

WOMEN'S INTERAGENCY HIV STUDY

QUESTION BY QUESTION SPECIFICATIONS

DISENROLLMENT FORM

This form is to be completed for each WIHS participant who has died, has stated an interest in withdrawing completely from the study (WIHS core or oral substudy), or has been determined by the site to be ineligible for the study. It is recommended that if a site would like to disenroll a participant for the latter reason (ineligibility), the case be discussed with the Project Director. **This form should NOT be completed for participants who are considered lost to follow-up, incarcerated, too ill to participate, or who have moved.**

Enter the participant ID number or affix the appropriate ID label in the space provided.

Enter the initials of the person completing the form.

The form version is pre-printed. Be sure that you are using a current version (04/01/04) and that all unused, outdated versions have been discarded.

Enter the number of the visit during which the participant disenrolled. If the participant has completed a visit (core or abbreviated) and disenrolled during the same visit window, the visit number on the DENR form should be recorded as the visit after the participant's last completed visit. If visit data and disenrollment data are entered into the WDMS for the same visit number, information in the VISITS table may be overwritten.

Enter the date on which the form is being completed.

1. Circle "yes" or "no" for each applicable type of disenrollment.
2. Circle the code appropriate to the reason for the participant's disenrollment. If the participant has died, circle (1) and answer Question #3.

If the participant has decided to withdraw completely from the study, circle (2) and answer Question #6. This code should be circled when a participant informs the WIHS staff that she no longer intends to participate in the study and does not wish further contact by study staff. If, however, a participant does not want to attend a particular study visit but may complete a future visit, complete a Missed Visit Form instead of a Disenrollment Form.

If the site makes the decision to disenroll a participant, circle (3). This code should be circled if either 1) the participant has been enrolled into the cardiovascular substudy (i.e., CVNOTI form has been completed and data entered) and never had a baseline carotid ultrasound scan completed, or 2) the ultrasound reading center reports that the participant's baseline US scan was done incorrectly. Skip to Question #7.

3. Enter the date of the participant's death. If the exact day is unknown, use a "15" (representing mid-month). If only the year is known, use "06" for the month and "30" for the day (representing mid-year). The midyear should not be used if prior to a known diagnosis or visit. Code as the last day of the year. If the entire date is unknown, enter -8.
4. Circle "1" (yes) or "2" (no) to indicate what the source(s) of the initial information regarding a participant's death was. If "other," please specify. This information will not be data entered and is only collected to aid in the abstraction of the death.

- 5a. Enter the location where the participant died. If she died in a facility, enter the specific address. If she died at home, just write "HOME" to assure confidentiality. This information will not be data entered and is only collected to aid in the abstraction of the death.
- 5b. Enter the city or county where the participant died. This information will not be data entered and is only collected to aid in the abstraction of the death. End the form here.
6. Specify the reason for the participant's withdrawal (i.e., disinterest, moving, etc.) on the line provided. End the form here.
7. Specify the reason for the site's decision to disenroll the participant. For cardiovascular substudy participants, if the baseline carotid ultrasound was never done, or if the baseline US was done incorrectly, record this here. End the form here.