

WOMEN'S INTERAGENCY HIV STUDY QUESTION BY QUESTION SPECIFICATIONS CLINICAL OUTCOME REPORTING FORM

The following guidelines are for reference when completing the WIHS Clinical Outcome Reporting (CORE) Form. PLEASE PRINT LEGIBLY WHERE APPLICABLE. Place the participant's valid WIHS identification number on each page where requested.

GENERAL INFORMATION

Event tracking number:

Print the event tracking number of the self-reported event. This eight-digit number can be found on the Ascertainment Tracking Checklist (ATC) and consists of the following: 1st digit – site number, remaining digits – unique tracking number.

If the CORE Form is being completed for an event discovered through active (i.e., registry match) or passive surveillance, no ATC will be generated for the event and the Event Tracking Number field should be left blank. In this case, data entry staff will enter “-1” into the field.

Reason for status change:

Circle all reasons that apply to describe the participant's status change.

- a) If the form is completed to report a participant's AIDS diagnosis, circle “1” and complete Section A (Source of Information) and Section B (Clinical Diagnosis). If the initial AIDS diagnosis is of a malignancy (i.e., Kaposi's sarcoma, brain lymphoma, non-Hodgkin's lymphoma, brain metastasis), also circle “2.”

Additionally, if the form is completed to report a single episode of bacterial pneumonia, circle “1” and complete Section A and Section B. It will be determined through analysis whether a participant had AIDS-defining bacterial pneumonia.

- b) If there is information on this report which pertains to a malignancy diagnosis (AIDS-related or non-AIDS-related), circle “2” and complete Section A (Source of Information) and Section B (Clinical Diagnosis). If it is an AIDS-related malignancy, also circle “1.”
- c) If the form is completed to report a diagnosis of tuberculosis, circle “3” and complete Section A (Source of Information) and Section B (Clinical Diagnosis).
- d) If the form is completed to report mortality information, circle “4” and complete Section A (Source of Information) and Section C (Information Relevant to Death). If an AIDS-related condition was found through death certificate abstraction, also circle “1” and complete Section B (Clinical Diagnosis) to report this condition.
- e) If the form is completed to report a chronic disease (non-HIV) diagnosis, circle “5” and complete Section A (Source of Information) and Section B (Clinical Diagnosis). The only chronic disease conditions currently reported on the CORE form include: Myocardial Infarction (MI, heart attack), Stroke (cerebral vascular accident, CVA), Congestive Heart Failure (CHF), and Hepatitis/Liver Disease. If the chronic disease diagnosis reported on the CORE Form is hepatitis/liver disease, Section D (Detailed Liver Abstraction Addendum) should also be completed.

NOTE: For diagnoses based on death information (i.e., death certificate alone or autopsy), if information is given on more than one AIDS-related condition, additional CORE Form(s) should be completed as applicable.

SECTION A. SOURCE OF INFORMATION

- A1. Circle only ONE code (1–10) to indicate the source of information for the event being reported. If there are multiple sources of information, complete an additional CORE Form for each source of information. If registry match or “other source” was the source of the reported information, specify the source on the line provided. Additionally, if registry match was the source of the reported information, complete Question A2. Otherwise, skip to Section B.

NOTE: Code three was specifically removed from the form when that response was deleted so that the other codes would remain compatible with previous versions of the form.

When transcribing information regarding prior abstractions from NERI MRA forms, circle code “1” (copy on file) when you requested the record (usually from an outside institution), you received a copy, filled out the CORE Form and then saved the copy of the record you received. Circle code “2” (copy not on file/abstracted) if you held the original chart in your hand (either you were in your home institution or you made an in-person visit someplace else), made no copies from it and abstracted the information from it.

- A2. Circle one code to indicate the registry search criteria used, if registry match was the source of the reported information. If “other,” specify the criteria used.

SECTION B. CLINICAL DIAGNOSIS

Complete a separate CORE Form for each clinical diagnosis reported.

- B1. Enter the date of diagnosis here using format MMDDYY where MM is the month, 01 = January, ..., 12 = December. DD is the day, from 01 = 1st day, ..., 31 = 31st day, and YY is the last 2 digits of the year, i.e., 90 = 1990, 91 = 1991. 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). If the entire date is unknown, check the box indicating it is missing.

For ascertainment of bacterial pneumonia only one ATC form will be generated per visit regardless of the number of episodes self-reported within the past year or since the participant’s last study visit. However, a separate CORE Form should be completed for each unique episode of bacterial pneumonia that is confirmed to have occurred since the participant’s last visit. All CORE Forms completed for self-reported bacterial pneumonia during a visit window will share the same event tracking number as that on the generated ATC. During analysis, bacterial pneumonia will only be considered as AIDS-defining when two or more instances have been confirmed in a one-year period.

