

CLINICAL OUTCOME REPORTING FORM

ID LABEL  
HERE --->

Form with grid for ID label entry: | | | - | | | | - | | | | | - | | | |

FORM COMPLETED BY:

Form with three lines for name entry: \_ \_ \_

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):

- a. Whole cohort ..... 1
- b. HIV+ ..... 2
- c. Medical release and self-report ..... 3
- d. Medical release only ..... 4
- e. Other ..... 5

WIHS ID #

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Specify: \_\_\_\_\_

**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.*)

\_\_\_ / \_\_\_ / \_\_\_      Missing   
M                      D                      Y

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

WIHS ID #

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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

WIHS ID #

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

WIHS ID #

[Empty box for WIHS ID #]

**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

WIHS ID #

	<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, Rebetrone (combination) .....	1	2