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 HAART Date: _____

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. Using the Definition of HAART (*see Appendix A)*, did this person ever use HAART?

□ No → ***SKIP TO Q5***

□ Yes

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

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

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

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

* ***See Appendix B for Drug Codes***

3. Did this participant use antiretroviral medications (ARTs) prior to HAART?

□ No

□ Yes **IF YES, RECORD ART HISTORY IN Section B**

□ Unknown

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

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

Most recent blood draw prior to or at HAART 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
□ NASBA
□ Chiron
□ 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*)

5. 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 HAART 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 HAART initiation.

a. DATE OF DIAGNOSIS MM/DD/YYYY	*b. DISEASE (Print diagnosis)*	*c. DISEASE CODE (See Appendix C)*	*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*		
___ ___/___ ___/___ ___ ___ ___	____________________________	___ ___	_____	_____	_____
___ ___/___ ___/___ ___ ___ ___	____________________________	___ ___	_____	_____	_____
___ ___/___ ___/___ ___ ___ ___	____________________________	___ ___	_____	_____	_____
___ ___/___ ___/___ ___ ___ ___	____________________________	___ ___	_____	_____	_____
___ ___/___ ___/___ ___ ___ ___	____________________________	___ ___	_____	_____	_____
___ ___/___ ___/___ ___ ___ ___	____________________________	___ ___	_____	_____	_____
___ ___/___ ___/___ ___ ___ ___	____________________________	___ ___	_____	_____	_____
___ ___/___ ___/___ ___ ___ ___	____________________________	___ ___	_____	_____	_____

Screening ID: _____

MACS ID: ___ ___ ___ ___ ___

Section B: Supplemental Abstraction

1. If the participant used ARTs **PRIOR** to HAART initiation, list those drugs below.

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		
6.			□ No □ Yes		
7.			□ No □ Yes		
8.			□ No □ Yes		
9.			□ No □ Yes		
10.			□ No □ Yes		
11.			□ No □ Yes		
12.			□ No □ Yes		
13.			□ No □ Yes		
14.			□ No □ Yes		
15.			□ No □ Yes		

If additional HIV RNA and/or T-cell results are available prior to the initiation of HAART, list this information below. Dates of the blood draws should be within 4 months of the initial HAART date. Results recorded here should be prior to the result listed in Section A, Question 4.

2. Other blood draw **PRIOR** to HAART initiation (before date in Section A, Q4.A)

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
□ NASBA
□ Chiron
□ 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*)

3. If additional regimen data can be located concerning regimens a participant switched to <u>after</u> their initial HAART 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		

4. Record HIV RNA and T-cell results **POST** HAART initiation. Do not include results more frequently than quarterly.

Start with results closest to HAART

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	

B. T-cell Results

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

Appendix A: Definition of HAART

≥ 2 NRTIs

+

≥ 1 PI **and/or** ≥ 1 NNRTI

OR 1 NRTI + ≥ 1 PI + ≥ 1 NNRTI

OR 1 NRTI + ≥ 2 PIs including (RTV* & SQV) + no NNRTIs

OR Abacavir + ≥ 2 NRTIs + no PIs + no NNRTIs

* Ritonavir/saquinavir with ritonavir at full dose (≥400mg or ≥3 pills per dose)

NOTE:

NRTI = Nuceloside reverse transcriptase inhibitor
NNRTI = Non-nuceloside reverse transcriptase inhibitor
PI = Protease inhibitor

Combivir counts as 2 NRTIs.
Trizivir counts as Abacavir + 2 NRTIs

If you come across any regimen that you think may be a HAART regimen but which does not fit into one of the above 4 definitions, contact Cindy Kleeberger at CAMACS at (410) 955-4320.

Antiretroviral Medications

Group A (NRTIs)	Group B (PIs)	Group C (NNRTIs)
□ 3-TC (Lamivudine, Epivir) □ Abacavir (Ziagen, 1592U89) □ Adefovir (Preveon, bis-POM PMPA, GS 840) □ AZT (Retrovir, Zidovudine, ZDV) □ Combivir (AZT+3TC) [1] □ d4T (stavudine, Zerit) □ ddC(dideoxycytidine, Zalcitabine, Hivid) □ ddI (dideoxyinosine, Didanosine, Videx) □ Tenofovir disoproxil (bis-POC PMPA, PMPA, Adenine Fumarate) □ Emtricitabine (FTC) □ Trizivir (AZT + 3TC + Abacavir) [2]	□ Amprenavir (Agenerase, 141W94) □ Indinavir (Crixivan) □ Nelfinavir (Viracept) □ Ritonavir (Norvir) - full dose [3] □ Ritonavir (Norvir) - low dose [4] □ Saquinavir (Invirase, Fortovase) □ Kaletra (Lopinavir/r, ABT-378/r) □ Tipranavir (PNU-140690) □ Atazanavir (BMS-232632)	□ Delavirdine (Rescriptor, U-90) □ Efavirenz (Sustiva, DMP266) □ Nevirapine (Viramune) □ Emivirine (MCK-442, Coactinon)
[1] Combivir counts as 2 drugs [2] Trizivir counts as 3 drugs **Total # from A:**_____	[3] Full dose: $400 mg, ≥3 pills/dose [4] Low dose: #200 mg, 1 or 2 pills/dose **Total # from B:**_____	**Total # from C:**_____

Definition of HAART (check which definition applies):

