and electrocardiogram, and an endometrial biopsy, which is a test to check the lining of your uterus or womb. These tests are used to insure that it is safe for you to join the study."**

2. Script to Review and Update Form 3

**"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 we first spoke with you about joining the Women's Health Initiative."**

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

1. **"Have you seen a doctor or other health care professional since we first spoke with you?"**

If "Yes," ask Questions 2 - 7.

If "No," ask Questions 4 - 7.

2. **"Since the first time we spoke with you, has your doctor or other health professional told you that you have any of the following health problems?"** (Read list.)

	<u>Ver. 3 Qx.</u>
<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.)

	<u>Ver. 3 Qx.</u>
<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>

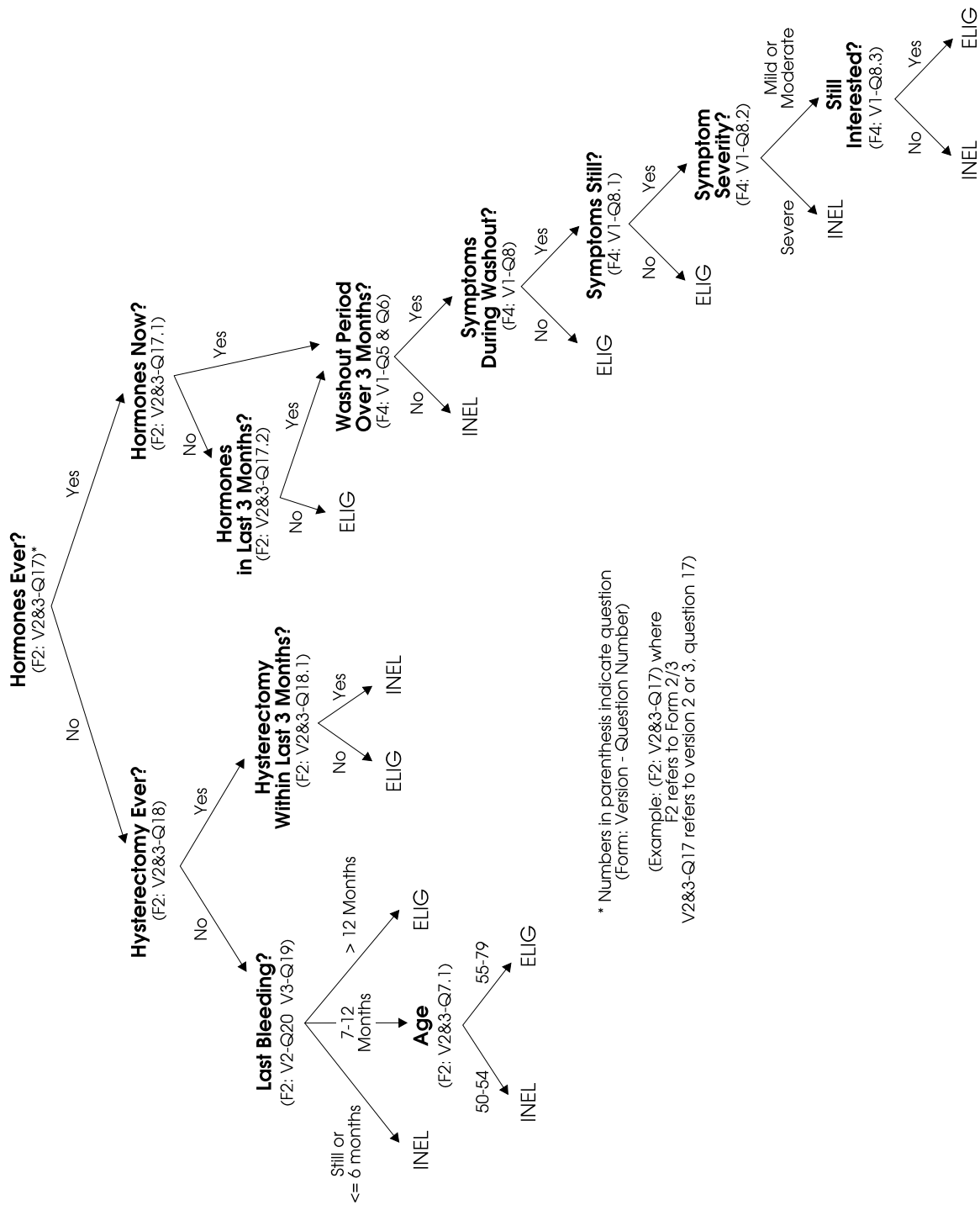
6. **"Do you plan to move away from the area in the next three years?"** **8**

