

MACS CLINICAL OUTCOME REPORTING FORM

Section A. GENERAL INFORMATION

1. MACS ID#: _____
2. Date of this report: _____
M M / D D / Y Y Y Y
3. Date of Birth: _____
M M / D D / Y Y Y Y
4. Person completing form: _____
5. Center: _____
6. Unique Identifier: _____
MACSID VISIT # ##

7. Reason for status change:

- (a) _____ Initial AIDS diagnosis
--complete Sections B & C
- (b) _____ AIDS update (new condition/additional diagnosis)
--complete Sections B & C
- (c) _____ AIDS update (modification of previous form)
--complete Sections B & C
- (d) _____ Other, non AIDS diagnosis, non-malignancy
--complete Sections B & D
- (e) _____ Malignancy
--complete Sections B, C (if AIDS-related) & F
- (f) _____ Malignancy update (modification of previous diagnosis)
--complete Sections B, C (if AIDS-related) & F
- (g) _____ Mortality
--complete Sections B, C.1 (if AIDS-related), E & F
(if malignancy-related)
- (h) _____ Mortality update
--complete Sections B, C.1 (if AIDS-related), E & F
(if malignancy-related)
- (i) _____ Other update (specify in Comments Section)

Section B. SOURCE OF INFORMATION

Place a check next to any that apply and complete with corresponding information.

1. Medical Records: (a) ___ Reviewed
(b) ___ Obtained
2. Telephone: (a) ___ M.D.
(b) ___ Other (Specify) _____

Comments: _____

Section C. AIDS DIAGNOSES

1. Individual AIDS Status:

- (1) _____ Definite
(CDC-defined AIDS or diagnosis by death certificate alone)
- (2) _____ Presumptive
(Clinical diagnosis only using CDC-defined guidelines)
- (3) _____ Probable
(Any reported/suspected case, not (yet) confirmed by medical records)

2. Self-reported CD4⁺ T-lymphocyte levels indicative of AIDS

- (1) Date CD4⁺ T-lymphocytes first observed less than 200 cells/ μ l or less than 14% of T-lymphocytes
- (2) Determination by MACS laboratory
1=No (outside)
2=Yes (MACS)

_____/_____/_____
M M D D Y Y Y Y

3. Diseases Indicative of Cellular Immunodeficiency and AIDS

Complete a separate line, items a-e, for each unique diagnosis of an AIDS related illness.

a. DATE OF DIAGNOSIS MON/DAY/YEAR	b. DISEASE (Print diagnosis)	c. DISEASE CODE (See Outcome Guidelines)	d. METHOD OF DIAGNOSIS (Code methods of diagnosis) 1=Histology at biopsy, 2=Necropsy, 3=Cytology, 4=Culture, 5=Serology, 6=Clinical diagnosis, 7=Radiology (MRI, imaging, etc.) 9=Subject self-report; 0=Cancer Registry	e. DIAGNOSIS STATUS 1=Definite, 2= Presumptive, 3=Probable (refer to guidelines for correct status according to methods of diagnosis)
_____/_____/_____	_____	---	_____	_____
_____/_____/_____	_____	---	_____	_____
_____/_____/_____	_____	---	_____	_____
_____/_____/_____	_____	---	_____	_____
_____/_____/_____	_____	---	_____	_____
_____/_____/_____	_____	---	_____	_____
_____/_____/_____	_____	---	_____	_____
_____/_____/_____	_____	---	_____	_____
_____/_____/_____	_____	---	_____	_____
_____/_____/_____	_____	---	_____	_____

Section D. - OTHER CONDITIONS/DISEASES (CONT)

3. OTHER DIAGNOSES/CONDITIONS NOT DIAGNOSTIC OF AIDS - complete a separate line, items a-d, for each condition/diagnosis (see guidelines for list of reportable conditions and corresponding codes)

a. <u>DATE OF DIAGNOSIS</u> MON/DAY/YEAR	b. <u>DISEASE</u> (Print diagnosis)	c. <u>DISEASE CODE</u> (ICD-9 codes)	d. <u>METHOD OF DIAGNOSIS</u> (Code methods of diagnosis) 1=Histology at biopsy; 2=Necropsy; 3=Cytology; 4=Culture; 5=Serology; 6=Clinical diagnosis; 7=Radiology (MRI, imaging, etc.); 9=Subject self-report
___/___/___	_____	_____	_____
___/___/___	_____	_____	_____
___/___/___	_____	_____	_____
___/___/___	_____	_____	_____
___/___/___	_____	_____	_____
___/___/___	_____	_____	_____
___/___/___	_____	_____	_____
___/___/___	_____	_____	_____
___/___/___	_____	_____	_____
___/___/___	_____	_____	_____
___/___/___	_____	_____	_____
___/___/___	_____	_____	_____
___/___/___	_____	_____	_____
___/___/___	_____	_____	_____
___/___/___	_____	_____	_____
___/___/___	_____	_____	_____

Comments: _____

Section E. INFORMATION RELEVANT TO DEATH - Complete all items in this section.

1a. Date of Death - Place a check next to cause of death and complete corresponding information. (If date of death is unknown, code as 09/09/9999.)

