

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.

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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: $\frac{1}{M} \frac{0}{D} / \frac{0}{D} \frac{1}{Y} / \frac{0}{Y} \frac{1}{Y}$

A4. ABTRACTOR'S INITIALS: _____

A5. DATE OF ABSTRACTION: $\frac{\quad}{M} / \frac{\quad}{D} / \frac{\quad}{Y}$

Screening ID #

SECTION B: REQUIRED ABSTRACTION

B1. Using the Definition of HAART (see Appendix A), do the medical records indicate that this person ever used HAART?

Yes..... 1
 No..... 2 (C5)

B2. When was HAART first prescribed? ___ M ___ / ___ D ___ / ___ Y ___

B3. List below the drugs that comprised the participant’s first HAART regimen:

List All Drug(s) in 1 st 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

B4. When this participant first used HAART, was she pregnant?

Yes..... 1
 No..... 2

B5. Did this participant use any antiretroviral medications (see Appendix B for list) prior to HAART?

Yes..... 1
 No..... 2
 Unknown..... 3

**IF YES, ART HISTORY
 WILL BE RECORDED IN
 SECTION C**

Screening ID #

B6. What are the HIV RNA and T-cell results at or just prior to their initiation of HAART?

DATES OF THE BLOOD DRAWS SHOULD BE WITHIN 6 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.

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
- 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. Was an AIDS diagnosis found at any point during the MRA process?

Yes 1

No 2

IF B7 = YES, DOCUMENT AIDS DIAGNOSIS IN C5 WHEN YOU GET THERE

Screening ID #

SECTION C: SUPPLEMENTAL ABSTRACTION

C1. If the person used ARTs **prior** to HAART initiation (**B5 = YES**), list all ARTs used **prior** to initial HAART date below. If person did not use ARTs prior to HAART or if this information cannot be found (**B5 = NO or UNKNOWN**), **CHECK BOX BELOW AND SKIP TO C2.**

Check here if no data is available on ARTs prior to HAART

Name of Drug	Drug Code*	Start Date (MM/DD/YY)	Prescribed Dosage (if available)
1.			
2.			
3.			
4.			
5.			
6.			
7.			
8.			
9.			
10.			
11.			
12.			
13.			
14.			
15.			

* See Appendix B for Drug Code information

Screening ID #

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

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

Screening ID #

If there are multiple HIV RNA and/or T-cell results within 6 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 QB6.A):

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
- Unknown 6
- Other: 7

(SPECIFY)

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%: ___ ___ ___ . ___ %

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

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 Chiron.....5 Roche Ultrasensitive...2 Unknown...6 NASBA.....3 Other.....7 Nuclisens.....4 _____
2.	Yes.....1 No.....2		Roche Amplicor.....1 Chiron.....5 Roche Ultrasensitive...2 Unknown...6 NASBA.....3 Other.....7 Nuclisens.....4 _____
3.	Yes.....1 No.....2		Roche Amplicor.....1 Chiron.....5 Roche Ultrasensitive...2 Unknown...6 NASBA.....3 Other.....7 Nuclisens.....4 _____
4.	Yes.....1 No.....2		Roche Amplicor.....1 Chiron.....5 Roche Ultrasensitive...2 Unknown...6 NASBA.....3 Other.....7 Nuclisens.....4 _____
5.	Yes.....1 No.....2		Roche Amplicor.....1 Chiron.....5 Roche Ultrasensitive...2 Unknown...6 NASBA.....3 Other.....7 Nuclisens.....4 _____
6.	Yes.....1 No.....2		Roche Amplicor.....1 Chiron.....5 Roche Ultrasensitive...2 Unknown...6 NASBA.....3 Other.....7 Nuclisens.....4 _____
7.	Yes.....1 No.....2		Roche Amplicor.....1 Chiron.....5 Roche Ultrasensitive...2 Unknown...6 NASBA.....3 Other.....7 Nuclisens.....4 _____
8.	Yes.....1 No.....2		Roche Amplicor.....1 Chiron.....5 Roche Ultrasensitive...2 Unknown...6 NASBA.....3 Other.....7 Nuclisens.....4 _____

Screening ID #

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.						

