WOMEN'S INTERAGENCY HIV STUDY
MUCOSAL IMMUNITY SUBSTUDY
FORM MINOTI: PARTICIPATION NOTIFICATION

INSTRUCTIONS:

USE THIS FORM TO DETERMINE IF PARTICIPANTS IDENTIFIED AS ELIGIBLE VIA REVIEW OF VISIT 28 DATA ARE STILL ELIGIBLE FOR ENROLLMENT.

QUESTIONS A1 THROUGH A5, SECTION C AND SECTION E OF THE FORM SHOULD BE ENTERED INTO APOLLO. IF A PARTICIPANT IS FOUND TO BE INELIGIBLE DUE TO CHANGES SINCE VISIT 28, DO NOT ENTER THE FORM INTO APOLLO.

A1. PARTICIPANT ID: ENTER NUMBER HERE ONLY IF ID LABEL IS NOT AVAILABLE |___| - |___|___| - |___|___|___|___| - |___|

A2. FORM VERSION: **0 4 / 0 1 / 0 9**

A3. FORM COMPLETED BY: |___|___|___|

A4. WIHS CORE VISIT: |___|___|

A5. DATE OF CORE VISIT: |___|___| / |___|___| / |___|___|
M D Y

NOTE FOR DATA ENTRY ONLY: AFTER ENTRY OF QUESTIONS A1 THROUGH A5, SKIP TO SECTION C.

A6. INDICATE EXPECTED ELIGIBILITY GROUP BASED ON VISIT 28 DATA:

HIV-uninfected..... 1 **(SECTION C)**
HIV-infected, on HAART, HIV RNA >50,000 2
HIV-infected, not on HAART, HIV RNA >50,000 3
HIV-infected, on HAART, undetectable HIV RNA 4
HIV-infected, not on HAART, undetectable HIV RNA for at least two WIHS visits (elite suppressor)..... 5

WIHS ID#

SECTION B. CURRENT ANTIRETROVIRAL USE

B1. PARTICIPANT'S CURRENT ANTIRETROVIRAL THERAPY:

INSTRUCTIONS: USING INFORMATION FROM THE ANTIRETROVIRAL DOSAGE FORM (*DSG*), CHECK OFF EACH MEDICATION THAT THE PARTICIPANT REPORTED TAKING WITHIN THE LAST THREE DAYS. INDICATE THE TOTAL NUMBER OF ARVS TAKEN FROM EACH CLASS IN THE GRAY BOXES.

Multi-Class Combination Drugs

262 ___ Atripla (Sustiva + Viread + Emtriva)

_____ **Total Multi-Class Drugs**

Nucleoside/Nucleotide Reverse Transcriptase Inhibitors (NRTIs)

227 ___ Combivir (AZT + 3TC)
239 ___ Emtriva (emtricitabine, FTC)
204 ___ Epivir (lamivudine, 3TC)
254 ___ Epzicom (Ziagen + Epivir)
092 ___ Retrovir (AZT, zidovudine, ZDV)
240 ___ Trizivir (abacavir + AZT + 3TC)
253 ___ Truvada (Viread + Emtriva)
147 ___ Videx & Videx EC (didanosine, ddI)
234 ___ Viread (tenofovir)
159 ___ Zerit (stavudine, d4T)
218 ___ Ziagen (abacavir, ABC)

_____ **Total NRTIs**

Non-Nucleoside Reverse Transcriptase Inhibitors (NNRTIs)

255 ___ Intelence (etravirine, TMC-125)
194 ___ Rescriptor (delavirdine)
220 ___ Sustiva (efavirenz)
191 ___ Viramune (nevirapine)

_____ **Total NNRTIs**

Protease Inhibitors (PIs)

238 ___ Aptivus (tipranavir)
212 ___ Crixivan (indinavir,)
210 ___ Invirase (saquinavir)
217 ___ Kaletra (lopinavir + ritonavir)
249 ___ Lexiva (fosamprenavir)
211 ___ Norvir (ritonavir)
256 ___ Prezista (TMC-114, darunavir)
243 ___ Reyataz (atazanavir)
216 ___ Viracept (nelfinavir)

_____ **Total PIs**

Entry Inhibitors (including Fusion Inhibitors)

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

_____ **Total Entry Inhibitors**

Integrase Inhibitors

264 ___ Isentress (raltegravir, MK-0518)

_____ **Total Integrase Inhibitors**

Cellular Inhibitors

207 ___ Droxia or Hydrea (hydroxyurea)

_____ **Total Cellular Inhibitors**

B2. CURRENT ANTIRETROVIRAL REGIMEN:

≥ 2 NRTI + (≥ 1 PI or ≥ 1 NNRTI) 1
1 NRTI + ≥ 1 PI + ≥ 1 NNRTI 2
≥ 2 NRTI + RALTEGRAVIR..... 3
ATRIPLA..... 4
OTHER HAART 5
NOT ON HAART..... 6

WIHS ID#

SECTION C. SPECIMEN COLLECTION

C1. HAS CPT PLASMA BEEN COLLECTED?

YES 1
NO ..... 2 **(E1)**

a. DATE CPT PLASMA COLLECTED |___|___| / |___|___| / |___|___|
M D Y

C2. HAS CVL BEEN COLLECTED?

YES 1
NO ..... 2 **(E1)**

a. DATE CVL COLLECTED |___|___| / |___|___| / |___|___|
M D Y

NOTE FOR DATA ENTRY ONLY: AFTER ENTRY OF SECTION C, SKIP TO SECTION E.

SECTION D. LABORATORY RESULTS

D1. MOST RECENT HIV ANTIBODY RESULT:

NOT DONE, KNOWN HIV-POSITIVE ..... 1 **(D2)**
DONE, HIV-NEGATIVE 2

a. Visit of most recent negative HIV AB result: |___|___|

b. Date of most recent negative HIV AB result: |___|___| / |___|___| / |___|___| **(SECTION E)**
M D Y

D2. MOST RECENT HIV-1 RNA RESULT:

GREATER THAN 50,000 ..... 1 **(b)**
LESS THAN 50,000, BUT NOT UNDETECTABLE ..... 2 **(b)**
UNDETECTABLE 3

a. HAS PARTICIPANT'S HIV-1 RNA BEEN UNDETECTABLE FOR HER PRIOR TWO WIHS VISITS?

YES, PARTICIPANT'S VIRAL LOAD HAS BEEN UNDETECTABLE FOR PRIOR TWO VISITS 1
NO 2

b. Visit of most recent HIV-1 RNA result: |___|___|

c. Date of most recent HIV-1 RNA result: |___|___| / |___|___| / |___|___|
M D Y

WIHS ID#

SECTION E. VERIFICATION OF ELIGIBILITY

INSTRUCTIONS: DETERMINE PARTICIPANT'S FINAL ELIGIBILITY GROUP BASED ON RESPONSES TO THE FOLLOWING QUESTIONS:

B2: CURRENT HAART STATUS
C1 and C2: COMPLETION OF SPECIMEN COLLECTION
D1: CURRENT HIV STATUS
D2: MOST RECENT HIV RNA LEVEL
D2a: DURATION OF HIV RNA UNDETECTABILITY

E1. FINAL ELIGIBILITY GROUP:

HIV-uninfected 1
HIV-infected, on HAART, HIV RNA >50,000 2
HIV-infected, not on HAART, HIV RNA >50,000 3
HIV-infected, on HAART, undetectable HIV RNA 4
HIV-infected, not on HAART, undetectable HIV RNA for at least two WIHS visits (elite suppressor) 5
Not eligible, specimens not collected 6
Not eligible, does not meet criteria for an eligibility group 7