

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

ID LABEL  
HERE --->

|\_| - |\_|\_| - |\_|\_|\_|\_| - |\_|

VISIT #:  
\_\_\_\_

FORM COMPLETED BY:  
\_\_\_\_\_

VERSION DATE **04/01/06**

A1. DATE OF BLOOD DRAW:

\_\_\_ \_\_\_ / \_\_\_ \_\_\_ / \_\_\_ \_\_\_  
M              D              Y

A2. Do you inject insulin 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>
a. Acarbose (Precose) .....	1	2 <b>(b)</b>	___ ___ / ___ ___ / ___ ___	_ _ _  :  _ _ _	AM.....1 PM.....2
b. Chlorpropamide (Diabinese) .....	1	2 <b>(c)</b>	___ ___ / ___ ___ / ___ ___	_ _ _  :  _ _ _	AM.....1 PM.....2
c. Glimepiride (Amaryl) .....	1	2 <b>(d)</b>	___ ___ / ___ ___ / ___ ___	_ _ _  :  _ _ _	AM.....1 PM.....2
d. Glipizide (Glucotrol) .....	1	2 <b>(e)</b>	___ ___ / ___ ___ / ___ ___	_ _ _  :  _ _ _	AM.....1 PM.....2
e. Glyburide (Micronase, Diabeta) .....	1	2 <b>(g)</b>	___ ___ / ___ ___ / ___ ___	_ _ _  :  _ _ _	AM.....1 PM.....2
g. Miglitol (Glyset) .....	1	2 <b>(h)</b>	___ ___ / ___ ___ / ___ ___	_ _ _  :  _ _ _	AM.....1 PM.....2
h. Orlistat (Xenical) .....	1	2 <b>(j)</b>	___ ___ / ___ ___ / ___ ___	_ _ _  :  _ _ _	AM.....1 PM.....2
j. Repaglinide (Prandin) .....	1	2 <b>(l)</b>	___ ___ / ___ ___ / ___ ___	_ _ _  :  _ _ _	AM.....1 PM.....2
l. Nateglinide (Starlix) .....	1	2 <b>(m)</b>	___ ___ / ___ ___ / ___ ___	_ _ _  :  _ _ _	AM.....1 PM.....2
m. Other	1	2 <b>(A5)</b>			AM.....1
SPECIFY: _____			___ ___ / ___ ___ / ___ ___	_ _ _  :  _ _ _	PM.....2

WIHS ID#

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...

Nucleoside/Nucleotide RTIs

- 204 \_\_\_ Epivir (lamivudine, 3-TC)
218 \_\_\_ Ziagen (abacavir)
092 \_\_\_ Retrovir (AZT, zidovudine, ZDV)
227 \_\_\_ Combivir (AZT + 3TC)
159 \_\_\_ Zerit (stavudine, d4T)
094 \_\_\_ Hivid (zalcitabine, ddC)
147 \_\_\_ Videx / Videx EC (didanosine, ddI)
240 \_\_\_ Trizivir (abacavir + AZT + 3TC)
234 \_\_\_ Viread (tenofovir)
239 \_\_\_ Emtriva (emtricitabine, FTC)
253 \_\_\_ Truvada (Viread + Emtriva)
254 \_\_\_ Epzicom (Ziagen + Epivir)

Protease Inhibitors

- 219 \_\_\_ Agenerase (amprenavir)
212 \_\_\_ Crixivan (indinavir)
217 \_\_\_ Kaletra (lopinavir + ritonavir)
216 \_\_\_ Viracept (nelfinavir)
211 \_\_\_ Norvir (ritonavir)
210 \_\_\_ Invirase or Fortovase (saquinavir)
243 \_\_\_ Reyataz (atazanavir)
238 \_\_\_ Aptivus (tipranavir)
249 \_\_\_ Lexiva (fosamprenavir)

Non-Nucleoside RTIs

- 194 \_\_\_ Rescriptor (delavirdine)
220 \_\_\_ Sustiva (efavirenz)
191 \_\_\_ Viramune (nevirapine)

Entry Inhibitors

- 233 \_\_\_ Fuzeon (T-20, enfuvirtide)

Other

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

Name of Drug:
Name of Drug:

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  
PM .....2

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/LIPID PANEL	Red-Top (SST)	4 ml	1	2 (i)	1 (B5)	2	_ _  mls.
		IF NO, SPECIFY REASON		i. _____				
B5.	NMR Lipoprofile	Purple-yellow (EDTA)	5 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. _____				

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**SECTION E. FOURTH BLOOD DRAW (120 MINUTES)**

E1. TIME OF FOURTH BLOOD DRAW:     |\_|\_| : |\_|\_|     AM.....1  
 PM .....2

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 ( <b>E4</b> )	2	_ _  mls.	
		IF NO, SPECIFY REASON		i. _____					
E4.	INSULIN	Red-Top (SST)	4 ml	1	2 (i)	1 ( <b>END</b> )	2	_ _  mls.	
		IF NO, SPECIFY REASON		i. _____					

<p><b>PROMPT: AFTER PROCESSING, SAMPLES FOR INSULIN, GLUCOSE AND LIPIDS WILL BE BATCHED AND THEN SHIPPED TO QUEST DIAGNOSTICS. SAMPLES FOR NMR LIPOPROTEIN WILL BE SHIPPED TO LIPOSCIENCES, INC. SEE THE WIHS MANUAL OF OPERATIONS, SECTION 25, FOR INSTRUCTIONS ON PROCESSING AND SHIPPING.</b></p>
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