

TEAR OFF AND DESTROY 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 AND DESTROY.

TEAR OFF AND DESTROY THIS FRONT PAGE ONCE ABSTRACTION IS COMPLETED

Screening ID #

SECTION B: REQUIRED ABSTRACTION

B1. Do the medical records indicate that this person has ever used any type of ART, as listed in Drug List 1/Appendix B (including mono or combo therapy or HAART)?

Yes..... 1
 No..... 2 **(ELIGIBLE AS ART-NAÏVE PARTICIPANT; END FORM)**

a. Do the medical records indicate that this person has ever used ddI (Videx, didanosine), ddC (Hivid, zalcitabine) or d4T (Zerit, stavudine), not during pregnancy or as part of PEP/PrEP?

Yes..... 1 **(NOT ELIGIBLE ; END FORM)**
 No..... 2

b. Date of first HAART use: |_|_|/|_|_|/|_|_|
 M D Y

B2. Circle the one response below that best describes the participant’s ART/HAART use history:

First HAART started after 12/31/04	1	Eligible; complete B5 and B6
Only ART/HAART use was during pregnancy before 1/1/05	2	Eligible; complete B3 and B6
Only ART/HAART use was for PEP/PrEP before 1/1/05	3	Eligible; complete B4 and B6
ART/HAART use for pregnancy before 1/1/05 + HAART started after 12/31/04	4	Eligible; complete B3, B5 and B6
ART/HAART use for PEP/PrEP before 1/1/05 + HAART started after 12/31/04	5	Eligible; complete B4, B5 and B6
ART/HAART use before 1/1/05 that was not for pregnancy or PEP/PrEP	6	Ineligible; end form
ART use that was not for pregnancy or PEP/PrEP before HAART	7	Ineligible; end form

START RABs6

B3. List the drugs that comprised the participant’s ART/HAART regimen taken during pregnancy.

List all drugs in pregnancy regimen	Drug Code*	Start Date (MM/DD/YY)	Prescribed Dosage (if available)
1.	_ _ _	_ _ / _ _ / _ _	
2.	_ _ _	_ _ / _ _ / _ _	
3.	_ _ _	_ _ / _ _ / _ _	
4.	_ _ _	_ _ / _ _ / _ _	
5.	_ _ _	_ _ / _ _ / _ _	

*See Appendix B for Drug Code information

END RABs6

Screening ID #

START RABs7

B4. List the drugs that comprised the participant’s ART/HAART regimen taken for PEP/PrEP.

List all drugs in PEP/PrEP regimen	Drug Code*	Start Date (MM/DD/YY)	Prescribed Dosage (if available)
1.	_ _ _ _	_ _ _ / _ _ _ / _ _ _	
2.	_ _ _ _	_ _ _ / _ _ _ / _ _ _	
3.	_ _ _ _	_ _ _ / _ _ _ / _ _ _	
4.	_ _ _ _	_ _ _ / _ _ _ / _ _ _	
5.	_ _ _ _	_ _ _ / _ _ _ / _ _ _	

*See Appendix B for Drug Code information

END RABs7

START RABs1

B5. List the drugs that comprised the participant’s first post-2004 HAART regimen.

List all drugs in first post-2004 HAART regimen	Drug Code*	Start Date (MM/DD/YY)	Prescribed Dosage (if available)
1.	_ _ _ _	_ _ _ / _ _ _ / _ _ _	
2.	_ _ _ _	_ _ _ / _ _ _ / _ _ _	
3.	_ _ _ _	_ _ _ / _ _ _ / _ _ _	
4.	_ _ _ _	_ _ _ / _ _ _ / _ _ _	
5.	_ _ _ _	_ _ _ / _ _ _ / _ _ _	

*See Appendix B for Drug Code information

END RABs1

B6. Are there HIV RNA and T-cell results at or within six months prior to post-2004 HAART initiation?

- Yes..... 1 **(GO TO B6A TO RECORD RESULTS)**
- No..... 2 **(PERSON INELIGIBLE; END FORM)**
- N/A; No post-2004 HAART taken..... 3 **(GO TO SECTION C)**

DATES OF THE BLOOD DRAWS SHOULD BE WITHIN SIX MONTHS OF THE INITIAL HAART DATE. IF BLOOD WAS DRAWN AT THE TIME OF FIRST HAART PRESCRIPTION, RECORD THESE RESULTS, OTHERWISE RECORD THE LAB RESULT FROM THE MOST RECENT DATE BEFORE HAART.

