
FORM:	6 - FINAL ELIGIBILITY ASSESSMENT
Version:	4 - June 1, 1995
Description:	Completed by Clinical Center (CC) staff; 2-page form; key-entered at CC.
When used:	At Screening Visit 3 (SV3), or at an earlier screening contact (if CC staff determine a participant is ineligible due to staff assessment of indicated medical conditions or interviewer impression).
Purpose:	To document CC staff assessment of participant's eligibility for Hormone Replacement Therapy (HRT), Dietary Modification (DM), and Observational Study (OS).

GENERAL INSTRUCTIONS

1. Include form in SV3 participant packet. For earlier screening visits, use as needed.
2. Affix a participant barcode label to the form.
3. Complete Items 1 - 4.
4. Review the Clinic Practitioner (CP) Office Use questions on *Form 2/3 - Eligibility Screen* and complete Items 5 - 8 needing CP review.
5. Complete Items 9 - 11 needing CP assessment of depression, drug use, and alcohol use.
6. Complete Items 12.1. - 12.3. recording staff assessment of the participant.
7. If you want to use clinical judgment to override the BMI or meals away from home eligibility criteria, complete Items 13 - 15 as appropriate.
8. Complete Item 16 after reviewing *Form 2/3* with the participant immediately before randomization or enrollment.
9. Complete Items 17 - 18, as appropriate.
10. Review the form for completeness.
11. Insert the form in the participant's file and forward to Data Entry.
12. Data Entry: Review the form for completeness and consistency. Return to interviewer with any questions or problem. Key-enter after you resolve any questions. Initial the first page of the form after key-entry.

Note: You must key-enter this form before you can randomize the participant into DM or HRT, or enroll her into OS.

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

Item Instructions

1. Date of contact Date you initiated the form and started recording data on the form. This may be at any time during screening but no later than SV3.

 Use a standard 2-digit format: month, day, and year order.

2. Completed by Standard 3-digit WHI employee ID of staff person initiating the form. (See common data items.)

3. Contact type Mark appropriate box. (See common data items.)

4. Visit type The contact at which you initiated the form. If you start the form between screening visits, mark the most recent past visit.

 Mark the appropriate box and enter the screening visit number. (See common data items.)

- 5.-8. Clinic Practitioner Review the indicated questions on *Form 2/3*. The question numbers for Ver. 3 of the assessment of *Form 2/3* forms are indicated in parenthesis.

 If the indicated question on *Form 2/3* does not need CP review, mark "8 - No CP Evaluation Required."

 If the response does need CP review, use your judgment to determine if the woman is ineligible or eligible based on the indicated condition. Consult your Principal Investigator (PI) as needed for guidelines.

 This is not the same as confirming that the information on *Form 2/3* was filled out correctly. CP assessment is an evaluation of the degree to which the specific condition meets the eligibility criteria as described in the protocol. Consult your PI for guidelines as needed. If the participant's responses to the questions on *Form 2/3* are not correct or have changed, correct the answers on *Form 2/3*.

 Mark "Ineligible" or "Eligible" as appropriate, and record the CP staff ID number in the space to the right of the boxes. WHILMA uses each of these questions when you run the eligibility determination. If you mark "Ineligible," WHILMA will return an INEL result for the question in the eligibility determination. If you mark Eligible, WHILMA will return a result of ELIG for the question. If you mark "8 - No CP Evaluation Required" and the corresponding question on *Form 2/3* indicates you need CP evaluation, WHILMA will return a result of INFO for the question.

 Data Entry: Do not key-enter the staff ID number.

5. Expected good health See description of Questions 5 - 8 above. Review the Heart Failure question on *Form* ≤ 3 years due to heart 2/3. If the participant's response is "0 - No," mark "8 - No CP Evaluation Required." failure If the participant's response is "1 - Yes," the CP determines if the participant is ineligible or eligible for HRT, DM, and OS due to her heart condition.

 0 - Ineligible. Mark if, based on your clinical judgment, the participant's survival is \leq 3 years due to her heart failure.

