WOMEN'S INTERAGENCY HIV STUDY

F31r: SPECIMENS COLLECTED DURING THE PHYSICAL EXAM – NEW RECRUITS

ID LABEL HERE ---> |__| - |__|__| - |__|__|__|__| - |__|

VISIT #: ___ ___

FORM COMPLETED BY: ___ ___ ___

VERSION DATE: **0 4 / 0 1 / 1 4**

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

SECTION B. URINE SPECIMENS

B1. DATE URINE SPECIMENS COLLECTED: |___|___|/|___|___|/|___|___|
M D Y

a. Time of collection: |__|__| : |__|__| AM……..1
PM……..2

PROMPT: IF SPECIMENS FOR URINALYSIS AND REPOSITORY ARE COLLECTED ON A DIFFERENT DATE THAN THE SPECIMEN FOR PREGNANCY TEST, RECORD THE DATE AND TIME SPECIMENS FOR URINALYSIS AND REPOSITORY WERE COLLECTED.

	SPECIMEN TYPE	LOCATION	YES	NO	IF NO, SPECIFY REASON	N/A
B2.	Pregnancy Test	Exam Site	1* **(B2a)**	2	_____ **(B3)**	3* **(B3)**
	a. RESULT:					
	POSITIVE..... 1					
	NEGATIVE 2					
	INDETERMINATE..... 3					
B3.	Urine for urinalysis	Local	1 **(B4)**	2	_____	
B4.	Urine for Repository§	Freeze Locally	1 **(C1)**	2	_____	

***** REQUIRED FOR EVERY WOMAN UNLESS SHE IS : S/P HYSTERECTOMY OR BILATERAL OOPHERECTOMY OR ≥ 50 YEARS OF AGE.
§ SAMPLE CAN BE KEPT AT ROOM TEMPERATURE FOR LOCAL TESTS CONDUCTED WITHIN 4 TO 6 HOURS. OTHERWISE KEEP SAMPLE AT 4°C UNTIL PROCESSING.

WIHS ID #

SECTION C. HAIR SPECIMEN

	SPECIMEN TYPE	LOCATION	YES	NO	IF NO, SPECIFY REASON	N/A
C1.	Hair	Central Lab	1* **(a)**	2	_____ **(D1)**	3** **(D1)**

**** Circle "N/A" only if participant is HIV-negative or HIV-positive and not reporting antiretroviral medication use in the past six months.**

PROMPT: IF PARTICIPANT IS ON A REGIMEN THAT CONTAINS TENOFOVIR (DRUG CODES 262, 253, 280, 287, 234), ASK IF PARTICIPANT IS WILLING TO HAVE 100 STRANDS OF HAIR COLLECTED. IF PARTICIPANT IS ON A REGIMEN THAT DOES NOT INCLUDE TENOFOVIR OR PREFERS NOT TO DONATE 100 STRANDS, COLLECT 30-40 STRANDS OF HAIR AS PER USUAL PROTOCOL.

NOTE:* *Tenofovir-containing regimens include the following drug codes: 234 (Viread), 253 (Truvada), 262 (Atripla), 280 (Complera), and 287 (Stribild).

a. Is participant on a tenofovir-containing regimen?

YES 1
NO ..... 2 **(collect 30-40 strands and go to C1c)**

b. Is participant willing to have 100 strands of hair taken?

YES ..... 1 **(collect 100 strands and go to C1c)**
NO ..... 2 **(collect 30-40 strands and go to C1c)**

c. From where was the sample taken?

Occipital region of scalp (preferred).....1
Nape / base of neck.....3
Other region of scalp 2

SPECIFY: _____

d. Date hair specimen collected: |___|___|/|___|___|/|___|___|
M D Y

WIHS ID #

SECTION D: GYN SPECIMENS

D1. DATE GYN SPECIMENS COLLECTED: |___|___|/|___|___|/|___|___|
M D Y

	SPECIMEN TYPE	LAB	YES	NO	IF NO, SPECIFY REASON	N/A
D2.	Minimum 6 ml CVL Fluid	Local for Aliquoting and Freezing	1 **(a)**	2	_____ **(D3)**	
	a.) IF YES, time of collection:		|___|___| : |___|___|		AM……..1 PM……..2	

IF CVL WILL NOT BE PROCESSED WITHIN 1 HOUR OF COLLECTION, KEEP SAMPLE AT LESS THAN 10°C TO PREVENT MICROBIAL GROWTH.

D4.	Slide for Bacterial Vaginosis Gram Stain	Central	1 **(D5)**	2	_____	
D5.	1 Swab for Chlamydia and gonorrhea testing	Local	1 **(D6)**	2	_____	3
D6.	1 Glass Slide for Pap Smear*	Central	1 **(D7)**	2	_____	
D7.	1 Cervical swab for HPV DNA*	Central Repository	1 **(D8)**	2	_____	
D8.	Optional: Swab in Diamonds Media for Trichomonas Culture	Exam Site	1 **(END)**	2	_____	3
D9.	Liquid Pap for CCSS**	Central	1 **(a)**	2	_____ **(END)**	3 **(END)**
	a.) IF YES, number of specimens:				1 specimen……1 2 specimens……2	

NOTES:

*D6 & D7. If participant is part of the Cervical Cancer Screening Substudy (CCSS), then circle "2" for "NO" for these questions, and enter "in CCSS" in the SPECIFY field.

D9. Indicate whether or not liquid Pap specimens for the CCSS were collected. If the participant is not a part of the CCSS, circle "3" for "NA" and end the form. If the participant is part of the substudy, but the specimen was not collected, circle "2" for "NO" and specify the reason the specimen was not collected. If the specimen was collected, circle "1" for "YES" and skip to **Question D9a to indicate the number of specimens collected.