

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 substudies), 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.

NOTE: 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 WIHSID 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 Be sure that you are using a current version and that all unused, outdated versions have been discarded.

Enter the number of the visit during which the participant disenrolled. This should be the visit number during which the disenrollment/death occurred, not the visit number during which the disenrollment/death was discovered.

If the participant has completed a visit (core or abbreviated) and disenrolled during the same visit window, the visit number on the *Disenrollment* (DENR) *Form* should be recorded as the visit after the participant's last completed visit. If visit data and disenrollment data are entered into Apollo 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, from WIHS core or selected substudies. If the participant disenrolls from a substudy not listed on the form, circle "yes" for "other substudy" and indicate the substudy in the specify field.
2. Circle the code appropriate to the reason for the participant's disenrollment. If the participant has died, circle (1) and proceed to **Question #3**.

If the participant has decided to withdraw completely from the study, circle (2) and skip to **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* (MVIS) *Form* instead of a *DENR*.

If the site makes the decision to disenroll a participant, circle (3). For participants disenrolling from the cardiovascular substudy, this code should be circled if either (1) the participant has been enrolled into the cardiovascular substudy (i.e., *CVNOTI* 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**.

If a participant at the Brooklyn site is deactivated for WIHS-V, circle (4). Skip to **Question #8**.

If a participant at any site other than Brooklyn is deactivated due to travel distance to the clinic (i.e., costs to attend visit exceed \$400), circle (5). Skip to **Question #8**.

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. Skip to **Question #8**.
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. Proceed to **Question #8**.
8. Indicate whether or not registry follow-up is permitted by the participant after her deactivation or disenrollment.