TEAR OFF THIS FRONT PAGE ONCE ABSTRACTION IS COMPLETED

DO NOT DATA ENTER THE INFORMATION CONTAINED IN THIS BOX

Participant Name: _____

Physician's Name: _____

Hospital/Clinic: _____

Self-Reported ART Date: _____

Date of first HIV seropositivity: ___ ___ / ___ ___ / ___ ___ ___ ___

M M D D Y Y Y Y

DO NOT DATA ENTER THE INFORMATION CONTAINED IN THIS BOX

INSTRUCTIONS:

THIS FRONT PAGE IS TO FACILITATE THE ABSTRACTION OF INFORMATION CONTAINED ON THIS FORM. ONCE ABSTRACTION IS COMPLETE, TEAR OFF THIS FRONT PAGE

TEAR OFF THIS FRONT PAGE ONCE ABSTRACTION IS COMPLETED

Screening ID: _____

MACS ID: ___ ___ ___ ___ ___

Date: ___ ___ / ___ ___ / ___ ___ ___ ___

M M D D Y Y Y Y

Abstractor: _____

Retrospective Medical Record Abstraction

INSTRUCTIONS:

This form should be completed for all HIV seropositive men.
There are 2 Sections of this form, a required section (Section A), and a supplemental section (Section B). For a participant to be eligible for enrollment, the information in Section A is required. If information can be found to complete Section B, that should be filled out as well. However, the information contained in Section B is not required to enroll a participant in the MACS.

Screening ID: _____

MACS ID: ___ ___ ___ ___ ___

Section A: Required Abstraction

1. Did this person ever use HIV antiretroviral therapies (ART)?

☐ No ➜ ***SKIP TO Q4***

☐ Yes

2. A. When was ART **FIRST** prescribed?

___ ___ / ___ ___ / ___ ___ ___ ___
M M D D Y Y Y Y

B. List below the drugs that comprised the participant's first ART regimen:

Name of Drug	Drug Code*	Start Date (MM/DD/YYYY)	Currently Using	Stop Date (MM/DD/YYYY)	Prescribed Dosage
1.			☐ No ☐ Yes		
2.			☐ No ☐ Yes		
3.			☐ No ☐ Yes		
4.			☐ No ☐ Yes		
5.			☐ No ☐ Yes		

* ***See Appendix A for Drug Codes***

3. What are the HIV RNA and T-cell results **PRIOR** to or at ART initiation?

Dates of the blood draws should be within 4 months of the initial ART date. If blood was drawn at time of first ART prescription, record these results, otherwise record the lab results from the most recent date before ART.

Most recent blood draw prior to or at ART initiation

A. HIV RNA

(1) Date of blood draw: ___ ___ / ___ ___ / ___ ___ ___ ___
M M D D Y Y Y Y

(2) Below limit of assay detection? ☐ No ☐ Yes

(3) Copies/ml: ___ ___,___ ___ ___,___ ___ ___
(*If undetectable, list lower limit of detection*)

(4) Assay kit [*check one*]:
- ☐ Roche Amplicor RNA
- ☐ Roche Ultrasensitive RNA
- ☐ Roche Tazman
- ☐ NASBA
- ☐ Other, Specify: _____
- ☐ Unknown

B. T-cell Count:

(1) Date of blood draw: ___ ___ / ___ ___ / ___ ___ ___ ___
M M D D Y Y Y Y

(2) Counts:

CD4#: ___ ___ ___ ___ CD4%: ___ ___ ___.___%
CD8#: ___ ___ ___ ___ CD8%: ___ ___ ___.___% (*if available*)
CD3#: ___ ___ ___ ___ CD3%: ___ ___ ___.___% (*if available*)

4. Diseases Indicative of Cellular Immunodeficiency and AIDS

A. Was this person ever diagnosed with an AIDS-defining illness?

☐ No ➜ **Go to Section B**

☐ Yes

B. Did the first AIDS diagnosis occur prior to the date when ART was first prescribed?

☐ No

☐ Yes ➜ **STOP here**

C. Please complete a separate line, items a-d, for each unique diagnosis of an AIDS related illness that occurred after ART initiation.