Screening ID #

Most recent blood draw prior to or at HAART initiation:

A. HIV RNA

i. Date of blood draw: ___ M ___ / ___ D ___ / ___ Y ___

ii. Below limit of assay detection? Yes 1 No..... 2

iii. Copies/ml (If undetectable, list lower limit of detection) ___ , ___ , ___

iv. Assay kit (circle one):

- Roche Amplicor RNA 1
Roche Ultrasensitive RNA 2
NASBA 3
Nuclisens 4
Chiron..... 5
Quantiplex 8
TaqMan 9
Bayer Branched DNA 10
Abbott Real Time PCR..... 11
Siemens bDNA..... 12
Unknown 6
Other:..... 7

SPECIFY: _____

B. T-cell Count:

i. Date of blood draw: ___ M ___ / ___ D ___ / ___ Y ___

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

B7. Is weight at HAART initiation or within three months prior to starting HAART available?

YES1
NO.....2 (SECTION C)

Screening ID #

B8. Weight at HAART initiation or within three months prior to starting HAART. If multiple weights are available, record the one closest to HAART initiation.

a. Weight: |_|_|_|_| LBS

b. Date: |_|_|_|_| / |_|_|_|_| / |_|_|_|_|
 M D Y

SECTION C: SUPPLEMENTAL ABSTRACTION

C2. If additional regimen data can be located concerning regimens a participant switched to after their initial HAART regimen, record this information below. If no additional data can be found, **CHECK BOX BELOW AND SKIP TO THE PROMPT ABOVE C3.**

Check here if no additional regimen results are available after initial HAART

START RABs3

List all drugs in 2 nd regimen	Drug Code*	Start Date (MM/DD/YY)	Prescribed Dosage (if available)
1.			
2.			
3.			
4.			
5.			

List all drugs in 3 rd regimen	Drug Code*	Start Date (MM/DD/YY)	Prescribed Dosage (if available)
1.			
2.			
3.			
4.			
5.			

Screening ID #

List all drugs in 4 th regimen	Drug Code*	Start Date (MM/DD/YY)	Prescribed Dosage (if available)
1.			
2.			
3.			
4.			
5.			

* See Appendix B for Drug Code information

END RABs3

If there are multiple HIV RNA and/or T-cell results within six months prior to the initial HAART date other than the draw listed in B6, list results of the 2nd most recent blood draw in C3. Results recorded in C3 should be prior to the results listed in Section B. If no additional results are available, CHECK BOX BELOW AND SKIP TO C4.

C3. 2nd most recent blood draw prior to HAART initiation (must be before date in B6A):

Check here if no additional prior HIV RNA/T-cell results are available

A. HIV RNA

i. Date of 2nd blood draw: _____ / _____ / _____
M D Y

ii. Below limit of assay detection? Yes 1 No 2

iii. Copies/ml (If undetectable, list lower limit of detection) _____ , _____ , _____

iv. Assay kit (**circle one**):

- Roche Amplicor RNA 1
- Roche Ultrasensitive RNA 2
- NASBA 3
- Nuclisens 4
- Chiron..... 5
- Quantiplex 8
- TaqMan 9
- Bayer Branched DNA 10
- Abbott Real Time PCR..... 11
- Siemens bDNA..... 12
- Unknown 6
- Other:..... 7

SPECIFY: _____

Screening ID #

B. T-cell Count:

i. Date of 2nd blood draw: _____ / _____ / _____
M / D / Y

ii. Counts:

CD4#: _____ CD4%: _____ %

(if available) CD8#: _____ CD8%: _____ %

(if available) CD3#: _____ CD3%: _____ %

C4. Record all available HIV RNA and T-cell results **post HAART initiation**, starting with results closest to HAART initiation date. **Do not include results more frequently than quarterly.** If no post-HAART test results are available, **CHECK BOX BELOW AND SKIP TO C5.**