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

C5. **ADDITIONAL COMMENTS** (e.g. exact AIDS diagnosis found in MRA, etc...):

Appendix A: Definition of HAART

≥ 2 NRTIs

+

≥ 1 PI **and/or** ≥ 1 NNRTI

OR 1 NRTI + ≥ 1 PI + ≥ 1 NNRTI

OR 1 NRTI + RTV*/SQV + no NNRTIs

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

* Must be full dose ritonavir (≥ 400 mg or >2 pills per dose).

NOTE: NRTI = Nucleoside reverse transcriptase inhibitor
NNRTI = Non-nucleoside 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 Lynn Kirstein at WDMAC at (410) 614-1340.

Antiretroviral Medications (Appendix A)		
Group A (NRTIs)	Group B (PIs)	Group C (NNRTIs)
<input type="checkbox"/> 3-TC (Lamivudine, Epivir)	<input type="checkbox"/> Amprenavir (Agenerase)	<input type="checkbox"/> Delavirdine (Rescriptor)
<input type="checkbox"/> Abacavir (Ziagen)	<input type="checkbox"/> Indinavir (Crixivan)	<input type="checkbox"/> Efavirenz (Sustiva)
<input type="checkbox"/> Adefovir (Preveon)	<input type="checkbox"/> Nelfinavir (Viracept)	<input type="checkbox"/> Nevirapine (Viramune)
<input type="checkbox"/> AZT (Retrovir, zidovudine)	<input type="checkbox"/> Ritonavir (Norvir), full dose*	<input type="checkbox"/> Emivirine (MCK-442, Coactinon)
<input type="checkbox"/> Combivir (AZT/3-TC)*	<input type="checkbox"/> Ritonavir (Norvir), low dose**	
<input type="checkbox"/> d4T (stavudine, Zerit)	<input type="checkbox"/> Saquinavir (Invirase, Fortovase)	
<input type="checkbox"/> ddC (dideoxycytidine, Hivid, Zalcitabine)	<input type="checkbox"/> Kaletra (Lopinavir)	
<input type="checkbox"/> ddI (dideoxyinosine, Videx, Didanosine)	<input type="checkbox"/> Tipranavir (PNU-140690)	
<input type="checkbox"/> Tenofovir disoproxil (bis-POC PMPA, Adenine Fumarate)	<input type="checkbox"/> Atazanavir (BMS-232632)	
<input type="checkbox"/> Emtricitabine (FTC)		
<input type="checkbox"/> Trizivir (AZT/3TC/Abacavir)**		
*Combivir counts as 2 drugs **Trizivir counts as 3 drugs	*Full dose: $\geq 400\text{mg}$, > 2 pills/dose **Low dose: $\leq 200\text{mg}$, 1-2 pills/dose	
Total # from A: _____	Total # from B: _____	Total # from C: _____

Definition of HAART (check which definition applies):

- ≥ 2 NRTI + (≥ 1 PI and/or ≥ 1 NNRTI)
- 1 NRTI + ≥ 1 PI + ≥ 1 NNRTI
- 1 NRTI + RTV*/SQV + 0 NNRTI (*Must be full-dose RTV)
- Abacavir + 2 NRTI + 0 PI + 0 NNRTI