 1 - Eligible. Mark if, based on your clinical judgment, the participant's expected survival is $>$ 3 years despite her heart failure.

6. Liver disease Evaluate liver disease for the two criteria given below.
See description of Questions 5 - 8 above. Review the Liver Disease questions on *Form 2/3*. If the participant's response is "0 - No," mark "8 - No CP Evaluation Required."
- 6.1. Expected good health \leq 3 years due to liver disease If the participant's response is "1 - Yes," determine if the participant is ineligible or eligible **for HRT, DM, and OS** due to her liver disease.
0 - Ineligible. Mark if, based on your clinical judgment, the participant's survival is \leq 3 years due to her liver disease.
1 - Eligible. Mark if, based on your clinical judgment, the participant's expected survival is $>$ 3 years despite her liver disease.
- 6.2. Chronic active hepatitis If the participant's response is "1 - Yes," determine if the participant is ineligible or eligible **for HRT and DM** due to chronic active hepatitis.
0 - Ineligible. Mark if the participant reports she has chronic active hepatitis and/or, based on your clinical judgment, she has chronic active hepatitis.
1 - Eligible. Mark if the participant reports she has liver problems, but does not have chronic active hepatitis and/or, based on your clinical judgment, she has chronic active hepatitis.
7. Bleeding problem requiring transfusion See description of Questions 5 - 8 above. Review the Bleeding Problem question on *Form 2/3*. If the participant's response is "0 - No," mark "8 - No CP Evaluation Required." If the participant's response is "1 - Yes," determine if the participant is ineligible or eligible **for HRT** due to the bleeding problem.
0 - Ineligible. Mark if the participant is ineligible because she had a bleeding problem requiring a transfusion.
1 - Eligible. Mark if the participant did not have a bleeding problem requiring a transfusion.
8. Long-term illness See description of Questions 5 - 8 above. Review the Long-Term Illness question on *Form 2/3*. If the participant's response is "0 - No," mark "8 - No CP Evaluation Required." If the participant's response is "1 - Yes," determine if the participant is ineligible or eligible **for HRT, DM, and OS** due to the long-term illness.
0 - Ineligible. Mark if, based on your clinical judgment, the participant's survival is \leq 3 years because of the long-term illness listed.
1 - Eligible. Mark if, based on your clinical judgment, the participant's survival is $>$ 3 years, despite the long-term illness listed.
- 9.-11. Clinic Practitioner assessment Use your judgment to determine if the woman is ineligible or eligible due to the indicated condition. Consult your PI for guidelines as needed. Mark "Ineligible" or "Eligible" as appropriate, and record your staff ID number in the space to the right of the boxes.

WHILMA uses the Questions 9 - 11 when you run the eligibility determination. If you mark "Ineligible," WHILMA will return an INEL result in the eligibility determination for this question. If you mark "Eligible," WHILMA will return a result of ELIG for the question. If you leave the question blank, WHILMA will return a result of INFO for the question.

Data Entry: Do not key-enter staff ID number.

9. Depression Ineligible/Eligible. Refer to Questions 96.1. - 97 on *Form 37 - Thoughts and Feelings*. The assessment is based on clinical judgment. If you mark "1 - Yes," the participant is ineligible **for HRT, DM, and OS.**
10. Drug use Ineligible/Eligible. This assessment is based on clinical judgment or participant report. If you mark "1 - Yes," the participant is ineligible **for HRT, DM, and OS.**
11. ETOH (alcohol) use Ineligible/Eligible. CP assessment may be based on clinical judgment and/or Item 3 on *Form 34 - Personal Habits* (Ver. 2). If you mark "1 - Yes," the participant is ineligible **for HRT, DM, and OS.**

It is appropriate and within the Nutritionist's scope to exclude a woman from DM if excess alcoholic beverages are noted on her *Form 62 - Four-Day Food Record (4DFR)* or *Form 60 - Food Frequency Questionnaire (FFQ)*, even if the excess consumption was not reported by the woman verbally or on other forms. The DM exclusion can be made without additional probing of the woman if the Nutritionist feels that additional information is not warranted. However, if the Nutritionist wishes to probe for additional information, it is within his or her scope to do so. The Nutritionist may wish to probe for, but should not be limited to, the following additional information:

- Whether this intake was typical or unusual due to a celebration or other social activity.
- If the woman has dietary patterns related to her alcohol consumption that would negatively impact her ability to achieve the goals of the intervention (e.g., does she skip meals, does she avoid entire food groups, does she eat foods of poor nutritional quality, etc.).
- The woman's willingness and/or ability to attend regular intervention sessions given her alcohol consumption.
- The woman's willingness and/or ability to complete regular intervention activities (e.g., self-monitoring, home activity assignments, etc.) given her alcohol consumption.

Because reliability of the information may be questionable, it is not appropriate for the Nutritionist to ask the woman questions about her desire and/or ability to reduce her alcohol consumption for study participation.

If the Nutritionist detects alcohol abuse that was not noted by other CC staff, she should contact the CP to collaboratively discuss the woman's eligibility status:

- If the woman is inappropriate for all study components, exclude her from all components by using this question.
- If the woman is appropriate for other study components, but is not appropriate for DM per the Nutritionist's judgment because of her alcohol use, exclude her from DM only using Question 12.1. described below.

12. Staff assessment Answer all three components of the question for each participant. Mark "0 - Ineligible" if, based on your clinical judgment, the woman is not a good candidate for the specific study for reasons not captured in other eligibility data items. (Make this determination regardless of the participant's eligibility or interest in the components.) Otherwise, mark "1 - Not Applicable." If you mark "Ineligible," specify the reason on the line provided. Record your staff ID number when you mark the answer.
- Data Entry: Do not key-enter the staff ID number.
- 12.1. Impression for DM Impressions left to the judgment of the interviewer or CC staff. (See general description of Question 12 above.) For example, if it is known that a woman eats only pancakes at every meal, her fat score may be acceptable, but she would not be a good candidate for DM. If a woman is obviously fixated on a particular subject that consumes all of her attention, she may not be a good candidate. In summary, these impressions are for excluding participants who have passed all the eligibility criteria you have assessed up to the current date, but who are obviously not good candidates.
- The following areas are to be considered when determining adherence related issues overrides for DM (1) weight loss as the motivation for joining DM, (2) history of weight cycling, (3) special diets or unusual eating patterns, and (4) ability to self-monitor as evidenced by satisfactorily completing a 4DFR. Review these areas when assessing eligibility with the DM Eligibility Checklist.
- We suggest the CC Lead or Group Nutritionist be involved in deciding whether a woman would be an appropriate candidate for DM if the woman does not read or write English (or Spanish) well.
- 0 - Ineligible. Mark if, based on CC staff judgment, the participant is not a good candidate for the DM. Specify the reason on the line provided.
- Data Entry: Key-enter the reasons specified.
- 1 - Not Applicable. Mark if, based on CC staff judgment, the participant is a good candidate for the DM.
- 12.2. Impression for HRT Impressions left to the judgment of the interviewer or CC staff. (See general description of Question 12 above.)
- 0 - Ineligible. Mark if, based on CC staff judgment, the participant is not a good candidate for the HRT. Specify the reason on the line provided.
- Data Entry: Key-enter the reasons specified.
- 1 - Not Applicable. Mark if, based on CC staff judgment, the participant is a good candidate for the HRT.
- 12.3. Impression for OS Impressions left to the judgment of the interviewer or CC staff. (See general description of Question 12 above.)
- 0 - Ineligible. Mark if, based on CC staff judgment, the participant is not a good candidate for the OS. Specify the reason on the line provided.
- Data Entry: Key-enter the reasons specified.
- 1 - Not Applicable. Mark if, based on CC staff judgment, the participant is a good candidate for the OS.