Check here if no HIV RNA or T-cell results are available post-HAART

START RABs4

A. HIV RNA Results (post-HAART)

Date (MM/DD/YY)	Result below limit of assay detection	HIV RNA (copies/mL) (If undetectable, list lower limit of detection)	Assay Kit (if available)	
1.	Yes.....1 No.....2		Roche Amplicor.....1 Roche Ultrasensitive.....2 NASBA.....3 Nuclisens.....4 Chiron.....5 Quantiplex.....8 TaqMan.....9	Bayer bDNA.....10 Abbott Real Time....11 Siemens bDNA.....12 Unknown.....6 Other.....7 _____
2.	Yes.....1 No.....2		Roche Amplicor.....1 Roche Ultrasensitive.....2 NASBA.....3 Nuclisens.....4 Chiron.....5 Quantiplex.....8 TaqMan.....9	Bayer bDNA.....10 Abbott Real Time....11 Siemens bDNA.....12 Unknown.....6 Other.....7 _____
3.	Yes.....1 No.....2		Roche Amplicor.....1 Roche Ultrasensitive.....2 NASBA.....3 Nuclisens.....4 Chiron.....5 Quantiplex.....8 TaqMan.....9	Bayer bDNA.....10 Abbott Real Time....11 Siemens bDNA.....12 Unknown.....6 Other.....7 _____
4.	Yes.....1 No.....2		Roche Amplicor.....1 Roche Ultrasensitive.....2 NASBA.....3 Nuclisens.....4 Chiron.....5 Quantiplex.....8 TaqMan.....9	Bayer bDNA.....10 Abbott Real Time....11 Siemens bDNA.....12 Unknown.....6 Other.....7 _____

Screening ID #

Date (MM/DD/YY)	Result below limit of assay detection	HIV RNA (copies/mL) (If undetectable, list lower limit of detection)	Assay Kit (if available)	
5.	Yes.....1 No.....2		Roche Amplicor.....1 Roche Ultrasensitive....2 NASBA.....3 Nuclisens.....4 Chiron.....5 Quantiplex.....8 TaqMan.....9	Bayer bDNA.....10 Abbott Real Time....11 Siemens bDNA.....12 Unknown.....6 Other.....7 _____

END RABs4

START RABs5

B. T-cell Results (post-HAART)

Date (MM/DD/YY)	CD4#	CD4%	CD8#	CD8%	CD3#	CD3%
1.						
2.						
3.						
4.						
5.						
6.						
7.						
8.						
9.						
10.						

END RABs5

XEROX C4 PARTS A AND B IF ADDITIONAL SPACES ARE NEEDED.

Screening ID #

C5. ADDITIONAL COMMENTS:

Appendix A: Definition of HAART

ABACAVIR + ANY OTHER 2 ANTIRETROVIRAL MEDICATIONS

TENOFOVIR + ANY OTHER 2 ANTIRETROVIRAL MEDICATIONS

ANY PI + ANY OTHER 2 ANTIRETROVIRAL MEDICATIONS

ANY NNRTI + ANY OTHER 2 ANTIRETROVIRAL MEDICATIONS

ISENTRESS OR TIVICAY + ANY OTHER 2 ANTIRETROVIRAL
MEDICATIONS

FUZEON + ANY OTHER 2 ANTIRETROVIRAL MEDICATIONS

SELZENTRY + ANY OTHER 2 ANTIRETROVIRAL MEDICATIONS

STRIBILD

NOTE: NRTI = Nucleoside reverse transcriptase inhibitor
NNRTI = Non-nucleoside reverse transcriptase inhibitor
PI = Protease inhibitor

If you come across any regimen that you think may be a HAART regimen but which does not fit into one of the above definitions, contact Christine Alden (calden@jhsph.edu) at WDMAC.

Combination Medications

- ___ Atripla (Sustiva + Viread + Emtriva)
- ___ Combivir (AZT + 3TC)
- ___ Epzicom (Ziagen + Efavirenz)
- ___ Trizivir (abacavir + AZT + 3TC)
- ___ Truvada (Viread + Emtriva)
- ___ Complera (emtricitabine + rilpivirine + tenofovir)
- ___ Stribild (FTC + Viread + EVG + cobicistat)

Entry Inhibitors

- ___ Fuzeon (T-20, enfuvirtide)
- ___ Selzentry (maraviroc)