□	≥ 2 NRTIs	+	≥ 1 PI	and/or ≥ 1 NNRTI
□	1 NRTI	+	≥ 1 PI	+ ≥ 1 NNRTI
□	1 NRTI	+	≥ 2 PIs including (RTV [5] & SQV)	+ no NNRTI
□	Abacavir + ≥ 2 NRTIs	+ no	PI	+ no NNRTI

[5] Ritonavir/saquinavir with ritonavir at full dose (>400mg or >3 pills per dose)

APPENDIX B: DRUG LIST

219 = 141W94 (Amprenavir, Agenerase)
218 = 1592U89 (Abacavir, Ziagen)
204 = 3-TC (Epivir, Lamivudine)
218 = Abacavir (Ziagen, 1592U89)
217 = ABT-378/r (Lopinavir/Ritonavir, Kaletra)
146 = Acyclovir (Zovirax)
224 = Adefovir
(Preveon, bis-POM PMPA, GS 840)
219 = Agenerase (Amprenavir, 141W94)
098 = AL-721 (by Praxis) (egg lecithin)
090 = Alpha Interferon
101 = Ampligen
219 = Amprenavir (Agenerase, 141W94)
243 = Atazanavir (BMS-232632)
092 = AZT (Retrovir, Zidovudine)
122 = Beta Interferon
234 = bis-POC PMPA (Tenofovir disoproxil,
Adenine Fumarate, GS 902)
224 = bis-POM PMPA
(Adefovir, Preveon, GS 840)
243 = BMS-232632 (Atazanavir)
128 = CD4
231 = cidofovir (vistide)
221 = Coactinon (MKC-442, Emivirine)
227 = Combivir (AZT + 3TC, Retrovir + Epivir)
239 = Corviracil (Emtricitabine, FTC)
212 = Crixivan (Indinavir)
159 = d4T (Zerit, Stavudine)
163 = ddA (dideoxyandenosine)
094 = ddC (dideoxycytidine, Zalcitabine, Hivid)
147 = ddI (dideoxyinosine, Didanosine, Videx/EC)
194 = Delavirdine (Rescriptor, U-90)
110 = Dextran-Sulfate
147 = Didanosine (ddI, dideoxyinosine, Videx/EC)
163 = Dideoxyandenosine (ddA)
094 = Dideoxycytidine (ddC, Zalcitabine, Hivid)
147 = Dideoxyinosine (ddI, Didanosine, Videx/EC)
220 = DMP266 (Efavirenz, Sustiva)
207 = Droxia (Hydroxyurea, Hydrea)
220 = Efavirenz (DMP266, Sustiva)
221 = Emivirine (MKC-442, Coactinon)
239 = Emtricitabine (Corviracil, FTC)
204 = Epivir (3-TC, Lamivudine)
210 = Fortovase (Saquinavir, Invirase)
239 = FTC (Emtricitabine, Corviracil)
224 = GS 840 (Adefovir, Preveon, bis-POM PMPA)
234 = GS 902 (Tenofovir disoproxil, bis POC PMPA,
Adenine Fumarate)
094 = Hivid (ddC, dideoxycytidine, Zalcitabine)
056 = HPA-23 (Ammonium-21-tungsto-9-anti-
moniate)
207 = Hydrea (Hydroxyurea, Droxia)
207 = Hydroxyurea (Droxia, Hydrea)
212 = Indinavir (Crixivan)
210 = Invirase (Saquinavir, Fortovase)
055 = Isoprinosine
217 = Kaletra (Lopinavir/Ritonavir, ABT-378/r)
204 = Lamivudine (3-TC, Epivir)
222 = Lobucavir
217 = Lopinavir/Ritonavir (Kaletra, ABT-378/r)
223 = Loviride
221 = MKC-442 (Emivirine, Coactinon)
216 = Nelfinavir (Viracept)
191 = Nevirapine (Viramune)
211 = Norvir (Ritonavir)
998 = Other antiviral
193 = Other protease inhibitors
233 = Pentafuside (T-20)
108 = Peptide T
238 = PNU-140690 (Tipranavir)
224 = Preveon
(Adefovir, bis-POM PMPA, GS 840)
194 = Rescriptor (Delavirdine, U-90)
092 = Retrovir (AZT, Zidovudine)
058 = Ribavirin (Virazole)
211 = Ritonavir (Norvir)
210 = Saquinavir (Invirase, Fortovase)
159 = Stavudine (Zerit, d4T)
057 = Suramin
220 = Sustiva (Efavirenz, DMP266)
192 = TAT inhibitors
233 = T-20 (Pentafuside)
234 = Tenofovir disoproxil (Adenine Fumerate, bis-
POC PMPA, GS 902)
238 = Tipranavir (PNU-140690)
240 = Trizivir (ABC + AZT + 3TC)
194 = U-90 (Delavirdine, Rescriptor)
179 = Vidarabine (adenosine arabinoside)
147 = Videx/EC (ddI, dideoxyinosine, Didanosine)
216 = Viracept (Nelfinavir)
191 = Viramune (Nevirapine)
058 = Virazole (Ribavirin)
231 = vistide (cidofovir)
094 = Zalcitabine (ddC, dideoxycytidine, Hivid)
159 = Zerit (d4T, Stavudine)
218 = Ziagen (Abacavir, 1592U89)
092 = Zidovudine (AZT, Retrovir)
146 = Zovirax (Acyclovir)

APPENDIX C: 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.