a. DATE OF DIAGNOSIS *mm/dd/yyyy*	***b. DISEASE*** *(Print diagnosis)*	***c. DISEASE CODE*** *(See Appendix B)*	***d. METHOD OF DIAGNOSIS*** *(Code methods of diagnosis) 1=Histology at biopsy, 3=Cytology, 4=Culture, 5=Serology, 6=Clinical diagnosis, 7=Radiology (MRI, imaging, etc.) 9=Subject self-report*		
__ __/__ __/__ __ __ __	____________________	__ __	____	____	____
__ __/__ __/__ __ __ __	____________________	__ __	____	____	____
__ __/__ __/__ __ __ __	____________________	__ __	____	____	____
__ __/__ __/__ __ __ __	____________________	__ __	____	____	____
__ __/__ __/__ __ __ __	____________________	__ __	____	____	____
__ __/__ __/__ __ __ __	____________________	__ __	____	____	____
__ __/__ __/__ __ __ __	____________________	__ __	____	____	____
__ __/__ __/__ __ __ __	____________________	__ __	____	____	____

Section B:

Additional Record Abstraction

1. If additional regimen data can be located concerning regimens a participant switched to <u>after</u> their initial ART regimen, record this information below:

List all drugs in 2nd regimen	Drug Code	Start Date (MM/DD/YYYY)	Currently Using	Stop Date (MM/DD/YYYY)	Prescribed Dosage
1.			☐ No ☐ Yes		
2.			☐ No ☐ Yes		
3.			☐ No ☐ Yes		
4.			☐ No ☐ Yes		
5.			☐ No ☐ Yes		

List all drugs in 3rd regimen	Drug Code	Start Date (MM/DD/YYYY)	Currently Using	Stop Date (MM/DD/YYYY)	Prescribed Dosage
1.			☐ No ☐ Yes		
2.			☐ No ☐ Yes		
3.			☐ No ☐ Yes		
4.			☐ No ☐ Yes		
5.			☐ No ☐ Yes		

List all drugs in 4th regimen	Drug Code	Start Date (MM/DD/YYYY)	Currently Using	Stop Date (MM/DD/YYYY)	Prescribed Dosage
1.			☐ No ☐ Yes		
2.			☐ No ☐ Yes		
3.			☐ No ☐ Yes		
4.			☐ No ☐ Yes		
5.			☐ No ☐ Yes		

Additional Laboratory Measurements

2. Record HIV RNA and T-cell results. Do not include results more frequently than quarterly.

Start with results closest to HIV seroconversion

A. HIV RNA Results

Date (MM/DD/YYYY)	HIV RNA (copies/mL)	Result below limit of assay detection	Assay Kit (if available)
		☐ No ☐ Yes	
		☐ No ☐ Yes	
		☐ No ☐ Yes	
		☐ No ☐ Yes	
		☐ No ☐ Yes	
		☐ No ☐ Yes	
		☐ No ☐ Yes	
		☐ No ☐ Yes	
		☐ No ☐ Yes	
		☐ No ☐ Yes	
		☐ No ☐ Yes	
		☐ No ☐ Yes	
		☐ No ☐ Yes	
		☐ No ☐ Yes	
		☐ No ☐ Yes	
		☐ No ☐ Yes	
		☐ No ☐ Yes	
		☐ No ☐ Yes	
		☐ No ☐ Yes	
		☐ No ☐ Yes	
		☐ No ☐ Yes	
		☐ No ☐ Yes	
		☐ No ☐ Yes	
		☐ No ☐ Yes	