Nucleoside/Nucleotide RTIs

- ___ Emtriva (emtricitabine, FTC)
- ___ Efavirenz (lamivudine, 3-TC)
- ___ Retrovir (AZT, zidovudine, ZDV)
- ___ Videx / Videx EC (didanosine, dDI)
- ___ Viread (tenofovir)
- ___ Zerit (stavudine, d4T)
- ___ Ziagen (abacavir)
- ___ Hivid (zalcitabine, ddC)

Non-Nucleoside RTIs

- ___ Intelence (etravirine, TMC 125)
- ___ Rescriptor (delavirdine)
- ___ Sustiva (efavirenz)
- ___ Viramune (nevirapine)
- ___ Edurant (rilpivirine)

Protease Inhibitors

- ___ Aptivus (tipranavir)
- ___ Crixivan (indinavir)
- ___ Invirase (saquinavir)
- ___ Kaletra (lopinavir + ritonavir)
- ___ Lexiva (fosamprenavir)
- ___ Norvir (ritonavir)
- ___ Prezista (TMC-114, darunavir)
- ___ Reyataz (atazanavir)
- ___ Viracept (nelfinavir)

Integrase Inhibitors

- ___ Isentress (raltegravir, MK 0518)
- ___ Tivicay (dolutegravir)

Definition of HAART (check which definition applies):

- Abacavir + 2 ART
- Tenofovir + 2 ART
- 1 PI + 2 ART
- 1 NNRTI + 2 ART
- Isentress OR Tivicay + 2 ART
- Fuzeon + 2 ART
- Selzentry + 2 ART
- Stribild

