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 15-digit number can be found on the ***Ascertainment Tracking Checklist*** (ATC) and consists of the following: the first eight digits are the participant's unique **WIHSID** number, the next two digits are the **visit number**, the next three digits are the **disease code**, and the last two digits are the **sequence digits**.

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."

b) If there is information on this report that 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.

NOTE: For diagnoses based on death information (i.e., death certificate alone or autopsy), if information is given on more than one ascertainable events, 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 "3" 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.

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*** (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 a cancer or TB, record the primary site of disease in Question B2a. If any disease other than cancer or TB is reported in Question B2, record "-1" for Questions B2a and B2b and skip to **Question B3**.

b. If the disease reported in Question B2 is a cancer or TB, record the additional site of disease in Question B2b. If there is no additional site of disease, record "-1" for Question B2b and skip to **Question B3.**

> **NOTE:** 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.

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 is NOT a tumor or cancer (i.e, disease code does NOT equal 101 through 112), skip to **Question B4**.

a. If the disease code in Question B3 is a tumor or cancer (i.e., disease code equals 101 through 112), indicate if the tumor is benign, in situ or malignant.

b. If the disease code in Question B3 is a tumor or cancer, indicate the histology type (e.g., adenocarcinoma, squamous cell, etc.).

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

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 ascertainable events that 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.

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) or "reported on death certificate" (i.e., Question 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." Underlying cause(s) of death will be recorded in COREs1. Other significant condition(s) will be recorded in COREs2.

If during the abstraction of a participant's death certificate, the cause of death is found to be an ascertainable event, Sections A, B and C of the ***CORE Form*** should be completed. All 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.

An additional ***CORE Form*** should be completed for each additional ascertainable disease cause listed. For example, if two ascertainable events 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. 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.

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.