Screening ID: ________________

MACS ID: ___ ___ ___ ___ ___

B. T-cell Results

Date (MM/DD/YYYY)	CD4#	CD4%	CD8#	CD8%	CD3#	CD3%
	___ ___ ___ ___	___ ___ ___ . ___	___ ___ ___ ___	___ ___ ___ . ___	___ ___ ___ ___	___ ___ ___ . ___
	___ ___ ___ ___	___ ___ ___ . ___	___ ___ ___ ___	___ ___ ___ . ___	___ ___ ___ ___	___ ___ ___ . ___
	___ ___ ___ ___	___ ___ ___ . ___	___ ___ ___ ___	___ ___ ___ . ___	___ ___ ___ ___	___ ___ ___ . ___
	___ ___ ___ ___	___ ___ ___ . ___	___ ___ ___ ___	___ ___ ___ . ___	___ ___ ___ ___	___ ___ ___ . ___
	___ ___ ___ ___	___ ___ ___ . ___	___ ___ ___ ___	___ ___ ___ . ___	___ ___ ___ ___	___ ___ ___ . ___
	___ ___ ___ ___	___ ___ ___ . ___	___ ___ ___ ___	___ ___ ___ . ___	___ ___ ___ ___	___ ___ ___ . ___
	___ ___ ___ ___	___ ___ ___ . ___	___ ___ ___ ___	___ ___ ___ . ___	___ ___ ___ ___	___ ___ ___ . ___
	___ ___ ___ ___	___ ___ ___ . ___	___ ___ ___ ___	___ ___ ___ . ___	___ ___ ___ ___	___ ___ ___ . ___
	___ ___ ___ ___	___ ___ ___ . ___	___ ___ ___ ___	___ ___ ___ . ___	___ ___ ___ ___	___ ___ ___ . ___
	___ ___ ___ ___	___ ___ ___ . ___	___ ___ ___ ___	___ ___ ___ . ___	___ ___ ___ ___	___ ___ ___ . ___
	___ ___ ___ ___	___ ___ ___ . ___	___ ___ ___ ___	___ ___ ___ . ___	___ ___ ___ ___	___ ___ ___ . ___
	___ ___ ___ ___	___ ___ ___ . ___	___ ___ ___ ___	___ ___ ___ . ___	___ ___ ___ ___	___ ___ ___ . ___
	___ ___ ___ ___	___ ___ ___ . ___	___ ___ ___ ___	___ ___ ___ . ___	___ ___ ___ ___	___ ___ ___ . ___
	___ ___ ___ ___	___ ___ ___ . ___	___ ___ ___ ___	___ ___ ___ . ___	___ ___ ___ ___	___ ___ ___ . ___
	___ ___ ___ ___	___ ___ ___ . ___	___ ___ ___ ___	___ ___ ___ . ___	___ ___ ___ ___	___ ___ ___ . ___
	___ ___ ___ ___	___ ___ ___ . ___	___ ___ ___ ___	___ ___ ___ . ___	___ ___ ___ ___	___ ___ ___ . ___
	___ ___ ___ ___	___ ___ ___ . ___	___ ___ ___ ___	___ ___ ___ . ___	___ ___ ___ ___	___ ___ ___ . ___
	___ ___ ___ ___	___ ___ ___ . ___	___ ___ ___ ___	___ ___ ___ . ___	___ ___ ___ ___	___ ___ ___ . ___
	___ ___ ___ ___	___ ___ ___ . ___	___ ___ ___ ___	___ ___ ___ . ___	___ ___ ___ ___	___ ___ ___ . ___
	___ ___ ___ ___	___ ___ ___ . ___	___ ___ ___ ___	___ ___ ___ . ___	___ ___ ___ ___	___ ___ ___ . ___
	___ ___ ___ ___	___ ___ ___ . ___	___ ___ ___ ___	___ ___ ___ . ___	___ ___ ___ ___	___ ___ ___ . ___

Repository Samples

3. Are specimens available in the local repository? ☐ No ☐ Yes

If YES, record the amount by date and type of specimen below.

Date MM/DD/YYYY	PBMC Vials		PBMC Pellets		Serum		Plasma		
	# vials	Amt per vial	# vials	Amt per vial	# vials	Amt per vial	# vials	Amt per vial	Anti-coagulant

Appendix A: Antiretroviral Medications [Code]

- ☐ Agenerase (amprenavir, 141W94) [219]
- ☐ Aptivus (tipranavir) [238]
- ☐ Atripla (efavirenz + emtricitabine + tenofovir) [262]
- ☐ Combivir (AZT+3TC)[1] [227]
- ☐ Crixivan (indinavir) [212]
- ☐ Emtriva (emtricitabine) [239]
- ☐ Enfuvirtide (Fuzeon, T-20, pentafuside) [233]
- ☐ Epivir (3-TC, lamivudine) [204]
- ☐ Epzicom (abacavir + lamivudine) [254]
- ☐ Hivid (ddC, dideoxycytidine, Zalcitabine) [094]
- ☐ Intelence (etravirine, TMC-125) [255]
- ☐ Invirase or Fortovase (saquinavir)[5] [210]
- ☐ Kaletra (lopinavir/ritonavir, ABT-378/r) [217]
- ☐ Lexiva (fosamprenavir) [249]
- ☐ Norvir (ritonavir) - full dose[3,5] [211]
- ☐ Norvir (ritonavir) - low dose[4] [211]
- ☐ Prezista (TMC-114, darunavir) [256]
- ☐ Rescriptor (delavirdine, U-90) [194]
- ☐ Retrovir (AZT, zidovudine, ZDV) [092]
- ☐ Reyataz (atazanavir) [243]
- ☐ Sustiva (efavirenz, DMP266) [220]
- ☐ Trizivir (AZT + 3TC + Abacavir)[2] [240]
- ☐ Truvada (emitricitabine + tenofovir) [253]
- ☐ Videx/Videx EC (ddI, dideoxylinosine, didanosine) [147]
- ☐ Viracept (nelfinavir) [216]
- ☐ Viramune (nevirapine) [191]
- ☐ Viread (Tenofovir, disoproxil fumarate) [234]
- ☐ Zerit (d4T, stavudine) [159]
- ☐ Ziagen (abacavir, 1592U89) [218]

