

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.*

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[Empty box for 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

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

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**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

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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
	<u>YES</u>	<u>NO</u>

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k.	Ascites (fluid in the belly) .....	1	2
l.	Spider angiomas (on skin) .....	1	2
m.	Hepatic encephalopathy: 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