WOMENS INTERAGENCY HIV STUDY INTENSIVE PK STUDY FORM PK05B: WEIGHT/SPECIMEN COLLECTION FORM FOR GROUP B PARTICIPANTS

SECTION A: GENERAL INFORMATION

- A1. PARTICIPANT ID: ENTER NUMBER HERE |_|-|_|-|_|-|_|-|_| |__|
- A2. LAST WIHS CORE VISIT #:
- A3. VERSION DATE:
- A4. DATE OF COLLECTION:

	/	/
M	D	Y

04/01/04

- A5. COLLECTOR'S INITIALS: _____
- A6. NAME OF TARGET MEDICATION (CIRCLE YES OR NO FOR EACH):

YES	<u>NO</u>
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- a. SUSTIVA (EFAVIRENZ) 1 2
- b. REYATAZ (ATAZANAVIR) 1 2

SECTION B: WEIGHT

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

1 71		1

WEIGHT (LBS)

SECTION C: URINE PREGNANCY TEST

SECTION D: TIMES OF BLOOD COLLECTIONS FOR PK SAMPLING

IN THE EVENING, COLLECT FIRST PK SAMPLE ('0' TIMEPOINT) AND RECORD THE TIME OF SAMPLING IN D1. INSTRUCT PARTICIPANT TO TAKE HER SUSTIVA AND/OR REYATAZ AND ANY OTHER MEDICATIONS THAT SHE USUALLY TAKES AT THE SAME TIME. (NOTE: IF PARTICIPANT IS ON BOTH SUSTIVA AND REYATAZ, SHE MUST TAKE THEM SIMULTANEOUSLY IN ORDER TO USE ONE GROUP B VISIT FOR BOTH DRUGS. IF SHE DOESN'T TAKE THE TWO MEDICATIONS AT THE SAME TIME, SHE MUST BE SCHEDULED FOR TWO DIFFERENT GROUP B VISITS TO EVALUATE EACH MEDICATION INDEPENDENTLY). PARTICIPANT SHOULD BE INSTRUCTED TO TAKE HER SUSTIVAAND/OR REYATAZ WITH FOOD IF THAT IS HER USUAL ROUTINE AT HOME. RECORD THE TIME OF SUSTIVA AND/OR REYATAZ DOSING IN D2 AND RECORD WHETHER PARTICIPANT TOOK SUSTIVA AND/OR REYATAZ WITH OR WITHOUT FOOD IN D3. SET ELECTRONIC TIMER.

D1. TIME OF BLOOD DRAW FOR FIRST _______ _______ AM......1 PK SAMPLE ('0' TIMEPOINT): PM2

- D2.
 TIME PARTICIPANT TOOK

 AM......1

 SUSTIVA AND/OR REYATAZ
 PM2
- D3. DID PARTICIPANT TAKE HER *SUSTIVA* AND/OR *REYATAZ* WITH OR WITHOUT FOOD? WITH FOOD 1 WITHOUT FOOD 2

	SAMPLE NUMBER	PK TIMEPOINT	TIME OF BLOOD DRAW
D4.	2	60 minutes (1 hr)	: AM1 PM2
D5.	3	120 minutes (2 hr)	: AM1 PM2
D6.	4	240 minutes (4 hr)	: AM1 PM2
D7.	5	360 minutes (6 hr)	: AM1 PM2
D8.	6	480 minutes (8 hr)	: AM1 PM2
D9.	7	720 minutes (12 hr)	: AM1 PM2
D10.	8	900 minutes (15 hr)	: AM1 PM2
D11.	9	1080 minutes (18 hr)	: AM1 PM2
D12.	10	1260 minutes (21 hr)	: AM1 PM2
D13.	11	1440 minutes (24 hr)	: AM1 PM2

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.