

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

WOMEN'S INTERAGENCY HIV STUDY
RETROSPECTIVE MEDICAL RECORD ABSTRACTION (RAB)

INSTRUCTIONS:

THERE ARE 2 SECTIONS OF THIS FORM, A REQUIRED SECTION (SECTION B), AND A SUPPLEMENTAL SECTION (SECTION C). FOR A PARTICIPANT TO BE ELIGIBLE FOR ENROLLMENT, THE INFORMATION IN SECTION B IS REQUIRED. IF INFORMATION CAN BE FOUND TO COMPLETE SECTION C, THAT SHOULD BE FILLED OUT AS WELL. HOWEVER, THE INFORMATION CONTAINED IN SECTION C IS NOT REQUIRED TO ENROLL A PARTICIPANT IN THE WIHS.

THROUGHOUT THIS FORM, ANTIRETROVIRAL THERAPY WILL BE REFERRED TO AS ART AND HIGHLY ACTIVE ANTIRETROVIRAL THERAPY WILL BE REFERRED TO AS HAART.

SECTION A: GENERAL INFORMATION

A1. SCREENING ID: _____

A2. WIHSID (IF ENROLLED): |__| - |__|__| - |__|__|__|__| - |__|

A3. FORM VERSION: **10/01/11**

A4. ABTRACTOR'S INITIALS: _____

A5. DATE OF ABSTRACTION: _____ / _____ / _____
M D Y

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%: ___ %

Screening ID #

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.			

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

Screening ID #

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 _____
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

Screening ID #

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.

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 NNTRI + ANY OTHER 2 ANTIRETROVIRAL MEDICATIONS

ISENTRESS + ANY OTHER 2 ANTIRETROVIRAL MEDICATIONS

FUZEON + ANY OTHER 2 ANTIRETROVIRAL MEDICATIONS

SELZENTRY + ANY OTHER 2 ANTIRETROVIRAL MEDICATIONS

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)

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)

Definition of HAART (check which definition applies):

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

Appendix B: DRUG LIST 1

204 = 3-TC (Epivir, lamivudine)	255 = Intelence (etravirine)
218 = abacavir (Ziagen)	210 = Invirase (saquinavir, Fortovase)
146 = acyclovir (Zovirax)	264 = Isentress (raltegravir)
224 = adefovir (Preveon)	055 = Isoprinosine
219 = Agenerase (amprenavir)	217 = Kaletra (lopinavir/ritonavir)
090 = alpha interferon	204 = lamivudine (3-TC, Epivir)
101 = Ampligen	249 = Lexiva (fosamprenavir)
219 = amprenavir (Agenerase)	222 = lobucavir
238 = Aptivus (tipranavir)	217 = lopinavir/ritonavir (Kaletra)
243 = atazanavir (Reyataz)	223 = loviride
262 = Atripla (Sustiva + Viread + Emtriva, efavirenz + tenofovir + emtricitabine)	265 = maraviroc (Selzentry)
092 = AZT (Retrovir, zidovudine)	216 = nelfinavir (Viracept)
122 = beta interferon	191 = nevirapine (Viramune)
263 = brecanavir	211 = Norvir (ritonavir)
128 = CD4	998 = Other antiviral
231 = cidofovir (Vistide)	108 = Peptide T
221 = coactinon (emivirine)	224 = Preveon (adefovir)
227 = Combivir (AZT + 3TC, Retrovir + Epivir)	256 = Prezista (darunavir)
280 = Complera (emtricitabine + rilpivirine + tenofovir)	264 = raltegravir (Isentress)
239 = Corviracil (Emtriva, emtricitabine, FTC)	194 = Rescriptor (delavirdine)
212 = Crixivan (indinavir)	092 = Retrovir (AZT, zidovudine)
159 = d4T (Zerit, stavudine)	243 = Reyataz (atazanavir)
163 = ddA (dideoxyandenosine)	058 = ribavirin (Virazole)
094 = ddC (dideoxycytidine, zalcitabine, Hivid)	276 = rilpivirine (Edurant)
147 = ddi (dideoxyinosine, didanosine, Videx, Videx EC)	211 = ritonavir (Norvir)
256 = darunavir (Prezista)	210 = saquinavir (Invirase, Fortovase)
194 = delavirdine (Rescriptor)	265 = Selzentry (maraviroc)
110 = dextran-sulfate	159 = stavudine (Zerit, d4T)
147 = didanosine (ddi, dideoxyinosine, Videx, Videx EC)	057 = suramin
163 = dideoxyandenosine (ddA)	220 = Sustiva (efavirenz)
094 = dideoxycytidine (ddC, zalcitabine, Hivid)	233 = T-20 (enfuvirtide, Fuzeon, ENF)
147 = dideoxyinosine (ddi, didanosine, Videx, Videx EC)	192 = TAT inhibitors
207 = Droxia (hydroxyurea, Hydrea)	234 = Tenofovir disoproxil (adenine fumarate, Viread)
276 = Edurant (rilpivirine)	238 = tipranavir (Aptivus)
220 = efavirenz (Sustiva)	240 = Trizivir (abacavir + zidovudine + lamivudine, ABC + AZT + 3TC)
221 = emivirine (Coactinon)	253 = Truvada (tenofovir disoproxil fumarate + emtricitabine, Viread + Emtriva, TDF + FTC)
239 = emtricitabine (Emtriva, Corviracil, FTC)	999 = Unknown antiviral
239 = Emtriva (emtricitabine, Coviracil, FTC)	266 = vicriviroc
233 = ENF (enfuvirtide, Fuzeon, T-20)	179 = Vidarabine (adenosine arabinoside)
233 = enfuvirtide (Fuzeon, T-20, ENF)	147 = Videx (ddi, dideoxyinosine, didanosine, Videx EC)
204 = Epivir (3-TC, lamivudine)	216 = Viracept (nelfinavir)
254 = Epzicom (abacavir + lamivudine, Ziagen + Epivir)	191 = Viramune (nevirapine)
255 = etravirine (Intelence)	058 = Virazole (ribavirin)
210 = Fortovase (saquinavir, Invirase)	234 = Viread (adenine fumarate, tenofovir disoproxil)
249 = fosamprenavir (Lexiva)	231 = Vistide (cidofovir)
239 = FTC (Emtriva, emtricitabine, Corviracil)	094 = zalcitabine (ddC, dideoxycytidine, Hivid)
233 = Fuzeon (enfuvirtide, T-20, ENF)	159 = Zerit (d4T, stavudine)
094 = Hivid (ddC, dideoxycytidine, zalcitabine)	218 = Ziagen (abacavir)
056 = HPA-23 (ammonium-21-tungsto-9-anti-moniatoe)	092 = zidovudine (AZT, Retrovir)
207 = Hydrea (hydroxyurea, Droxia)	146 = Zovirax (acyclovir)
207 = hydroxyurea (Droxia, Hydrea)	
212 = indinavir (Crixivan)	