

WOMEN'S INTERAGENCY HIV STUDY

SECTION 17: INTERIM EVENTS PROTOCOL

A. OBJECTIVES

1. To increase ascertainment of important outcomes including AIDS-defining events, malignancies, tuberculosis (non-AIDS defining among HIV-negative participants), death, and specific chronic disease conditions.

NOTE: Starting at visit 17, the interim events protocol became optional. Starting at visit 21, the protocol was discontinued entirely.

2. To provide additional contact with WIHS staff to enhance long-term retention.

B. PARTICIPANT ELIGIBILITY AND ENROLLMENT

Enrollment of participants into the Interim Events Protocol will begin at WIHS visit 10. Those participants with CD4 < 200 at visit 10 will be eligible for participation in the Protocol and will be contacted approximately halfway between visit 10 and visit 11. Additionally, those participants who report CD4 < 200 at subsequent visits will be contacted approximately halfway between the visit at which CD4 < 200 and their next scheduled visit.

C. SURVEILLANCE

1. ACTIVE SURVEILLANCE

- 1) The site will generate a list of women who had CD4 < 200 (by WIHS laboratory) at the last WIHS visit. It is recommended that each month the data manager generate a list of which women need to be called that month and send the list to the appropriate subsite.
- 2) Interim events phone calls should occur at approximately the midpoint between WIHS visits, i.e., three months after the WIHS core visit.
- 3) The staff member who initiates the call will keep a log of calls made and their outcomes (i.e., reached patient, left message). The staff member will make at least three attempts to call each participant during different times of the day and week.
- 4) The staff member should have the Interim Events Form, an Ascertainment Tracking Checklist (ATC) and a Disenrollment Form on hand.
- 5) Each AIDS-defining illness or cancer reported by the woman should be noted on the Interim Events Form and the date and location of the event on the ATC.

2. PASSIVE SURVEILLANCE

When a woman, family member or clinician calls the WIHS site to report an event, the same procedures will be followed as above, with the appropriate notation made on the Interim Events Form, question #1.

D. ASCERTAINMENT

1. DEATHS

If the person answering the phone volunteers that the participant has died, the WIHS staff member will fill out a Disenrollment Form and note the death on the ATC. The Interim Events

Form in this case will only be used to note whether the death was reported through active or passive surveillance and who reported the death.

For women who have died, a consent form should be mailed to a family member for permission to abstract any charts pertaining to the death. If the form is not mailed back within a month, a second attempt should be made. The Outcomes Ascertainment Protocol will be followed in the ascertainment of the reported death.

2. EVENTS

Events reported through interim phone calls will be treated like self-reported events reported during the regular WIHS visit. Some confirmation of reported event(s) is necessary; usually this will involve medical record abstraction.

- 1) The interviewer at the next WIHS visit will be provided with a list of abstractable events reported from the interim phone call and make sure that consents are obtained for each event after the core interview has been completed.
- 2) After consent has been obtained, abstraction should proceed just as it does for events reported during the WIHS core visit.
- 3) Abstraction for the interim phone call and the subsequent core visit should occur in tandem so that events reported both on the phone call and at the core visit are not abstracted twice. An Ascertainment Control Sheet (ACS) should be completed for both contacts – the ACS for the core visit should be coded with the appropriate disposition code for whether the event was abstracted or not, and the ACS for the interim contact should be coded as “7” (event abstracted elsewhere).
- 4) Events ascertained through interim phone calls will be flagged in the database so those analyzing data can choose whether to use them.

If the participant does not return for her next WIHS visit following the interim contact, a consent form should be mailed to the participant for permission to abstract any charts pertaining to the reported interim events. If the form is not mailed back within a month, a second attempt should be made.