
FORM:	28 – PARTICIPANT TREATMENT ASSIGNMENT: CaD
Version:	1 - October 1, 2004
Description:	Completed by Clinical Center (CC) staff as interview or by participant as a self-administered form; 2-page form (plus 1-page reason code sheet for staff); key-entered at CC.
When used:	At the close-out visit when you give the CaD participant her CaD treatment assignment.
Purpose:	To document information about stopping study pills, completing <i>Form 33 – Medical History Update</i> , and participant’s perceived treatment assignment before providing the CaD participant with her treatment assignment information

GENERAL INSTRUCTIONS

1. Administer as an interview or provide this form to the participant before she has received her treatment assignment information. However, if the participant insists on getting her treatment assignment information before completing this form, you should provide her with the appropriate information.
2. Once the form has been completed, run *WHIP9758 – CaD Study Treatment Assignment*. Provide one copy to the participant and file a second copy in the participant’s chart. Provide a copy of the report for her health care provider, if she requests one.
3. Review the form for completeness and forward to Data Entry.
4. Data Entry: Key-enter the form into WHILMA. See *Vol. 5 - Data System, Section 7.1 - Key-Entry* for specific instructions on how to key-enter this form. Initial the first page after key-entry.
5. File the key-entered form in the participant’s file.

Item Instructions

Date Received contact	Record the date that the interview is conducted with the participant or the date on which the participant is unblended (if self-administered).
Reviewed by	Standard 3-digit WHI employee ID of staff person completing the form.
Contact Type	Mark appropriate box. (See common data items.)
Visit Type	Contact for which the participant completed the form. Mark appropriate oval or box for visit type and number. (See common data items.)
Form Administration	Method used to administer form to participant: 1 - Self: Participant completed the form by herself. 2 - Group: Participant completed the form with a group of other participants. 3 - Interview: CC staff completed entire form as an interview. 4 - Assistance: Participant needed partial assistance from CC staff or others to complete the form.
1	<p>Stopped study pills No/Yes</p> <p>0 – No: If the participant says “No”, counsel the participant to stop her CaD study pills and discuss the importance of stopping study pills now that the trial is over.</p> <p>1 – Yes: Respond to the additional items about when study pills were stopped and what symptoms has the participant had since stopping.</p>
1.1	<p>Stopped before or during visit</p> <p>1 – Before: Mark if the participant says she stopped study pills at any time <u>before</u> the transition (close-out) visit.</p> <p>2 – During: Mark if the participant was taking study pills and then stopped them <u>at the transition (close-out) visit</u>.</p>
2.	<p>Filled out <i>Form 33</i> No/Yes. Record whether or not the participant says she has filled out the <i>Form 33 – Medical History Update</i> after receipt of the NHLBI letter.</p> <p>0 – No: If the participant says she has not completed <i>Form 33</i>, ask her to fill out a <i>Form 33</i> now by saying, “Why don’t you fill out the form now, while I get your treatment assignment information?” Hand the participant a <i>Form 33</i> with the appropriate “health problems and health care since” date filled in.</p> <p>1 – Yes.</p>
3	<p>Perceived treatment assignment Record which treatment arm the participant perceived she was assigned to <u>before</u> she stopped her study pills. If she names a treatment arm, ask her why she thought that (see below).</p> <p>1 – Active hormones</p> <p>2 – Inactive placebo pills</p> <p>9 – Don’t know</p>
Reason for perception	<p>Write in the reason the participant gives for thinking she was in the treatment arm she named. Text is not data entered.</p> <p>Refer to the <i>Reason Codes for Form 25</i> sheet and record the corresponding 2-digit reason codes for up to three reasons in the Office Use Box.</p>

Experienced Worsening Symptoms	<p>Record appropriate reason codes under this section if the participant says that she thought she was in a particular treatment arm because she had experienced worsening (or <u>new</u>) symptoms before she stopped study pills.</p> <ul style="list-style-type: none">1 – Bloating2 – Gas3 – Stomach upset4 – Heartburn5 – Constipation6 – Kidney Stones7 – Hypercalcemia18 – Other symptoms
Experienced Improvement in (or absence of) Symptoms	<p>Record appropriate reason codes under this section if the participant says that she thought she was in a particular treatment arm because she had experienced an improvement in (or absence of) symptoms before she stopped study pills.</p> <ul style="list-style-type: none">21 – Bloating22 – Gas23 – Stomach upset24 – Heartburn25 – Constipation26 – Kidney Stones27 – Hypercalcemia38 – Other symptoms
Other	<p>Record appropriate reason codes under this section if the participant says that she thought she was in a particular treatment arm because she had experienced other symptoms before stopping her study pills.</p> <ul style="list-style-type: none">41 – Told by family member or friend42 – Told by personal health care provider43 – Told by WHI staff44 – Read it on a report45 – Pill appearance, taste, or smell46 – Diagnosed with a medical condition88 – Other99 – Don't know