13. Clinical Practitioner override of BMI > 40 for HRT
 BMI > 40 was removed as an eligibility criterion by council in March 1996. It is not necessary to use this question and WHILMA does not use this item in determining a woman's eligibility.
 CCs should continue to exercise clinical discretion for a participant with a high BMI (i.e., BMI > 40 kg/m²). There should be few safety or adherence concerns for HRT-eligible participants with a high BMI. If you decide the participant is not a good candidate for HRT based on extreme BMI values, record as staff impressions on *Form 6 - Final Eligibility Assessment*; item 12.2 HRT.
14. Clinic Practitioner override of BMI < 18 for HRT
 BMI < 18 override option for HRT; this is independent of the BMI < 18 override for DM that the Nutritionist completes in Question 14 below. A Nutritionist's decision to override the criteria (or not override the criteria) for DM does not affect the CP's override for HRT.
 Mark "1 - Override" to override the ineligible result. Use your judgment to determine if the participant would be a good candidate for HRT. Consult with your PI as needed.
 Clinic Practitioner staff code
 Standard 3-digit WHI employee ID of the CP who overrides the BMI < 18 criterion for HRT.
15. Nutritionist override of BMI > 40 for DM
 BMI > 40 was removed as an eligibility criterion by council in March 1996. It is not necessary to use this question and WHILMA does not use this item in determining a woman's eligibility.
16. Nutritionist override of BMI < 18 for DM
 BMI < 18 override option for DM; this is independent of the BMI < 18 override for HRT that the CP completes in Question 13 above. A CP's decision to override the criteria (or not override the criteria) for HRT does not effect the Nutritionist answer for DM.
 If the Nutritionist determines that the participant should be eligible for DM even though she has a BMI < 18, mark "1 - Override" to override the ineligibility.
 Nutritionist staff code
 Standard 3-digit WHI employee ID of the Nutritionist who overrides the BMI < 18 criterion for DM.
17. Nutritionist override of meals away from home > 10 for DM
 If the Nutritionist determines that the participant should be eligible for DM even though she has ten or more meals prepared away from home each week, mark "1 - Override" to override the ineligibility. Before implementing the override, evaluate if having ten or meals prepared away from home each week will negatively impact her performance in the DM if she is randomized to Intervention. Consider the following:
- **Study goals.** Assess the woman's ability to meet the study goals. A woman who has ten or more meals prepared away from home each week will have difficulty reducing her fat intake to the level required for the study. Even if she reports that she can make low-fat choices when eating meals prepared away from home, it is unlikely that a woman who meets the eligibility criteria for fat intake (> 32% calories) will be able to accurately assess her ability to make the kind of choices necessary to meet the study goals.
 - **Lifestyle.** Assess if the woman's lifestyle is compatible with the demands of the study. The number of meals prepared away from home each week can indicate a woman's lifestyle and related ability to meet the demands of the study. Frequent meals prepared away from home may indicate a lifestyle that is too complicated or busy to accommodate the time commitment required for successful participation.

- **Willingness to change.** If a woman reports a willingness to change her “meals away from home” behavior, assess her reasons for having more than ten meals prepared away from home and evaluate whether they are, in fact, changeable. Women who report willingness to change current behavior are not necessarily appropriate candidates for DM. They may report willingness and/or desire for change, even if the change is unrealistic, in order to become eligible.
 - **Other.** Assess other pertinent criteria per Nutritionist discretion.
- Nutritionist staff code Standard 3-digit WHI employee ID of the Nutritionist who overrides the "Meals away from home > 10" criterion for DM.
18. Review *Form 2/3* at SV3 Review *Form 2/3* at SV3 using procedures and script described with *Form 2/3* instructions. Mark "1 - Reviewed" only after you have followed the script to review *Form 2/3* at SV3 (or same day you randomize the woman to DM and/or HRT or enroll her in OS).
19. Review at later date No/Yes. Interviewer assessment of need for later review of eligibility. Mark "0 - No" if the participant is ineligible and there is no reason to review the participant's eligibility at a later date. Mark "1 - Yes" if the woman is ineligible for any temporary reason and is willing to have you contact her in the future for possible participation.
- 19.1. Review date Date for later review.
- 19.2. Reason Specify reason for reviewing eligibility at a later date.
Data Entry: Do not key-enter the reason.
20. HRT pill counts Space to record HRT enrollment bottle adherence for CCs that do not do direct data entry of the HRT enrollment pill adherence.