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."**

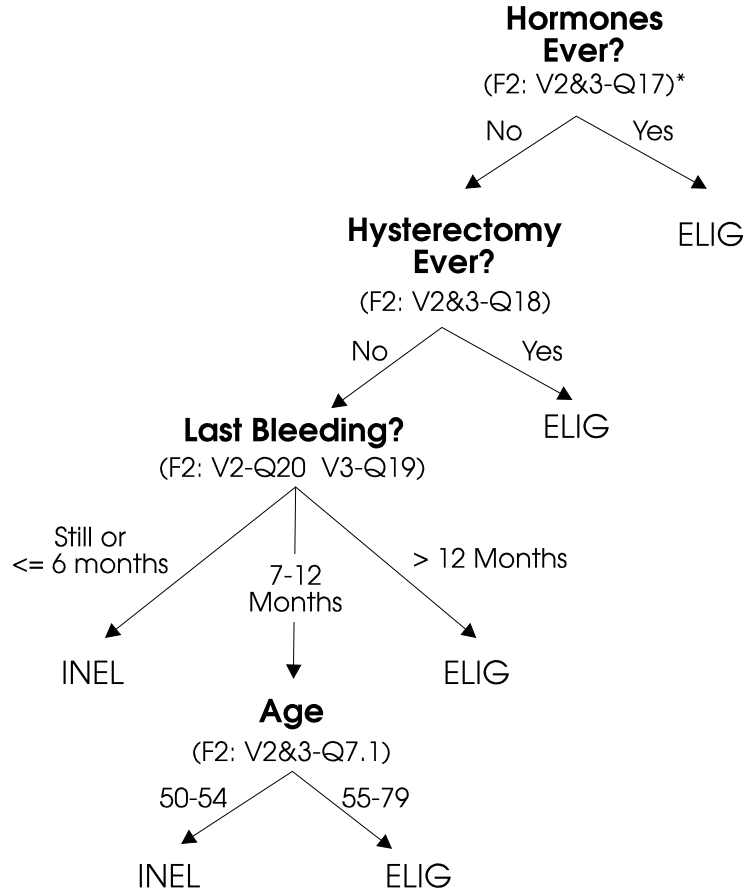
(If participant answered "Yes" to any item, update the information on *Form 3 - Eligibility Screen* as described in Step C.2., "Reviewing and Updating *Form 3* at SV3" above, and run an eligibility determination.)

**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./23.5.	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*
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. | Contact date        | Record the date of the contact.   |
| 2. | Contacted by        | Standard 3-digit WHI employee ID.   |
| 3. | Contact type        | Mark the appropriate oval or box. (See common data items.) This form is usually completed over the phone.                             |
| 4. | Visit type          | Mark "Screening" and "0" if completed before SV1. Mark "Screening" and "1" only if you administer the form to the participant at SV1. |
| 5. | Form administration | On the mark-sense (English) form, the number 3 oval is filled in to signify that the form was interviewer-administered.               |

**Item Instructions**

- |      |                                 |  |
|------|---------------------------------|--|
|      | Contact information<br>(page 1) | Complete contact information (name, address, and phone numbers) based on interest survey or other information provided by participant. Complete call attempt information to document efforts to contact participant.<br><br>Data Entry: Do not key-enter or scan this information.                     |
| 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               | Record 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              | An other 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.   |
| 7.2. | Age 47 - 49                     | Mark "__ Age 47 - 49" if the answer to Question 7.1. indicates this choice. The woman may be age-eligible at a later date.   |

- 7.3. Age 50 - 79 Mark "\_\_ Age 50 - 79" if the answer to Question 7.1. indicates this choice. The woman is age-eligible.
- 7.4. Age <47 or 80+ Mark "\_\_ Age < 47 or 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: Do not key-enter name of study.
- 9.2. Excluded study No/Yes. 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. 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 or Cytrin), 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 do not 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 low blood sugar.
- 23.1. Age at onset The age the woman was told she had sugar diabetes. If the age at onset is less than 21 and the participant has been taking insulin shots, she is ineligible.
- 23.2. Diabetic coma ever No/Yes. This includes only 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 ever? 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 "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 any DM or HRT component but may be eligible at a later date.
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.

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.
- 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 *Form 6*, based on survivability.
- 29.3. Liver disease No/Yes. If the woman answers "1 - Yes," refer to 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 *Form 6*, 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 *Form 6*, 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 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 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 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 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 DM, HRT, or OS.
- 34.1. What kind of help The kind of help needed.
- 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. If she answers "Yes" or "Don't know" go to the next question.
- 35.1. Able to attend regular meetings for 1 year No/Yes.
- Women who are interested in DM participation must be available for the first 6 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 necessary to achieve a change in women's 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 signs an HRT consent in the future.
- 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 the text.
37. Help needed No/Yes.
- Language Data Entry: English or Spanish version of the form. (See common data items.)