

<p>WOMEN'S INTERAGENCY HIV STUDY QUESTION BY QUESTION SPECIFICATIONS ASCERTAINMENT TRACKING CHECKLIST (ATC)</p>
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The Ascertainment Tracking Checklist (ATC) and the ACSR ATC are to be completed by the interviewer during administration of the F22HX form when an ascertainable event (either diagnosis or procedure) is reported by the participant.

- A1. WIHS ID:** This is the identification number assigned to the participant at the time of the screening visit.
- A2. WIHS Study Visit #:** This field indicates the WIHS visit number at which the participant reported the event to the interviewer.
- A3. Form Version:** The form version is pre-printed on the form.
- A4. Form Completed By:** Enter the initials of the person completing the form.
- A9.** Circle “1” (yes) or “2” (no) to indicate whether or not the WIHS site has obtained a signed medical record release from the participant.
- A10.** Use A10, columns b–e, as a checklist during administration of the interview to indicate where to collect further information from self-reported events.

Column b: Write in the event (either diagnosis or procedure) self-reported during the interview. If the participant indicates that she had more than one episode of the reported event (e.g., had bacterial pneumonia diagnosed three times since her last study visit), each episode reported should be listed on a separate line of the table.

Column c: Write the form number and question number during which the event was self-reported.

Column d: Write the date of diagnosis or procedure since the participant’s last study visit. If the participant reports more than one episode of a single event, a date should be provided for each occurrence.

Column e: Write the name of the provider and the address of the institution at which the self-reported event can be confirmed. If the participant reports more than one episode of a single event, the provider’s name and the institution’s address should be provided for each occurrence.

NOTE: Multiple episodes of an event must be clearly delineated on the ATC.

DATA ENTRY INSTRUCTIONS:

If the same self-reported event is listed on the ATC multiple times, enter in Column e “multiple locations – see ATC.”

ABSTRACTION INSTRUCTIONS:

During abstraction, when you encounter an Apollo ATC Report with the location listed as “multiple locations – see ATC,” you will need to manually review the paper ATC to obtain the date of event, the provider’s name and the institution’s address for each episode of that event during the visit window. Each self-reported event should be abstracted, with a CORE Form completed for each confirmed episode of AIDS, cancer, TB or cardiovascular disease. No CORE Form will be completed for confirmed biopsies.

APOLLO ASCERTAINMENT TRACKING CHECKLIST (ATC) REPORT:

The Apollo Ascertainment Tracking Checklist Report is a form generated by Apollo upon entry of ascertainable events into F22HX (Follow-up Health History) or the Disenrollment Form (DENR), and additional data into the Ascertainment Tracking Checklist (ATC) and ACSR ATC.

Data from the Apollo ATC Report should be entered into Apollo on site. For **all confirmed events**, the site clinician should complete a Clinical Outcome Reporting (CORE) Form. If a diagnosis cannot be confirmed, due to inability to obtain relevant medical records or other reasons (i.e., A11 = 4, 5, 6, 8 or 9), or is not confirmed after review of medical records (i.e., A12 = 2), do not complete a CORE Form, but continue to enter the Apollo ATC Report locally.

No CORE Form will be completed for biopsies. For **liver biopsies**, a copy of the pathology report will be obtained and sent to WDMAC for central review. The central reviewer will complete a copy of the Liver Biopsy Abstraction (QCLB) Form. For **other biopsies**, the site should attempt to collect and donate biopsy specimens as per the ACSR protocol.

The following guidelines are for reference when completing the Apollo Ascertainment Tracking Checklist (ATC) Report. PLEASE PRINT LEGIBLY WHERE APPLICABLE.

- A1. WIHSID:** This is the identification number assigned to the participant at the time of the screening visit. This field will be automatically entered in the Apollo ATC Report.
- A2. WIHS Study Visit Number:** This is the number of the visit at which the event was reported. The visit number will be automatically entered in the Apollo ATC Report.
- A3. Form Version:** The form version will be automatically entered in the Apollo ATC Report.
- A4. Form Completed By:** The initials of the interviewer who completed the ATC form should be entered in this field.
- A5. Cohort:** This field denotes the participant's HIV status. "1" indicates that the woman is seronegative. "2" indicates that the woman is seropositive. "4" indicates that the woman is a seroconverter. This field will be automatically entered in the Apollo ATC Report.
- A6. Tracking Number:** The Event Tracking Number (ETN) is a unique number assigned to each self-reported event. The ETN will be automatically entered in the Apollo ATC Report. The ETN should be recorded on the CORE Form for all confirmed self-reported events to provide a link between the ATC and the CORE Form.
- A7. Visit Date:** This field denotes the end of the abstraction window. It is the date of the interview during which the participant reported the event. This field will be automatically entered in the Apollo ATC Report.
- A8. Previous Visit Date:** This field denotes the start of the abstraction window. It is the date of the interview prior to the one at which the participant reported the event. This field will be automatically entered in the Apollo ATC Report.
- A9. Medical Record Release:** Circle "yes" (1) or "no" (2) to indicate whether the WIHS site has the participant's signed medical record release.
- A10. a. Disease Code:** This field refers to the numeric code from the Disease Code List that is associated with the reported event. This field will be automatically entered in the Apollo ATC Report. The Disease Code List can be found in the WIHS Manual of Operations, Section 12, Appendix B.
b. Self-reported condition: The event reported by the participant will be pre-printed in this area. This information is taken from the Ascertainment Tracking Checklist (ATC) or the ACSR ATC. This field will be automatically entered in the Apollo ATC Report.