Appendix B: DRUG LIST 1

219 = 141W94 (Amprenavir, Agenerase)	094 = Hivid (ddC, dideoxycytidine, Zalcitabine)
218 = 1592U89 (Abacavir, Ziagen)	056 = HPA-23 (Ammonium-21-tungsto-9-antimoniate)
204 = 3-TC (Epivir, Lamivudine)	207 = Hydrea (Hydroxyurea, Droxia)
218 = Abacavir (Ziagen, 1592U89)	207 = Hydroxyurea (Droxia, Hydrea)
217 = ABT-378/r (Lopinavir/Ritonavir, Kaletra)	212 = Indinavir (Crixivan)
146 = Acyclovir (Zovirax)	210 = Invirase (Saquinavir, Fortovase)
224 = Adefovir (Preveon, bis-POM PMPA, GS 840)	055 = Isoprinosine
219 = Agenerase (Amprenavir, 141W94)	217 = Kaletra (Lopinavir/Ritonavir, ABT-378/r)
098 = AL-721 (by Praxis) (egg lecithin)	204 = Lamivudine (3-TC, Epivir)
090 = Alpha Interferon	222 = Lobucavir
101 = Ampligen	217 = Lopinavir/Ritonavir (Kaletra, ABT-378/r)
219 = Amprenavir (Agenerase, 141W94)	223 = Loviride
243 = Atazanavir (BMS-232632)	221 = MKC-442 (Emivirine, Coactinon)
092 = AZT (Retrovir, Zidovudine)	216 = Nelfinavir (Viracept)
122 = Beta Interferon	191 = Nevirapine (Viramune)
234 = bis-POC PMPA (Tenofovir disoproxil, Adenine Fumarate, GS 902)	211 = Norvir (Ritonavir)
224 = bis-POM PMPA (Adefovir, Preveon, GS 840)	998 = Other antiviral
243 = BMS-232632 (Atazanavir)	193 = Other protease inhibitors
128 = CD4	233 = Pentafuside (T-20)
231 = didofovir (vistide)	108 = Peptide T
221 = Coactinon (MKC-442, Emivirine)	238 = PNU-140690 (Tipranavir)
227 = Combivir (AZT + 3TC, Retrovir + Epivir)	224 = Preveon (Adefovir, bis-POM PMPA, GS 840)
239 = Corviracil (Emtricitabine, FTC)	194 = Rescriptor (Delavirdine, U-90)
212 = Crixivan (Indinavir)	092 = Retrovir (AZT, Zidovudine)
159 = d4T (Zerit, Stavudine)	058 = Ribavirin (Virazole)
163 = ddA (dideoxyadenosine)	211 = Ritonavir (Norvir)
094 = ddC (dideoxycytidine, Zalcitabine, Hivid)	210 = Saquinavir (Invirase, Fortovase)
147 = ddI (dideoxyinosine, Didanosine, Videx/EC)	159 = Stavudine (Zerit, d4T)
194 = Delavirdine (Rescriptor, U-90)	057 = Suramin
110 = Dextran-Sulfate	220 = Sustiva (Efavirenz, DMP266)
147 = Didanosine (ddI, dideoxyinosine, Videx/EC)	192 = TAT inhibitors
163 = Dideoxyadenosine (ddA)	233 = T-20 (Pentafuside)
094 = Dideoxycytidine (ddC, Zalcitabine, Hivid)	234 = Tenofovir disoproxil (Adenine Fumerate, bis-POC PMPA, GS 902)
147 = Dideoxyinosine (ddI, Didanosine, Videx/EC)	238 = Tipranavir (PNU-140690)
220 = DMP266 (Efavirenz, Sustiva)	240 = Trizivir (ABC + AZT + 3TC)
207 = Droxia (Hydroxyurea, Hydrea)	194 = U-90 (Delavirdine, Rescriptor)
220 = Efavirenz (DMP266, Sustiva)	999 = Unknown antiviral
221 = Emivirine (MKC-442, Coactinon)	179 = Vidarabine (adenosine arabinoside)
239 = Emtricitabine (Corviracil, FTC)	147 = Videx/EC (ddI, dideoxyinosine, Didanosine)
204 = Epivir (3-TC, Lamivudine)	216 = Viracept (Nelfinavir)
210 = Fortovase (Saquinavir, Invirase)	191 = Viramune (Nevirapine)
239 = FTC (Emtricitabine, Corviracil)	058 = Virazole (Ribavirin)
224 = GS 840 (Adefovir, Preveon, bis-POM PMPA)	231 = vistide (didofovir)
234 = GS 902 (Tenofovir disoproxil, bis POC PMPA, Adenine Fumarate)	094 = Zalcitabine (ddC, dideoxycytidine, Hivid)
	159 = Zerit (d4T, Stavudine)
	218 = Ziagen (Abacavir, 1592U89)
	092 = Zidovudine (AZT, Retrovir)
	146 = Zovirax (Acyclovir)