

WOMEN'S INTERAGENCY HIV STUDY
F29: BLOOD SPECIMEN COLLECTION FORM

ID LABEL - - -
HERE --->

VISIT #: FORM COMPLETED BY:

VERSION DATE REVISED 10/01/13

ANY MISSING OR INCOMPLETE TEST RESULTS MUST BE EXPLAINED ON THIS FORM.

A0. DOES PARTICIPANT FALL INTO ANY OF THE FOLLOWING CATEGORIES:

a. ELITE CONTROLLER, I.E., AT CORE VISIT PRIOR TO CURRENT VISIT, DID PARTICIPANT HAVE UNDETECTABLE VIRAL LOAD AND WAS PARTICIPANT NOT ON ANTIRETROVIRALS?

YES 1
NO 2
N/A (participant HIV-) 3

PROMPT: IF A0a = YES, COLLECT TUBES LABELED "EVENT," I.E., TUBES C5, AND C12 – C14.

b. ART-NAÏVE AT FIRST ART/HAART VISIT:

i. WAS PARTICIPANT ART NAÏVE PRIOR TO THIS VISIT?

YES 1
NO 2 (A0c)
N/A (participant HIV-) 3 (A0c)

ii. HAS PARTICIPANT STARTED ART/HAART SINCE HER LAST VISIT?

YES 1
NO 2

PROMPT: IF A0bii = YES, COLLECT TUBES LABELED "EVENT," I.E., TUBES C5, AND C12 – C14.

c. SEROCONVERTER, I.E., WAS PARTICIPANT IDENTIFIED AS A SEROCONVERTER AT HER LAST CORE VISIT?

YES 1
NO 2

PROMPT: IF A0c = YES, COLLECT TUBES LABELED "EVENT," I.E., TUBES C5, AND C12 – C14.

e. PARTICIPANT IN MUSKULOSKELTAL (MSK) SUBSTUDY?

YES 1
NO 2

PROMPT: IF A0e = YES, COLLECT TUBES LABELED FOR "MSK SUBSTUDY," I.E., TUBES C6, AND C15 – C17.

A. BLOOD DRAW

A1. DATE BLOOD DRAWN: / /
M D Y

A2. TIME BLOOD DRAWN: |__|__| : |__|__| AM..... 1
PM..... 2

a. IS THIS PARTICIPANT’S FIRST OR SECOND BLOOD DRAW FOR THIS VISIT?

FIRST..... 1
 SECOND..... 2

A3. PHLEBOTOMIST'S INITIALS

A4. When was the last date and time you had anything to eat or drink other than water, including gum, tea or coffee.

a. DATE: / / b. TIME: |__|__| : |__|__| AM..... 1
M D Y PM 2

A5. **INTERVIEWER:** WAS PARTICIPANT FASTING FOR BLOOD DRAW, I.E., DID SHE HAVE **NOTHING** TO EAT OR DRINK OTHER THAN WATER FOR AT LEAST EIGHT HOURS PRIOR TO BLOOD DRAW?

FASTING.....1
 NOT FASTING2

A6. WERE CPT TUBES CENTRIFUGED IN CLINIC; (i.e., PRIOR TO SENDING TO LAB FOR PROCESSING)?

YES..... 1
 NO..... 2 (A8)
 N/A (Not drawn this date)..... 3 (A8)

A7. TIME CPT TUBES CENTRIFUGED: |__|__| : |__|__| AM..... 1
PM 2

A8. WAS GOLD OR TIGER-TOP SST TUBE FOR METABOLIC PANEL (TC, HDL-C, TRIG, LDL-C, insulin) CENTRIFUGED IN CLINIC WITHIN 1 HOUR OF COLLECTION; (i.e., PRIOR TO SENDING TO LAB FOR PROCESSING)?

YES..... 1
 NO..... 2 (SECTION C)
 N/A (Not drawn this date)..... 3 (SECTION C)

A9. TIME TUBES CENTRIFUGED: |__|__| : |__|__| AM..... 1
PM 2

C. BLOOD DRAW (LISTED IN ORDER OF CORRECT BLOOD DRAW)

PROMPT: TUBES SHADED IN GRAY ARE FOR SUBSTUDIES AND WILL NOT BE COLLECTED FROM ALL PARTICIPANTS. SEE CHECKLIST IN A0 AND FOOTNOTES FOR DETAILS.

