

# MACS CLINICAL OUTCOME REPORTING FORM

## Section A. GENERAL INFORMATION

1. MACS ID#: \_\_\_\_\_
2. Date of this report: \_\_\_\_\_  
M M / D D / Y Y
3. Date of Birth: \_\_\_\_\_  
M M / D D / Y Y
4. Person completing form: \_\_\_\_\_
5. Center: \_\_\_\_\_

6. 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)

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## 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) \_\_\_\_\_

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Comments: \_\_\_\_\_

\_\_\_\_\_

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\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

**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<sup>+</sup> T-lymphocyte levels indicative of AIDS**

(1) Date CD4<sup>+</sup> T-lymphocytes first observed less than 200 cells/ $\mu$ 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

\_\_\_\_\_

**3. Diseases Indicative of Cellular Immunodeficiency and AIDS**

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

<b>a. DATE OF DIAGNOSIS</b> MON/DAY/YEAR	<b>b. DISEASE</b> (Print diagnosis)	<b>c. DISEASE CODE</b> (See Outcome Guidelines)	<b>d. METHOD OF DIAGNOSIS</b> (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	<b>e. DIAGNOSIS STATUS</b> 1=Definite, 2= Presumptive, 3=Probable (refer to guidelines for correct status according to methods of diagnosis)
____/____/____	_____	____	_____	_____
____/____/____	_____	____	_____	_____
____/____/____	_____	____	_____	_____
____/____/____	_____	____	_____	_____
____/____/____	_____	____	_____	_____
____/____/____	_____	____	_____	_____
____/____/____	_____	____	_____	_____
____/____/____	_____	____	_____	_____
____/____/____	_____	____	_____	_____







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

**1. Date of Death** - Place a check next to cause of death and complete corresponding information. (If date of death is unknown, code as 01/01/01.)

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

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

	<u>ICD CODE</u>	
<u>Condition</u> (Print Diagnosis)	<u>Character Prefix</u> (if applicable)	<u>Numeric Code</u>
Primary Diagnosis: _____	___	_____. ____
Secondary Diagnoses: (a) _____	___	_____. ____
(b) _____	___	_____. ____
(c) _____	___	_____. ____
(d) _____	___	_____. ____
(e) _____	___	_____. ____
(f) _____	___	_____. ____
(g) _____	___	_____. ____

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

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

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

**Section E. INFORMATION RELEVANT TO DEATH (CONT)**

**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

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. Self-report	1	2	9						
f. 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