

**WOMENS INTERAGENCY HIV STUDY
INTENSIVE PK STUDY
FORM PK05A: WEIGHT/SPECIMEN COLLECTION FORM
FOR GROUP A PARTICIPANTS**

SECTION A: GENERAL INFORMATION

- A1. PARTICIPANT ID: ENTER NUMBER HERE ONLY IF ID LABEL IS NOT AVAILABLE - - -
- A2. LAST WIHS CORE VISIT #:
- A3. VERSION DATE: 04/01/09
- A4. DATE OF COLLECTION: M / D / Y
- A5. COLLECTOR'S INITIALS:
- A6. NAME OF TARGET MEDICATION (**CIRCLE YES OR NO FOR EACH**):
- | | <u>YES</u> | <u>NO</u> |
|---|------------|-----------|
| d. RALTEGRAVIR (<i>ISENTRESS</i>) | 1 | 2 |

SECTION B: WEIGHT

- B1. WEIGHT OF PARTICIPANT IN POUNDS (LBS):
(ROUND TO NEAREST 1.0 POUND)
WEIGHT (LBS)

SECTION C: URINE PREGNANCY TEST

- C1. URINE PREGNANCY TEST
- | | |
|--------------------|---|
| PREGNANT | 1 |
| NOT PREGNANT | 2 |
| NOT DONE | 3 |
- SPECIFY REASON: _____

SECTION D: TIMES OF BLOOD COLLECTIONS FOR PK SAMPLING

- D1. TIME PARTICIPANT TOOK TARGET MEDICATION THE EVENING BEFORE PK SAMPLING: : AM..... 1
PM 2
- a. TIME POINT OF **D1** CONFIRMED BY:
- | | |
|---|---|
| TELEPHONE INTERVIEW | 1 |
| WITNESSED DOSE IN CLINICAL CENTER | 2 |

WIHS ID #

IN THE MORNING, COLLECT FIRST PK SAMPLE ('0' TIMEPOINT) AND RECORD THE TIME OF SAMPLING IN D2. INSTRUCT PARTICIPANT TO TAKE HER TARGET ANTIRETROVIRAL MEDICATION (*Isentress*) AND ANY OTHER MEDICATION THAT SHE USUALLY TAKES AT THE SAME TIME. PARTICIPANT SHOULD BE INSTRUCTED TO TAKE HER ANTIRETROVIRAL MEDICATIONS WITH FOOD IF THAT IS HER USUAL ROUTINE AT HOME. RECORD THE TIME OF HAART DOSING IN D3 AND RECORD WHETHER THE PARTICIPANT TOOK HER MEDICATIONS WITH OR WITHOUT FOOD IN D4. SET ELECTRONIC TIMER.

D2. TIME OF BLOOD DRAW FOR FIRST PK SAMPLE ('0' TIMEPOINT): _____ : _____ AM.....1
 PM.....2

D3. TIME PARTICIPANT TOOK TARGET MEDICATION: _____ : _____ AM.....1
 PM.....2

D4. DID PARTICIPANT TAKE HER TARGET MEDICATION(S) WITH OR WITHOUT FOOD?
 WITH FOOD 1
 WITHOUT FOOD 2

	SAMPLE NUMBER	PK TIMEPOINT	TIME OF BLOOD DRAW
D5.	2	30 minutes (1/2 hr)	_____ : _____ AM.....1 PM.....2
D6.	3	60 minutes (1 hr)	_____ : _____ AM.....1 PM.....2
D7.	4	120 minutes (2 hr)	_____ : _____ AM.....1 PM.....2
D8.	5	150 minutes (2.5 hr)	_____ : _____ AM.....1 PM.....2
D9.	6	180 minutes (3 hr)	_____ : _____ AM.....1 PM.....2
D10.	7	240 minutes (4 hr)	_____ : _____ AM.....1 PM.....2
D11.	8	300 minutes (5 hr)	_____ : _____ AM.....1 PM.....2
D12.	9	360 minutes (6 hr)	_____ : _____ AM.....1 PM.....2
D13.	10	480 minutes (8 hr)	_____ : _____ AM.....1 PM.....2
D14.	11	720 minutes (12 hr)	_____ : _____ AM.....1 PM.....2

PROMPT: URINE PREGNANCY TESTS SHOULD BE PERFORMED IN THE LOCAL LAB. PK SAMPLES WILL BE PROCESSED, BATCHED AND THEN SHIPPED WITHIN ONE MONTH TO DR. LESLIE BENET'S LAB.