	<u>TEST TYPE</u>	<u>TUBE TYPE</u> (Tube Vol)	<u>WHOLE BLOOD VOLUME</u>	<u>a.) SPECIMEN COLLECTED</u>			<u>b.) REQUIRED VOLUME COLLECTED</u>		<u>c.) ESTIMATED VOLUME COLLECTED</u>
				<u>YES</u>	<u>NO</u>	<u>N/A</u>	<u>YES</u>	<u>NO</u>	
C1.	HIV Ab ^a	Red-Top (3 ml) IF NO SPECIFY REASON	1-2 ml	1	2	3 ^a	1 (C2)	2	_ _ mls.
<i>^a Not required after visit one on HIV-seropositive women.</i>									
C2.	Liver/Renal Function	Red-Top or SST (5 ml) IF NO SPECIFY REASON	2-5 ml	1	2		1 (C3)	2	_ _ mls.
C3.	TC, HDL-C, TRIG, LDL-C, insulin ^b	Tiger-top SST (10 ml) IF NO SPECIFY REASON	8.5 ml	1	2	3 ^b	1 (C4)	2	_ _ mls.
<i>^b Collect <u>once per year only</u>, at even-numbered visits. Specimen should be collected regardless of whether or not participant is fasting.</i>									
C4.	Serum Repository	Red-Top or SST (10 ml) IF NO SPECIFY REASON	8.5 ml	1	2		1 (C5)	2	_ _ mls.
C5.	Serum Repository EVENT ^c	Red-Top or SST (10 ml) IF NO SPECIFY REASON	8.5 ml	1	2	3 ^c	1 (C6)	2	_ _ mls.
<i>^c Collect only from selected participants (i.e., elite controllers, ART/HAART initiators, seroconverters), to be identified at the core visit from prior visit data.</i>									
C6.	Serum for MSK Substudy ^d	Red-Top or SST (10 ml) IF NO SPECIFY REASON	8.5 ml	1	2	3 ^d	1 (C7)	2	_ _ mls.
<i>^d Collect only from participants in the MSK Substudy, once at visits 35-40 for baseline, and again at visits 39-44 for follow-up.</i>									
C7.	Plasma & Cells Repository	CPT Tube (10 ml) IF NO SPECIFY REASON	8 ml	1	2		1 (C8)	2	_ _ mls.

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				<u>YES</u>	<u>NO</u>	<u>N/A</u>	<u>YES</u>	<u>NO</u>	
C8.	Plasma & Cell Repository	CPT Tube (10 ml) IF NO SPECIFY REASON	8 ml	1	2		1 (C9)	2	_ _ mls.
C9.	Plasma & Cell Repository	CPT Tube (10 ml) IF NO SPECIFY REASON	8 ml	1	2		1 (C10)	2	_ _ mls.
C10.	Plasma & Cell Repository	CPT Tube (10 ml) IF NO SPECIFY REASON	8 ml	1	2		1 (C11)	2	_ _ mls.
C11.	Plasma & Cell Repository	CPT Tube (10 ml) IF NO SPECIFY REASON	8 ml	1	2		1 (C12)	2	_ _ mls.
C12.	Cell Repository EVENT ^c	CPT Tube (10 ml) IF NO SPECIFY REASON	8 ml	1	2	3 ^c	1 (C13)	2	_ _ mls.
C13.	Cell Repository EVENT ^c	CPT Tube (10 ml) IF NO SPECIFY REASON	8 ml	1	2	3 ^c	1 (C14)	2	_ _ mls.
C14.	Cell Repository EVENT ^c	CPT Tube (10 ml) IF NO SPECIFY REASON	8 ml	1	2	3 ^c	1 (C15)	2	_ _ mls.
C15.	Cells for MSK Substudy ^d	CPT Tube (10 ml) IF NO SPECIFY REASON	8 ml	1	2	3 ^d	1 (C16)	2	_ _ mls.
C16.	Cells for MSK Substudy ^d	CPT Tube (10 ml) IF NO SPECIFY REASON	8 ml	1	2	3 ^d	1 (C17)	2	_ _ mls.

^c Collect only from selected participants (i.e., elite controllers, ART/HAART initiators, seroconverters), to be identified at the core visit from prior visit data.

^d Collect only from participants in the MSK Substudy, once at visits 35-40 for baseline, and again at visits 39-44 for follow-up.

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				<u>YES</u>	<u>NO</u>	<u>N/A</u>	<u>YES</u>	<u>NO</u>	
C17.	Cells for MSK Substudy ^d	CPT Tube <i>(10 ml)</i> IF NO SPECIFY REASON	8 ml	1	2	3 ^d	1 (C19)	2	_ _ mls.
				i. _____					
^d Collect only from participants in the MSK Substudy, once at visits 35-40 for baseline, and again at visits 39-44 for follow-up.									
C19.	CBC/Diff ^f	Lavender-Top <i>(3 ml)</i> IF NO SPECIFY REASON	2.5 ml	1	2	3 ^f	1 (C20)	2	_ _ mls.
				i. _____					
^f For HIV-seronegative participants, collect annually at even-numbered visits only.									
C20.	T-Cell Subsets ^g	Lavender-Top <i>(3 ml)</i> IF NO SPECIFY REASON	2.5 ml	1	2	3 ^g	1 (C21)	2	_ _ mls.
				i. _____					
^g Not required after visit one for HIV-seronegative women.									
C21.	EDTA Plasma ^h	Lavender-Top <i>(6 ml)</i> IF NO SPECIFY REASON	5-6 ml	1	2	3 ^h	1 (C22)	2	_ _ mls.
				i. _____					
^h Collect from HIV-seropositive participants only. Includes plasma to be used for viral quantification by RNA PCR.									
C22.	HgA1c ^b	Lavender-Top <i>(3 ml)</i> IF NO SPECIFY REASON	2.5 ml	1	2	3 ^b	1 (C23)	2	_ _ mls.
				i. _____					
^b Collect <u>once per year only</u> , at even-numbered visits. Specimen should be collected regardless of whether or not participant is fasting.									
C23.	Glucose ⁱ	Gray-Top <i>(3 ml)</i> IF NO SPECIFY REASON	2.5 ml	1	2	3 ⁱ	1 (END)	2	_ _ mls.
				i. _____					
ⁱ Collect <u>once per year only</u> , at even-numbered visits. Specimen should be collected only if participant is fasting.									