

WOMEN'S INTERAGENCY HIV STUDY
METABOLIC STUDY: MS01 SPECIMEN COLLECTION FORM

ID LABEL HERE ---> |_| - |_|_| - |_|_|_|_| - |_|

VISIT #: _____ FORM COMPLETED BY: _____

VERSION DATE **10/01/07**

A1. DATE OF BLOOD DRAW: _____ / _____ / _____
M D Y

A2. Do you take insulin (either by injection or inhaler) OR take any of the following oral medications: a thiazolidinedione [including pioglitazone (Actos) or rosiglitazone (Avandia)] OR metformin (Glucophage) for diabetes, or to help control your blood sugar?

YES 1
 NO 2

A3. Do you currently take any other prescribed medications for diabetes or to lower your blood sugar?

YES 1
 NO 2 **(A6)**

A4. Do these include any of the following?	<u>YES</u> <u>NO</u>		<u>i. DATE LAST TAKEN</u>	<u>ii. TIME LAST TAKEN</u>	<u>iii. AM/PM INDICATOR</u>
	1	2	___/___/___	_ _ : _ _	AM.....1 PM.....2
a. Acarbose (Precose)	1	2 (b)	___/___/___	_ _ : _ _	AM.....1 PM.....2
b. Chlorpropamide (Diabinese)	1	2 (c)	___/___/___	_ _ : _ _	AM.....1 PM.....2
c. Glimepiride (Amaryl)	1	2 (d)	___/___/___	_ _ : _ _	AM.....1 PM.....2
d. Glipizide (Glucotrol)	1	2 (e)	___/___/___	_ _ : _ _	AM.....1 PM.....2
e. Glyburide (Micronase, Diabeta)	1	2 (g)	___/___/___	_ _ : _ _	AM.....1 PM.....2
g. Miglitol (Glyset)	1	2 (h)	___/___/___	_ _ : _ _	AM.....1 PM.....2
h. Orlistat (Xenical)	1	2 (j)	___/___/___	_ _ : _ _	AM.....1 PM.....2
j. Repaglinide (Prandin)	1	2 (l)	___/___/___	_ _ : _ _	AM.....1 PM.....2
l. Nateglinide (Starlix)	1	2 (m)	___/___/___	_ _ : _ _	AM.....1 PM.....2
m. Other	1	2 (A5)	___/___/___	_ _ : _ _	AM.....1 PM.....2
SPECIFY: _____			___/___/___	_ _ : _ _	AM.....1 PM.....2

A5. IN THE LAST EIGHT (8) HOURS, HAS PARTICIPANT TAKEN ANY OF THE MEDICATIONS LISTED IN QUESTIONS A4a – A4I?

YES 1 (PROMPT, BELOW)
 NO 2

PROMPT: IF PARTICIPANT HAS TAKEN ANY OF THE DIABETES MEDICATIONS LISTED IN QUESTIONS A4a – A4I IN THE LAST EIGHT (8) HOURS (A5 = 1), SHE MAY NOT PARTICIPATE IN THE GLUCOSE TOLERANCE TEST (GTT) AT THIS TIME. PLEASE RESCHEDULE THE PARTICIPANT FOR A GLUCOSE TOLERANCE TEST AND COMPLETE A NEW MS01 AT THAT TIME.

A6a. HAND PARTICIPANT ANTIVIRAL PHOTO MEDICATION CARDS. GO THROUGH CARDS WITH PARTICIPANT, SAYING THE NAME OF EACH DRUG ALOUD AND ASKING HER TO TELL YOU “YES” OR “NO” WHETHER SHE HAS TAKEN THIS DRUG IN THE LAST 3 DAYS.

CHECK BELOW NEXT TO EACH DRUG PARTICIPANT REPORTS HAVING TAKEN. FOR DRUGS NOT LISTED, CHECK “OTHER ANTI-VIRAL,” RECORD NAME AS STATED BY PARTICIPANT AND FILL IN CORRESPONDING 3-DIGIT DRUG CODE FROM DRUG LIST 1.

I’m going to ask about any antiretroviral medications you may have taken **in the last 3 days**. In addition to all your prescribed medications, please include any antiretroviral medications you have taken as part of a research study, including those in which you may have been blinded to the study medication. In the last 3 days, have you taken...

Combination Medications

- 262 ___ Atripla (Sustiva + Viread + Emtriva)
- 227 ___ Combivir (AZT + 3TC)
- 254 ___ Epzicom (Ziagen + Efavirenz)
- 240 ___ Trizivir (abacavir + AZT + 3TC)
- 253 ___ Truvada (Viread + Emtriva)
- 280 ___ Complera (FTC + RPV + TDF)

Non-Nucleoside RTIs

- 255 ___ Intelence (etravirine, TMC 125)
- 194 ___ Rescriptor (delavirdine)
- 220 ___ Sustiva (efavirenz)
- 191 ___ Viramune (nevirapine)
- 276 ___ Edurant (rilpivirine, TMC 278)

Entry Inhibitors

- 233 ___ Fuzeon (T-20, enfuvirtide)
- 265 ___ Selzentry (maraviroc)

Protease Inhibitors

- 238 ___ Aptivus (tipranavir)
- 212 ___ Crixivan (indinavir)
- 210 ___ Invirase (saquinavir)
- 217 ___ Kaletra (lopinavir + ritonavir)
- 249 ___ Lexiva (fosamprenavir)
- 211 ___ Norvir (ritonavir)
- 256 ___ Prezista (TMC-114, darunavir)
- 243 ___ Reyataz (atazanavir)
- 216 ___ Viracept (nelfinavir)

