

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

ID LABEL - - -
HERE --->

VISIT #: FORM COMPLETED BY:

VERSION DATE REVISED **10/01/15**

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 C6, AND C13 – C15.

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 C6, AND C13 – C15.

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 C6, AND C13 – C15.

e. PARTICIPANT IN MUSCULOSKELETAL (MSK) SUBSTUDY?

YES 1
NO 2

PROMPT: IF A0e = YES, COLLECT TUBES LABELED FOR "MSK SUBSTUDY," I.E., TUBES C7, AND C16 – C18.

f. PARTICIPANT COMPLETED HCV TREATMENT AT PRIOR VISIT ACCORDING TO VCS?

YES 1
NO 2

PROMPT: IF A0f = YES, COLLECT TUBE LABELED FOR "SERUM HCV TX COMPLETED," I.E., TUBE C5.

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.									
C2.	Liver/Renal Function	Red-Top or SST (5 ml) IF NO SPECIFY REASON	2-5 ml	1	2		1 (C3)	2	_ _ mls.
				i. _____					
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.									
C4.	Serum Repository	Red-Top or SST (10 ml) IF NO SPECIFY REASON	8.5 ml	1	2		1 (C5)	2	_ _ mls.
				i. _____					
C5.	Serum HCV med tx completed ^j	Red-Top or SST (10 ml) IF NO SPECIFY REASON	8.5 ml	1	2	3 ^j	1 (C6)	2	_ _ mls.
				i. _____					
^j Collect only from participants with indication on Visit Control Sheet (VCS) that they have completed HCV treatment at prior visit.									
C6.	Serum Repository EVENT ^c	Red-Top or SST (10 ml) IF NO SPECIFY REASON	8.5 ml	1	2	3 ^c	1 (C7)	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.									

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				<u>YES</u>	<u>NO</u>	<u>N/A</u>	<u>YES</u>	<u>NO</u>	
C7.	Serum for MSK Substudy ^d	Red-Top or SST (10 ml) IF NO SPECIFY REASON	8.5 ml	1	2	3 ^d	1 (C8)	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.									
C8.	Plasma & Cells Repository	CPT Tube (10 ml) IF NO SPECIFY REASON	8 ml	1	2		1 (C9)	2	_ _ mls.
				i. _____					
C9.	Plasma & Cell Repository	CPT Tube (10 ml) IF NO SPECIFY REASON	8 ml	1	2		1 (C10)	2	_ _ mls.
				i. _____					
C10.	Plasma & Cell Repository	CPT Tube (10 ml) IF NO SPECIFY REASON	8 ml	1	2		1 (C11)	2	_ _ mls.
				i. _____					
C11.	Plasma & Cell Repository	CPT Tube (10 ml) IF NO SPECIFY REASON	8 ml	1	2		1 (C12)	2	_ _ mls.
				i. _____					
C12.	Plasma & Cell Repository	CPT Tube (10 ml) IF NO SPECIFY REASON	8 ml	1	2		1 (C13)	2	_ _ mls.
				i. _____					
C13.	Cell Repository EVENT ^c	CPT Tube (10 ml) IF NO SPECIFY REASON	8 ml	1	2	3 ^c	1 (C14)	2	_ _ mls.
				i. _____					
C14.	Cell Repository EVENT ^c	CPT Tube (10 ml) IF NO SPECIFY REASON	8 ml	1	2	3 ^c	1 (C15)	2	_ _ mls.
				i. _____					
C15.	Cell Repository EVENT ^c	CPT Tube (10 ml) IF NO SPECIFY REASON	8 ml	1	2	3 ^c	1 (C16)	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.

	TEST TYPE	TUBE TYPE (Tube Vol)	WHOLE BLOOD VOLUME	a.) SPECIMEN COLLECTED			b.) REQUIRED VOLUME COLLECTED		c.) ESTIMATED VOLUME COLLECTED
				YES	NO	N/A	YES	NO	
C16.	Cells for MSK Substudy ^d	CPT Tube (10 ml) IF NO SPECIFY REASON	8 ml	1	2	3 ^d	1 (C17)	2	_ _ mls.
				i. _____					
C17.	Cells for MSK Substudy ^d	CPT Tube (10 ml) IF NO SPECIFY REASON	8 ml	1	2	3 ^d	1 (C18)	2	_ _ mls.
				i. _____					
C18.	Cells for MSK Substudy ^d	CPT Tube (10 ml) 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 (3 ml) 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 (3 ml) 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 (6 ml) 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 (3 ml) IF NO SPECIFY REASON	2.5 ml	1	2	3 ^b	1 (C23)	2	_ _ mls.
				i. _____					

^b Collect once per year only, at even-numbered visits. Specimen should be collected regardless of whether or not participant is fasting.

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				<u>YES</u>	<u>NO</u>	<u>N/A</u>	<u>YES</u>	<u>NO</u>	
C23.	Glucose ⁱ	Gray-Top <i>(3 ml)</i> IF NO SPECIFY REASON	2.5 ml	1	2	3 ⁱ	1 (END)	2	_ _ ml.
				i. _____					

ⁱ Collect once per year only, at even-numbered visits. Specimen should be collected only if participant is fasting.