- a. Write the name of the facility at which the participant was diagnosed. This may differ from the facility or institution listed on the ATC form (question A6d) if the participant named the wrong facility during her interview. If so, record the actual facility at which the diagnosis was received in this question.
- b. Record the address of the facility or institution named in question B1b above.
- B2. Print the clinical diagnosis on this line. Diagnoses for which the Outcomes Ascertainment Protocol requires ascertainment can be found in Appendix B of Section 12 of the Manual of Operations.
- a. If the disease reported in question B2 is metastatic cancer, record the body location to where the cancer has metastasized in question B2a. If metastatic disease is diagnosed and reported sometime after the primary cancer, review your records to ensure that the primary cancer was confirmed, also. If both primary and metastatic cancers were reported at the same visit, an ATC will be generated for each. If both are confirmed, attach a completed CORE Form to each

respective ATC. If only the primary cancer was reported, only one ATC will be generated. If you confirm primary cancer and also find documentation of metastatic cancer, attach two CORE Forms with the same Event Tracking Number to the ATC for the primary cancer.

If any disease other than metastatic cancer is reported in question B2, record “-1” for question B2a and skip to question B3.

- B3. Enter the disease code corresponding to the clinical diagnosis here. These codes can be found in Appendix B of Section 12 of the Manual of Operations.

If the disease code recorded in question B3 ≠ 101 (cervical cancer) or 110 (other cancer), skip question B3a and proceed to question B4.

CD4 cell counts < 200 or CD4 % < 14% (code 245) or general “AIDS” (code 220) are not abstracted from self-report, but are collected and reported only when obtained from registry matches.

Disease code 170 (MAI/MAC) should be reported on the CORE Form when a registry match is made for the combined events “MAI/MAC/M. Kansasi.” Disease code 165 (CMV elsewhere in body) should be reported when a registry match is made for “Disseminated CMV.” Disease code 124 (TB elsewhere in body) should be reported when a registry match is made for “extra-pulmonary TB.” Disease code 175 (cryptococcal infection in blood or elsewhere) should be reported when a registry match is made for “cryptococcal infection.”

Disease code 221 (AIDS at death) should be entered when “AIDS” is listed as a cause of death on the participant's death certificate, but no specific AIDS-related conditions are reported.

Disease code 330 (heart disease, non-specified) should not be reported on the CORE Form. This code was printed on the ATC form when a participant self reported “any other heart disease” on F22 during visit 13; however, a CORE Form should only be completed if during abstraction it is determined that the participant was diagnosed with one of the reportable heart conditions (i.e., myocardial infarction – 331; congestive heart failure – 332; stroke – 333). Beginning with visit 14, ATC forms will no longer be generated for disease code 330.

- a. If the disease code in question B3 = 101 or 110, and the disease recorded in question B2 = anal or cervical cancer, indicate if the cancer is in situ.

PROMPT: IF DISEASE CODE = 320 (HEPATITIS/LIVER DISEASE), COMPLETE SECTION D OF THIS FORM (DETAILED LIVER DISEASE ABSTRACTION ADDENDUM).

- B4. Enter the method(s) of diagnosis here. Up to THREE different methods may be coded.

If bronchoscopy was used to diagnose PCP without further differentiation to cytology or biopsy, code as if cytology was performed.

Note that “necropsy” can only be a method for a diagnosis made from an autopsy report and should be used as a confirmation of at least one other method of diagnosis.

For AIDS-related diagnoses which are based on death alone (i.e., no autopsy confirmation), the method of diagnosis should be “reported on death certificate.”

If the diagnosis is based on registry match, code as “no confirmation/clinician report.” During analysis, diagnoses obtained via registry match will be distinguished from others through the response to Question A1.

If the CORE Form is being completed to report a heart disease or hepatitis/liver disease diagnosis (i.e., disease codes 331, 332, 333, 320), this question should be coded as “no confirmation/clinician report.” This is because ascertainment of these events is based solely on

finding the diagnosis clearly stated in the participant's chart; no supporting documentation in the chart is needed.

B5. Consult the WIHS Criteria for Clinical Diagnoses in Appendix A of Section 12 of the Manual of Operations and then enter the category which best describes the confidence of diagnosis for the condition ascertained and reported on the CORE Form:

1. Definitive – If the record reflects that the criteria outlined in the “definitive” column were met in making the diagnosis, circle “1.”
2. Presumptive – If the definitive standard was not met, the diagnosis may be made presumptively by meeting a lesser standard. These criteria are outlined in the “presumptive” column. Note that some diagnoses can only be made definitively. For those diagnoses determined to be presumptive, circle “2.”
3. Indeterminate – This must be selected when the method of diagnosis is “no confirmation/clinician report” (this includes registry match and chronic disease diagnoses) or “reported on death certificate” (i.e., B4 = 8 or 9). It should not be selected if any other method of diagnosis is reported in question B4.