Nucleoside/Nucleotide RTIs

- 239 ___ Emtriva (emtricitabine, FTC)
- 204 ___ Epivir (lamivudine, 3-TC)
- 092 ___ Retrovir (AZT, zidovudine, ZDV)
- 147 ___ Videx / Videx EC (didanosine, ddI)
- 234 ___ Viread (tenofovir)
- 159 ___ Zerit (stavudine, d4T)
- 218 ___ Ziagen (abacavir)

Other

- 207 ___ Droxia or Hydrea (hydroxyurea)
- ___ Other anti-viral(s) (from Drug List 1)

Integrase Inhibitors

- 264 ___ Isentress (raltegravir, MK 0518)

Specify name of “other” antiviral:
Specify name of “other” antiviral:

→ Drug Code:

→ Drug Code:

b. ENTER THE TOTAL NUMBER OF MEDICATIONS THE PARTICIPANT REPORTED TAKING IN QUESTION A6a:

PROMPT: IF QUESTION A6b = 0, SKIP TO QUESTION A8.

A10. ASK PARTICIPANT TO LIST ALL MEDICATIONS SHE HAS TAKEN IN THE LAST THREE DAYS, AND THE DATE AND TIME SHE LAST TOOK EACH MEDICATION. COMPLETE COLUMNS a, b, c AND d.

START MS01s2

	a. DRUG NAME	b. DATE LAST TAKEN	c. TIME LAST TAKEN	d. AM/PM INDICATOR
i.	_____	___/___/___	_ : _	AM.....1 PM.....2
ii.	_____	___/___/___	_ : _	AM.....1 PM.....2
iii.	_____	___/___/___	_ : _	AM.....1 PM.....2
iv.	_____	___/___/___	_ : _	AM.....1 PM.....2
v.	_____	___/___/___	_ : _	AM.....1 PM.....2
vi.	_____	___/___/___	_ : _	AM.....1 PM.....2

END MS01s2

A10e. ENTER THE TOTAL NUMBER OF MEDICATIONS THE PARTICIPANT REPORTED TAKING IN QUESTION A10a: |_|_|

SECTION B. FIRST BLOOD DRAW (FASTING)

B1. TIME OF FIRST BLOOD DRAW: |_|_| : |_|_| AM.....1
PM2

B2. PHLEBOTOMIST'S INITIALS _ _ _

	<u>TEST TYPE</u>	<u>TUBE TYPE</u>	<u>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>YES</u>	<u>NO</u>	
B3.	GLUCOSE	Gray Top	2 ml	1	2 (i)	1 (B4)	2	_ _ mls.
		IF NO, SPECIFY REASON		i. _____				
B4.	INSULIN	Red-Top (SST)	4 ml	1	2 (i)	1 (PROMPT)	2	_ _ mls.
		IF NO, SPECIFY REASON		i. _____				

PROMPT: IF QUESTION A2 = 1, SKIP TO PROMPT AT END OF FORM. OTHERWISE, PLEASE HAVE PATIENT DRINK 75G GLUCOSE LOAD WITHIN 5 MINUTES AND CONTINUE WITH SPECIMEN DRAW.

B6. DID THE PARTICIPANT FULLY DRINK GLUCOSE (75G GLUCOSE LOAD)?

YES..... 1 **(B6a)**
 NO..... 2

SPECIFY REASON: _____ **(END FORM)**

a. TIME GLUCOSE LOAD ADMINISTERED: |__| |__| : |__| |__| AM..... 1
 PM 2

SECTION C. SECOND BLOOD DRAW (30 MINUTES)

C1. TIME OF SECOND BLOOD DRAW: |__| |__| : |__| |__| AM..... 1
 PM 2

C2. PHLEBOTOMIST'S INITIALS _____

	<u>TEST TYPE</u>	<u>TUBE TYPE</u>	<u>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>YES</u>	<u>NO</u>	
C3.	GLUCOSE	Gray Top	2 ml	1	2 (i)	1 (C4)	2	__ __ mls.
		IF NO, SPECIFY REASON		i. _____				
C4.	INSULIN	Red-Top (SST)	4 ml	1	2 (i)	1 (D1)	2	__ __ mls.
		IF NO, SPECIFY REASON		i. _____				

SECTION D. THIRD BLOOD DRAW (60 MINUTES)

D1. TIME OF THIRD BLOOD DRAW: |__| |__| : |__| |__| AM..... 1
 PM 2

D2. PHLEBOTOMIST'S INITIALS _____

	<u>TEST TYPE</u>	<u>TUBE TYPE</u>	<u>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>YES</u>	<u>NO</u>	
D3.	GLUCOSE	Gray Top	2 ml	1	2 (i)	1 (E1)	2	__ __ mls.
		IF NO, SPECIFY REASON		i. _____				

WIHS ID #

SECTION E. FOURTH BLOOD DRAW (120 MINUTES)

E1. TIME OF FOURTH BLOOD DRAW: |__| |__| : |__| |__| AM.....1
PM2

E2. PHLEBOTOMIST'S INITIALS __ _ __

	<u>TEST TYPE</u>	<u>TUBE TYPE</u>	<u>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>YES</u>	<u>NO</u>	
E3.	GLUCOSE	Gray Top	2 ml	1	2 (i)	1 (E4)	2	__ __ mls.
		IF NO, SPECIFY REASON		i. _____				
E4.	INSULIN	Red-Top (SST)	4 ml	1	2 (i)	1 (END)	2	__ __ mls.
		IF NO, SPECIFY REASON		i. _____				

PROMPT: AFTER PROCESSING, SAMPLES FOR INSULIN AND GLUCOSE WILL BE BATCHED AND THEN SHIPPED TO QUEST DIAGNOSTICS. SEE THE WIHS MANUAL OF OPERATIONS, SECTION 25, FOR INSTRUCTIONS ON PROCESSING AND SHIPPING.