Appendix B: DRUG LIST 1

204 = 3-TC (Epivir, lamivudine)	221 = emivirine (Coactinon)	194 = Rescriptor (delavirdine)
218 = abacavir (Ziagen)	239 = emtricitabine (Emtriva, Corviracil, FTC)	092 = Retrovir (AZT, zidovudine)
285 = ACTG A5303 (Prezista, Norvir, Emtriva + Viread and Selzentry blinded trial)	239 = Emtriva (emtricitabine, Coviracil, FTC)	243 = Reyataz (atazanavir)
146 = acyclovir (Zovirax)	285 = Emtriva, Norvir, Prezista + Viread and Selzentry blinded trial (ACTG A5303)	058 = ribavirin (Virazole)
224 = adefovir (Preveon)	233 = ENF (enfuvirtide, Fuzeon, T-20)	276 = rilpivirine (Edurant, TMC 278)
219 = Agenerase (amprenavir)	233 = enfuvirtide (Fuzeon, T-20, ENF)	211 = ritonavir (Norvir)
090 = alpha interferon	204 = Epivir (3-TC, lamivudine)	248 = SC 351125 (SCH C)
101 = Ampligen	254 = Epzicom (abacavir sulfate + lamivudine, Ziagen + Epivir)	248 = SCH C (SC 351125)
219 = amprenavir (Agenerase)	255 = etravirine (Intelence, TMC 125)	266 = SCH-417690 (vicriviroc)
238 = Aptivus (tipranavir)	210 = Fortovase (saquinavir, Invirase)	258 = SP01A (Samaritan Pharma oral entry inhibitor)
243 = atazanavir (Reyataz)	249 = fosamprenavir (Lexiva)	258 = Samaritan Pharma oral entry inhibitor (SP01A)
262 = Atripla (Sustiva + Viread + Emtriva, efavirenz + tenofovir + emtricitabine)	239 = FTC (Emtriva, emtricitabine, Corviracil)	210 = saquinavir (Invirase, Fortovase)
092 = AZT (Retrovir, zidovudine)	233 = Fuzeon (enfuvirtide, T-20, ENF)	265 = Selzentry (maraviroc)
122 = beta interferon	284 = GS-9137 (elvitegravir)	159 = stavudine (Zerit, d4T)
263 = brecaonavir (GW640385)	268 = GS-9137 (elvitegravir) blinded trial	057 = suramin
128 = CD4	283 = GS-9350 (Cobicistat)	287 = Stribild (FTC+Viread+EVG+cobicistat)
231 = cidofovir (Vistide)	263 = GW640385 (brecaonavir)	220 = Sustiva (efavirenz, DMP266)
221 = coactinon (emivirine)	094 = Hivid (ddC, dideoxycytidine, zalcitabine)	233 = T-20 (enfuvirtide, Fuzeon, ENF)
283 = cobicistat (GS-9350)	056 = HPA-23 (ammonium-21-tungsto-9-antimoniate)	192 = TAT inhibitors
282 = cobicistat-boosted darunavir (blinded trial comparing cobicistat-boosted darunavir to ritonavir-boosted darunavir)	207 = Hydrea (hydroxyurea, Droxia)	256 = TMC-114 (Prezista, darunavir)
227 = Combivir (AZT + 3TC, Retrovir + Epivir)	207 = hydroxyurea (Droxia, Hydrea)	255 = TMC 125 (Intelence, etravirine)
280 = Complera (emtricitabine + rilpivirine + tenofovir)	212 = indinavir (Crixivan)	267 = TMC278 blinded trial
239 = Corviracil (Emtriva, emtricitabine, FTC)	255 = Intelence (etravirine, TMC 125)	276 = TMC 278 (rilpivirine, Edurant)
212 = Crixivan (indinavir)	210 = Invirase (saquinavir, Fortovase)	234 = Tenofovir disoproxil (adenine fumarate, Viread)
159 = d4T (Zerit, stavudine)	264 = Isentress (raltegravir, MK 0518)	238 = tipranavir (Aptivus)
163 = ddA (dideoxyadenosine)	055 = Isoprinosine	286 = Tivicay (dolutegravir, S/GSK1349572)
094 = ddC (dideoxycytidine, zalcitabine, Hivid)	217 = Kaletra (lopinavir/ritonavir)	240 = Trizivir (abacavir + zidovudine + lamivudine, ABC + AZT + 3TC)
147 = ddi (dideoxyinosine, didanosine, Videx, Videx EC)	257 = L-00870810 (Merck integrase inhibitor)	253 = Truvada (tenofovir disoproxil fumarate + emtricitabine, Viread + Emtriva, TDF + FTC)
244 = DPC 083	204 = lamivudine (3-TC, Epivir)	265 = UK-427, 857 (maraviroc)
256 = darunavir (Prezista, TMC-114)	249 = Lexiva (fosamprenavir)	999 = Unknown antiviral
194 = delavirdine (Rescriptor)	222 = lobucavir	266 = vicriviroc (SCH-417690)
110 = dextran-sulfate	217 = lopinavir/ritonavir (Kaletra)	269 = vicriviroc blinded trial
147 = didanosine (ddi, dideoxyinosine, Videx, Videx EC)	223 = loviride	179 = Vidarabine (adenosine arabinoside)
163 = dideoxyadenosine (ddA)	264 = MK 0518 (Isentress, raltegravir)	147 = Videx (ddi, dideoxyinosine, didanosine, Videx EC)
094 = dideoxycytidine (ddC, zalcitabine, Hivid)	265 = maraviroc (Selzentry)	216 = Viracept (nelfinavir)
147 = dideoxyinosine (ddi, didanosine, Videx, Videx EC)	257 = Merck integrase inhibitor (L-00870810)	191 = Viramune (nevirapine)
286 = dolutegravir (Tivicay, S/GSK1349572)	216 = nelfinavir (Viracept)	058 = Virazole (ribavirin)
207 = Droxia (hydroxyurea, Hydrea)	191 = nevirapine (Viramune)	234 = Viread (adenine fumarate, tenofovir disoproxil)
276 = Edurant (rilpivirine, TMC 278)	211 = Norvir (ritonavir)	231 = Vistide (cidofovir)
220 = efavirenz (Sustiva)	285 = Norvir, Prezista, Emtriva + Viread and Selzentry blinded trial (ACTG A5303)	094 = zalcitabine (ddC, dideoxycytidine, Hivid)
284 = elvitegravir (GS-9137)	998 = Other antiviral	159 = Zerit (d4T, stavudine)
268 = elvitegravir (GS-9137) blinded trial	193 = Other protease inhibitors	218 = Ziagen (abacavir)
278 = elvitegravir + cobicistat booster (blinded trial)	108 = Peptide T	092 = zidovudine (AZT, Retrovir)
	224 = Preveon (adefovir)	146 = Zovirax (acyclovir)
	256 = Prezista (darunavir, TMC-114)	
	285 = Prezista, Norvir, Emtriva + Viread and Selzentry blinded trial (ACTG A5303)	
	264 = raltegravir (Isentress, MK 0518)	