- (1) ___ Death, from AIDS with a prior report or earlier AIDS diagnosis ____/____/____
M M D D Y Y Y Y
- (2) ___ Death, from AIDS, without an AIDS diagnosis prior to death report ____/____/____
M M D D Y Y Y Y
- (3) ___ Death, not from AIDS ____/____/____
M M D D Y Y Y Y
- (4) ___ Death, unknown cause ____/____/____
M M D D Y Y Y Y

1b. Location of Death (State): _____

1c. If different from 1b., Residence at time of death (State): _____

2. Causes of death: (If causes of death are unknown, list as "unknown" and code 799.9 (ICD-9). If NDI, report ICD-9/ICD-10 codes as ordered in NDI file.)

<u>Condition</u> (Print Diagnosis)	<u>ICD-9</u>		<u>ICD-10</u>	
	Alpha	Numeric	Alpha	Numeric
Primary Diagnosis (NDI = Entity Code 1): _____	___	_____ . _____	___	_____ . _____
Secondary Diagnoses (NDI = Entity Code 2+):				
(a) _____	___	_____ . _____	___	_____ . _____
(b) _____	___	_____ . _____	___	_____ . _____
(c) _____	___	_____ . _____	___	_____ . _____
(d) _____	___	_____ . _____	___	_____ . _____
(e) _____	___	_____ . _____	___	_____ . _____
(f) _____	___	_____ . _____	___	_____ . _____
(g) _____	___	_____ . _____	___	_____ . _____
Underlying Cause (NDI only): _____	___	_____ . _____	___	_____ . _____

3. Source of information for cause of death (Check source):

- (1) ___ Death Certificate
- (5) ___ SSDI (Social Security Death Index)
- (2) ___ Autopsy
- (6) ___ NDI (National Death Index)
- (3) ___ Personal Report
- (4) ___ Other (Specify): _____

Section E. INFORMATION RELEVANT TO DEATH (CONT)

4. Autopsy performed: (1) ___ No (2) ___ Yes (9) ___ Don't Know

5. Autopsy tissue obtained by MACS Center: (1) ___ No (2) ___ Yes (8) ___ NA (9) ___ Don't Know

(If no autopsy was performed, check (8) NA)

6. Were the medical records reviewed for signs of encephalopathy? (Check only one)

- (1) ___ No review
- (2) ___ MACS neurologist review
- (3) ___ Outcome specialist review

7. Did participant have indications of encephalopathy?

(If no review in Q.6 then leave blank. Refer to guidelines for acceptable coding patterns.)

- (1) ___ No signs of encephalopathy/dementia before death
- (2) ___ HIV encephalopathy/dementia present
- (8) ___ Other confounding condition precludes ascertainment of HIV dementia (e.g., toxoplasmosis, lymphoma, metabolic encephalopathies)
(Specify): _____
- (9) ___ Don't know because records are inadequate

Section F. CANCER DIAGNOSIS (Complete Section for each diagnosis)

Please use ICD-0-3 codes for site(s) and type of cancer.

1. **Site of primary cancer** (Topography/Site): _____
 (If participant presents with multiple sites, but primary site is unknown, code C80.9 and list all the sites in Q5)

2. **Type of primary cancer** (Morphology/Type): _____ / _____

3. **Date of diagnosis:** _____ / _____ / _____
 (Use date of biopsy when available) M M D D Y Y Y Y

4. **Methods of Diagnosis:** (Circle appropriate answer)

	<u>Was the procedure performed/available?</u>			<u>Did the data support diagnosis?</u>			<u>Has copy of report been obtained?</u>		
	<u>N</u>	<u>Y</u>	<u>DK</u>	<u>N</u>	<u>Y</u>	<u>DK</u>	<u>N</u>	<u>Y</u>	<u>DK</u>
a. Biopsy	1	2	9	1	2	9	1	2	9
b. Autopsy	1	2	9	1	2	9	1	2	9
c. Clinical evidence	1	2	9	1	2	9	1	2	9
d. Death Certificate	1	2	9	1	2	9	1	2	9
e. Cancer Registry	1	2	9	1	2	9	1	2	9
f. Self-report	1	2	9						
g. Others (e.g. cytology (1), imaging (2), biochemical markers (3)): (Specify)									
I. _____	1	2	9	1	2	9	1	2	9
ii. _____	1	2	9	1	2	9	1	2	9
iii. _____	1	2	9	1	2	9	1	2	9

Section F. CANCER DIAGNOSIS (CONT)

5. Progression of cancer:

N Y DK

a. Has cancer progressed to multiple sites?

1 2 9

b. If yes, list all sites:

- 1) _____
- 2) _____
- 3) _____
- 4) _____
- 5) _____
- 6) _____

6. Availability of tissues specimens:

	<u>Biopsy Specimens</u>				<u>Autopsy Specimens</u>			
	<u>Not available</u>	<u>Accessible, not obtained</u>	<u>Obtained</u>	<u>DK</u>	<u>Not Available</u>	<u>Accessible, not obtained</u>	<u>Obtained</u>	<u>DK</u>
a. Slides	1	2	3	9	1	2	3	9
b. Paraffin-embedded blocks	1	2	3	9	1	2	3	9
c. Fixed, unprocessed tissues	1	2	3	9	1	2	3	9
d. Frozen tissues	1	2	3	9	1	2	3	9
e. Others (Specify)								
1) _____	1	2	3	9	1	2	3	9
2) _____	1	2	3	9	1	2	3	9