

WOMEN'S INTERAGENCY HIV STUDY
CLINICAL OUTCOME REPORTING FORM

ID LABEL
HERE ---> | - | | | - | | | | | - | |

FORM COMPLETED BY:
____ _

VERSION DATE: 04/01/01

DATE OF THIS REPORT: ___ ___ / ___ ___ / ___ ___
 M D Y

EVENT TRACKING NUMBER: ___ ___ ___ ___ ___ ___ ___ ___
(from ACS)

REASON FOR STATUS CHANGE (circle all that apply):

- a. AIDS diagnosis
 Complete sections A & B 1

- b. Malignancy
 Complete sections A & B 2

- c. Tuberculosis
 Complete sections A & B 3

- d. Mortality
 Complete sections A & C 4

- e. Chronic disease (non-HIV) diagnosis
 Complete sections A & B 5

NOTE: *If chronic disease diagnosis = hepatitis/liver disease
(i.e., disease code = 320), also complete Section D of this form.*

WIHS ID #

SECTION A. SOURCE OF INFORMATION

A1. SOURCE OF INFORMATION – Circle ONE source of information for this event. If there are multiple sources of information, complete additional CORE Forms.

Medical Records:

- a. Copy on file 1
- b. Copy not on file/Abstracted 2

Death Certificate 4

Autopsy 5

Registry Sources:

- a. AIDS Registry 6

Source: _____

- b. Cancer Registry 7

Source: _____

- c. TB Registry 8

Source: _____

- d. Death Registry 9

Source: _____

Other Source 10

Source: _____

PROMPT: IF SOURCE OF INFORMATION IS REGISTRY MATCH (A1 = 6, 7, 8 OR 9), COMPLETE A2 BELOW. OTHERWISE, SKIP TO SECTION B.

A2. Registry Search Criteria (circle one):

- Whole cohort 1
- HIV+ 2
- Medical release and self-report 3
- Medical release only 4
- Other 5

Specify: _____

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[Empty box for WIHS ID #]

SECTION B. CLINICAL DIAGNOSIS

Complete a separate CORE Form for each unique diagnosis.

B1. Date of Diagnosis *(If date of diagnosis is unknown, check the box to indicate it is missing.)*

____ / ____ / ____
M D Y

Missing

B2. Disease *(Print diagnosis.)*

a. If Disease (question B2) = metastatic cancer,
to what body location has cancer metastasized?
*(If Disease ≠ metastatic cancer,
enter “-1” in question B2a.)*

B3. Disease Code *(See Manual of Operations, Section 11, for list of disease codes.)*

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

B4. Method(s) of Diagnosis *(Circle the code(s) for up to THREE methods of diagnosis.)*

- Histology at biopsy 1
- Necropsy 2
- Cytology 3
- Culture 4
- Serology 5
- Clinical Diagnosis 6
- Radiology (MRI, imaging, etc.) 7
- No confirmation/clinician report 8
- Reported on death certificate 9
- Unknown, other diagnosis -9

B5. Confidence *(“Indeterminate” should be circled if B4 = 8 or 9. See CORE Form QxQs.)*

- Definitive 1
- Presumptive 2
- Indeterminate 3

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SECTION C. INFORMATION RELEVANT TO DEATH

Complete all items in this section.

C1. Date of death *(If date of death is unknown, check the box to indicate it is missing.)*

____ / ____ / ____ Missing
 M D Y

C2. Source of initial information about death *(Circle yes or no for each.)*

	<u>YES</u>	<u>NO</u>
a. Report of family/friends	1	2
b. Hospital	1	2
c. Death certificate search	1	2
d. Obituary notice	1	2
e. Report from health care provider or social service provider	1	2
f. AIDS surveillance	1	2
g. Other source	1	2

Specify: _____

C3. Place of Death *(Circle one.)*

- Hospital (Inpatient) 1
- ER/Outpatient 2
- Nursing Home 3
- Hospice/Extended Care Facility 4
- Residence 5
- Other location 6

Specify: _____

C4. Location of Death

- a. County: _____ b. City: _____
- c. State: _____ d. Country: _____

C5. Manner of Death *(Circle one.)*

- Natural 1
- Accident 2
- Suicide 3
- Homicide 4
- Pending investigation 5
- Could not be determined 6
- Not stated on certificate 7

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C6. Causes of death (*If causes of death are unknown, list as "unknown."*)

Condition
(*print diagnosis*)

Immediate Cause: _____

Underlying Cause(s): (a) _____

(b) _____

(c) _____

(d) _____

(e) _____

(f) _____

(g) _____

Other Significant Conditions: (a) _____

(b) _____

(c) _____

(d) _____

(e) _____

(f) _____

(g) _____

C7. Autopsy performed:

Yes 1

No 2

Don't know -8

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SECTION D. DETAILED LIVER ABSTRACTION ADDENDUM

PROMPT: COMPLETE THIS ADDENDUM ONLY IF THE RESPONSE TO QUESTION B3 = 320 (HEPATITIS/LIVER DISEASE).

D1. Is there serologic evidence of a new Hepatitis C virus infection?

- Yes 1
- No 2

D2. Is there a clinical diagnosis of an acute, symptomatic Hepatitis C syndrome?

- Yes 1
- No 2

D3. Is there a clinical diagnosis of cirrhosis?

- Yes 1
- No 2

D4. Is there a clinical diagnosis of other liver disease?

- Yes 1
- No 2 (PROMPT)

a. SPECIFY: _____

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. In the notes referring to any of the above diagnoses is there mention of:

	<u>YES</u>	<u>NO</u>
a. Nausea and/or vomiting	1	2
b. Abdominal pain	1	2
c. Decreased appetite	1	2
d. Fever	1	2
e. Myalgia (muscle aches)	1	2
f. Pruritus (itching)	1	2
g. Weight loss	1	2
h. Malaise	1	2
i. Jaundice (yellow skin/eyes)	1	2
j. Enlarged liver	1	2

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	<u>YES</u>	<u>NO</u>
k. Ascites (fluid in the belly)	1	2
l. Spider angiomas (on skin)	1	2
m. Hepatic endephalopathy: altered mental status (AMS), coma, asterixis (flapping tremor)	1	2
n. Varicies noted on endoscopy	1	2
o. Increased serum ammonia	1	2
p. Increased transaminases ALT (SGPT), AST (SCOT), GGT	1	2
q. Increased bilirubin and alkaline phosphatase	1	2
r. Decreased albumin	1	2
s. Prolonged PT/PTT	1	2
t. Liver biopsy (abstract pathology report)	1	2
u. Treatment: ribiviron, interferon alpha, Rebetron (combination) ..	1	2