NOTE: If a participant has at least one “definitive” AIDS diagnosis, then her status on file will be “definitive,” regardless of subsequent “presumptive” diagnoses.

SECTION C. INFORMATION RELEVANT TO DEATH

NOTE: If a participant dies, sites are responsible for finding and abstracting the participant's death certificate. All items in Section C should be completed.

- C1. Enter the date of death using format MMDDYY where MM is the month, 01 = January, ..., 12 = December. DD is the day, from 01 = 1st day, ..., 31 = 31st day, and YY is the last 2 digits of the year, i.e., 90 = 1990, 91 = 1991. 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, check the box indicating it is missing.
- C2. 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.
- C3. Circle the code corresponding to the participant's place of death. If the place of death is “other location,” specify the place of death on the line provided, but do not give an address of a personal residence (be careful about protecting participant confidentiality).
- C4. On the lines provided specify the: a) county, b) city, c) state, and d) country of death. If the participant died in a country other than the U.S., fill in the lines that apply and record -1 for the fields that are not applicable/not available.
- C5. Circle the code corresponding to the participant's manner of death.
- C6. Enter the immediate cause of death, any underlying cause(s) of death, and any other significant condition(s). If the specific cause is unknown, write “unknown.”

If during the abstraction of a participant's death certificate, the cause of death is found to be AIDS-related, sections A, B and C of the CORE Form should be completed with the AIDS-related cause of death reported in Section B. All AIDS-related causes of death listed on the death certificate should be reported on a CORE Form, regardless of whether or not they have been previously reported.

Additionally, if during the abstraction of a participant's death certificate, the cause of death is found to be MI, stroke or CHF, sections A, B and C of the CORE Form should be completed with the heart disease reported in Section B. If the cause of death is found to be hepatitis/liver disease, sections A, B, C and D of the CORE Form should be completed. Causes of death listed on the death certificate that are reportable chronic diseases should be reported on a CORE Form, regardless of whether or not they have been previously reported.

An additional CORE Form should be completed for each additional AIDS-related or chronic disease cause listed. For example, if two AIDS-related conditions are listed as causes of death, one condition would be reported on the CORE Form that reports the participant's death. The second condition would be reported on a second CORE Form completed for that event only. Or, if one AIDS-related condition and one chronic disease condition are listed as causes of death, one condition would be reported on the CORE Form that reports the participant's death, with the other reported on a second CORE Form. The same event tracking number should be written on all CORE Forms that report causes of death for one participant. This will allow for easy tracking of those events confirmed through death certificate abstraction.

Fields for recording ICD-9 codes have been removed from the CORE Form. Please enter “-1” into these fields in the WDMS.

- C6i. Enter the total number of underlying cause(s) of death recorded in question C6.
- C6ii. Enter the total number of other significant conditions recorded in question C6.
- C7. Circle the appropriate category indicating whether or not an autopsy was performed.

SECTION D. DETAILED LIVER ABSTRACTION ADDENDUM

PROMPT: COMPLETE THIS ADDENDUM IF THE RESPONSE TO ANY OF QUESTIONS C34a (fatty liver); C34b (alcoholic liver disease); C34c (cirrhosis); C34ci (ascites); C34cii (varicies); C34ciii (hepatic encephalopathy); C35 (new diagnosis of hepatitis C); C38 (recommended for liver biopsy); or C40 (liver transplant) = YES.

- D1. Indicate whether serologic evidence was found in the participant's medical record to indicate a new hepatitis C infection.
- D2. Indicate if there was a clinical diagnosis of an acute, symptomatic hepatitis C infection.
- D3. Indicate if there was a clinical diagnosis of cirrhosis.
- D4. Indicate if there was a clinical diagnosis of any other liver disease. If YES, write the diagnosis in the specify field in question D4a. If NO, skip to the prompt following question D4a.

PROMPT: IF ALL OF QUESTIONS D1–D4 = NO, SKIP TO END OF FORM. OTHERWISE, IF ANY OF D1–D4 = YES, PROCEED TO QUESTION D5.

- D5. If the participant has been diagnosed with any of the conditions listed in questions D1–D4, indicate whether or not any of the symptoms listed in subquestions D5i – D5n and D5s – D5u were mentioned in the participant's medical record. If D5t (liver biopsy) is “yes,” complete the Liver Biopsy Abstraction Form and an ACSR ATC.