[1] Combivir counts as 2 drugs
[2] Trizivir counts as 3 drugs
[3] Full dose: ≥400 mg, ≥3 pills/dose
[4] Low dose: ≤200 mg, 1 or 2 pills/dose
[5] Ritonavir/saquinavir with ritonavir at full dose (>400mg or >3 pills per dose)

APPENDIX B: CDC-DEFINED AIDS DIAGNOSES

CODE	CONDITION
01	Kaposi's sarcoma
02	Pneumocystis carinii pneumonia
03	Toxoplasmosis (at a site other than or in addition to liver, spleen, muscle or lymph nodes)
04	Cryptosporidiosis with diarrhea persisting > 1 month
05	Isosporiasis with diarrhea persisting > 1 month
06	Histoplasmosis, disseminated, at a site other than or in addition to lungs or cervical or hilar lymph nodes
07	Cytomegalovirus infection histopathologically documented (of an organ other than liver, spleen, or lymph nodes) or diagnosis by serology culture alone. If CMV retinitis or CMV polyradiculitis, code as indicated below, 08 or 27, respectively.
08	CMV Retinitis, eye unknown
27	CMV polyradiculitis. Usually developing in a patient with advanced immune deficiency who has evidence of CMV infection elsewhere, e.g., CMV retinitis, colitis, with the subacute onset of lower extremity weakness, sacral/back pain, sphincter disturbance. Cerebrospinal fluid analyses usually show a marked inflammatory response with elevated WBC, total protein, and in 50%, positive CMV culture. Autopsy confirmation may be present with demonstration of CMV in the lumbosacral nerve roots.
09	Primary Lymphoma of brain
10	Diffuse, undifferentiated B-cell *non-Hodgkin's lymphoma*. includes the following histologic types: a. small noncleaved Lymphoma of (either Burkitt or non-Burkitt type) b. immunoblastic sarcoma (equivalent to any of the following, although not necessarily all in combination: immunoblastic lymphoma, large-cell lymphoma, diffuse histiocytic lymphoma, diffuse undifferentiated lymphoma, or high-grade lymphoma)
11	Diffuse, undifferentiated B-cell *non-Hodgkin's lymphoma metastatic to brain*
12	Progressive multifocal leukoencephalopathy (Papovavirus infection, brain)
13	HIV encephalopathy (dementia) determined to be probable after review by Neuropsychology working group
14	Candida esophagitis; tracheal, bronchial or pulmonary candidiasis
15	*Atypical (non-tuberculous) mycobacterial infection*, (disseminated at a site other than or in addition to lungs, skin or cervical hilar lymph nodes), *not specified*
16	Atypical (non-tuberculous) mycobacterial infection, (disseminated at a site other than or in addition to lungs, skin, or cervical hilar lymph nodes) specified as *M. avium-intracellular*

17 Other atypical (non-tuberculous) mycobacterial infection, (disseminated at a site other than or in addition to lungs, skin or cervical hilar lymph nodes), *please specify* (other organism).

18 Disseminated M.T.B. (*mycobacterium tuberculosis*)

19 Cryptococcal infection extrapulmonary - not otherwise specified

20 Cryptococcal infection extrapulmonary - meningitis

21 Cryptococcal infection extrapulmonary - other internal organ

22 Cryptococcal infection extrapulmonary - blood

23 Chronic mucocutaneous herpes simplex infection persisting > 1 month; or herpes simplex bronchitis, pneumonitis, or esophagitis

24 Coccidioidomycosis disseminated (at a site other than or in addition to lungs or cervical or hilar lymph nodes)

25 Salmonella (non-typhoid) septicemia, recurrent

26 *Wasting Syndrome*: findings of profound involuntary weight loss > 10% of baseline body weight plus either chronic diarrhea (at least two loose stools per day for $\geq$ 30 days) or chronic weakness and documented fever (for $\geq$ 30 days, intermittent or constant) in the absence of a concurrent illness or condition other than HIV infection that could explain the findings (e.g., cancer, tuberculosis, cryptosporidiosis, or other specific enteritis.)

50 Pulmonary Tuberculosis

51 *Recurrent pneumonia* (more than one episode in a 1-year period), acute (new x-ray evidence not present earlier) pneumonia diagnosed by both: a) culture (or other organism-specific diagnostic method) obtained from a clinically reliable specimen of a pathogen that typically causes pneumonia (other than *Pneumocystis carinii* or *Mycobacterium tuberculosis*), and b) radiologic evidence of pneumonia; cases that do not have laboratory confirmation of a causative organism for one of the episodes of pneumonia will be considered to be presumptively diagnosed. Recurrent pneumonia diagnostic date is the date that the 2nd episode is diagnosed.