- c. **Form and Question Number:** The form and question number associated with the event will be pre-printed in this area. This information is taken from the ATC / ACSR ATC. This field will be automatically entered in the Apollo ATC Report.
- d. **Date of First Diagnosis Since (MONTH) Study Visit:** The date of the event (diagnosis or procedure) will be pre-printed in this area. This information is reported by the participant and recorded on the ATC / ACSR ATC by the interviewer. This field will be automatically entered in the Apollo ATC Report.
- e. **Name of Provider/Address of Institution:** The provider name and address of institution will be pre-printed in this area. This information is reported by the participant and recorded on the ATC / ACSR ATC by the interviewer. This field will be automatically entered in the Apollo ATC Report.

NOTE: If the Apollo ATC Report is printed before the Ascertainment Tracking Checklist (ATC) or ACSR ATC has been data entered, the form and question number, the date of first diagnosis, and the name of provider/address of institution will not be pre-printed on the Apollo ATC Report.

A11. Ascertainment Disposition: Circle one code to indicate whether a medical record was obtained for the specified event during the reported period. If a medical record from the specified time period was obtained, 1, 2 or 3 must be circled. If a medical record was found but it is outside the specified time period (in other words, no record was found for the specified time period), 4 must be circled. If the medical record was not obtained and therefore not abstracted, circle either 4, 5, 6, 8 or 9. If the event is abstracted on another Apollo ATC report, circle code 7. If codes 4, 5, 6, 7, 8 or 9 are circled, no CORE Form should be completed for the event.

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| 1 | No written request/within institution | If the medical record reported on the Apollo ATC Report is within the same site as the staff and they are able to verbally ask the primary care provider for the chart without a written request, circle this code. |
| 2 | Obtained via written permission | If the medical record on the Apollo ATC Report was requested in writing and <u>sent</u> to the site, circle this code. |
| 3 | Obtained via in-person visit or phone call | If the abstractionist visited the institution to obtain the medical record on the Apollo ATC Report, or if the event was confirmed via a phone call with the participant's clinician, circle this code. |
| 4 | No record (for the specified time period) on file | Use this code when all possibilities have been exhausted to locate the medical record and it cannot be obtained. If this code is circled, skip to question A13. |
| 5 | Record not released | Use this code if the institution refuses to release the record, either through the mail or by allowing the staff to visit the Medical Record Department. If this code is circled, skip to question A13. |
| 6 | Event date out-of-range | Use this code if you receive an Apollo ATC Report where the Date of First Diagnosis Since (MONTH) Study Visit is beyond the scope of the protocol. This includes any illness or cancer reported as occurring before 1980. In these cases, the staff should not request the record and should circle this code. If this code is circled, skip to question A13. |

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| 7 | Event ascertained elsewhere | Use this code when the event has been reported on another Apollo ATC Report. If this code is circled, skip to question A13. |
| 8 | Unable to request record | Use this code when the record cannot be requested because the information on the Ascertainment Tracking Checklist is incomplete and/or the record is unobtainable (e.g., an overseas hospitalization, a diagnosis which was never treated by a physician). This should be coded after <u>all</u> efforts to recontact the participant and/or obtain the missing data have been exhausted. If this code is circled, skip to question A13. |
| 9 | Other reason event not ascertained | Use this code when the event is not ascertained via medical record abstraction for a reason other than those listed above, e.g., event is ascertained solely via registry match, event is a duplicate report that was not ascertained, event was dropped from outcomes protocol before abstraction was completed, etc. |

A12. Was Event Ascertained: The purpose of this question is to track whether a self-reported diagnosis is confirmed from the medical records – not whether or not the medical records were found. This question relates to the self-reported diagnosis in question A10a/A10b only. If additional unreported diagnoses are found during the ascertainment of a self-reported event, complete a CORE Form for each additional event found. No additional Apollo ATC Report should be generated for events discovered through passive surveillance.

Always circle “1” for this question if the pathology report for a liver biopsy was obtained and sent to WDMAC for central review. Always circle “1” for this question if the biopsy specimen for ACSR donation was obtained and sent to the ACSR. Do not complete a CORE Form for any confirmed biopsies.

A13. Medical Record Completed By: Enter the initials of the medical record abstractionist.