
FORM:	16 - CALCIUM/VITAMIN D ELIGIBILITY ASSESSMENT
Version:	3 - December 15, 1997
Description:	Combined interview and staff assessment form, completed by Clinical Center (CC) staff; 1-page form; key-entered at CC.
When used:	At first annual visit.
Purpose:	To document eligibility and CC staff assessment of participant's eligibility for Calcium and Vitamin D (CaD) clinical trial.

GENERAL INSTRUCTIONS

1. Include form in annual visit file for CaD-eligible participants.
2. Affix a participant barcode label to the form.
3. Complete Items 1 - 4.
4. Ask the participant questions 5 - 9, using the script printed on the form. Stop the interview if any responses result in ineligibility for CaD (i.e., response arrow goes to "Ineligible" box).
5. Complete Items 10 - 11, recording eligibility assessment of expected good health and dementia. When evaluating good health, ask participant if she is on kidney dialysis. If she is on dialysis, she is ineligible. Refer to CP as appropriate.
6. Complete Items 12, recording staff assessment of the participant's eligibility for CaD.
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 CaD.
13. File the key-entered form in the participant's file.

Item Instructions

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| 1. | Date of contact | Date you initiated the form and started recording data on the form. This date should be between four weeks before and four weeks after the target annual visit date. |
| 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.
Mark the appropriate box and enter the visit number. (See common data items.) |
| 5. | Interest in CaD | No/Yes. Mark the appropriate box to indicate the participant's interest in joining CaD. If "No" (0) is marked, the participant is not eligible for CaD, and the interview can be stopped. |
| 5.1. | Vitamin D intake | No/Yes. Mark the appropriate box to indicate the participant's willingness to keep her daily use of vitamin D supplements (besides her study pills) to 600 IU or less. If "No" (0) is marked, the participant is not eligible for CaD, and the interview can be stopped. |
| 6. | Current corticosteroids | No/Yes. Mark the appropriate box to indicate whether or not the participant is currently taking any oral corticosteroids. Common oral corticosteroids are listed in <i>Vol. 2, Section 4.2.4.6. - Current Medications and Current Supplements Inventory Review</i> . If "Yes" (1) is marked, the participant is ineligible, and the interview can be stopped. |
| 7. | Calcitriol | No/Yes. If "Yes" (1) is marked, the participant is not eligible for CaD, and the interview can be stopped. |
| 8. | Kidney or bladder stones | No/Yes. Mark the appropriate box to indicate whether or not the participant has <u>ever</u> had kidney or bladder stones (i.e., renal or urinary calculi). If "Yes" (1) is marked, the participant is not eligible for CaD, and the interview can be stopped. |
| 9. | Hypercalcemia | No/Yes. Mark the appropriate box to indicate whether or not the participant has <u>ever</u> had hypercalcemia (i.e., high levels of calcium in her blood). If "Yes" (1) is marked, the participant is not eligible for CaD, and the interview can be stopped. |
| 10.-12. | Clinical and staff assessment | Ineligible/Eligible. Evaluate whether or not Clinic Practitioner (CP) referral is needed, based on changes in health or cognitive status since initial CT randomization.

If CP review is warranted, document appropriate information in the "Notes" box and refer the participant to the CP. If referred, the CP review should determine the participant's eligibility based on expected good health or dementia. When evaluating good health, specifically ask the participant if she is on kidney dialysis. If she is on dialysis, she is ineligible. Consult your Principal Investigator (PI) as needed for guidelines. CP assessment is an evaluation of the degree to which the participant's health and cognitive status meet the eligibility criteria as described in the protocol.

Mark "Ineligible" or "Eligible" as appropriate, and record the staff ID number (or CP ID number, if referral is made) in the space to the right of the boxes. If you mark "Ineligible," for either Question 10, 11 or 12, 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. |

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

10. Expected good health ≤ 3 years
- Ask the participant if she has had any changes in her health condition since she was randomized to CT. If the participant reports no changes and no CP review is needed, mark "Eligible" (1) and record your staff ID number.
- If the participant reports that a chronic illness has worsened, she has developed a new diagnosis, or you feel that CP review is needed, document the participant's report of her health changes in the "Notes" box and refer the form to the CP. The CP will determine if further evaluation of the participant is needed.
- 0 - Ineligible. Mark if, based on your clinical judgment, the participant's survival is ≤ 3 years due to her current health condition.
- 1 - Eligible. Mark if, based on your clinical judgment, the participant's expected survival is > 3 years despite her current health condition.
11. Dementia
- Ask the participant if she has noticed any changes in her ability to remember or think since she was randomized to CT. If the participant reports no changes and no CP review is needed, mark "Eligible" (1) and record your staff ID number.
- If the participant reports changes in her cognitive status or you feel that CP review is needed, document the concerns in the "Notes" box and refer the form to the CP. The CP will determine if further evaluation of the participant is needed.
- 0 - Ineligible. Mark if, based on your clinical judgment, the participant has developed a dementia.
- 1 - Eligible. Mark if, based on your clinical judgment, the participant's cognitive status is appropriate (e.g., participant is alert, oriented, and responds appropriately to questions).
12. Staff impression for CaD
- Mark "0 - Ineligible" if, based on your impression, the woman is not a good candidate for CaD **for reasons not captured in other eligibility data items**. (Make this determination regardless of the participant's eligibility or interest in CaD.) Otherwise, mark "1 - Eligible." If you mark "Ineligible," specify the reason in the Notes section. Record your staff ID number when you mark the answer.
- Data Entry: Do not key-enter the staff ID number.
- CaD formulation to be dispensed
- Based on the participant's expressed preference (see *Section 7.1.4.1 - CaD Study Pill Taste Test Procedure*), mark the appropriate box for the form of CaD - chewable or swallowable - to be dispensed to the participant.