WOMEN'S INTERAGENCY HIV STUDY

METABOLIC STUDY: MS01 SPECIMEN COLLECTION FORM

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

VISIT #: ___ ___

FORM COMPLETED BY: ___ ___ ___

VERSION DATE **06/13/03**

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

A2. Do you inject insulin for diabetes, or to help control your blood sugar?

YES.....1 **(END FORM)**
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. Did these include any of the following?	YES	NO	i. DATE LAST TAKEN	ii. TIME LAST TAKEN	iii. AM/PM INDICATOR
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 **(f)**	___ ___/___ ___/___ ___	|___|___| : |___|___|	AM.....1 PM.....2
f. Metformin (Glucophage)	1	2 **(g)**	___ ___/___ ___/___ ___	|___|___| : |___|___|	AM.....1 PM.....2
g. Miglitiol (Glyset)	1	2 **(h)**	___ ___/___ ___/___ ___	|___|___| : |___|___|	AM.....1 PM.....2
h. Orlistat (Xenical)	1	2 **(i)**	___ ___/___ ___/___ ___	|___|___| : |___|___|	AM.....1 PM.....2
i. Piogliatazone (Actos)	1	2 **(j)**	___ ___/___ ___/___ ___	|___|___| : |___|___|	AM.....1 PM.....2
j. Repaglinide (Prandin)	1	2 **(k)**	___ ___/___ ___/___ ___	|___|___| : |___|___|	AM.....1 PM.....2
k. Rosiglitazone (Avandia)	1	2 **(l)**	___ ___/___ ___/___ ___	|___|___| : |___|___|	AM.....1 PM.....2

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A4. Did these include any of the following?	YES	NO	i. DATE LAST TAKEN	ii. TIME LAST TAKEN	iii. AM/PM INDICATOR
l. Starlix (Nateglinide)	1	2 **(m)**	___ ___/___ ___/___ ___	|___|___| : |___|___|	AM……1 PM……2
m. Other Specify: _____	1	2 **(A5)**	___ ___/___ ___/___ ___	|___|___| : |___|___|	AM……1 PM……2

A5. **PROMPT: IF PARTICIPANT HAS TAKEN ANY OF THE DIABETES MEDICATIONS LISTED IN QUESTIONS A4a – A4l IN THE LAST EIGHT (8) HOURS, SHE IS NOT ELIGIBLE TO PARTICIPATE IN THE GLUCOSE TOLERANCE TEST (GTT) PORTION OF THE METABOLIC STUDY.**

IN THE LAST EIGHT (8) HOURS, HAS PARTICIPANT TAKEN ANY OF THE MEDICATIONS LISTED IN QUESTIONS A4a – A4l?

YES.....1 **(END FORM)**
NO.....2

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 TODAY.**

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 **today**. 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. Today, have you taken…

Nucleoside/Nucleotide RTIs

204 __ Epivir (lamivudine, 3-TC)
218 __ Ziagen (abacavir, 1592U89)
092 __ Retrovir (AZT, zidovudine, ZDV)
227 __ Combivir (AZT + 3TC)
159 __ Zerit (stavudine, d4T)
094 __ Hivid (dideoxycytidine, zalcitabine, ddC)
147 __ Videx / Videx EC (dideoxyinosine, didanosine, ddI)
240 __ Trizivir (abacavir + AZT + 3TC)
234 __ Viread (tenofovir, bis-POC-PMPA)
239 __ Coviracil (emtricitabine, FTC)

Non-Nucleoside RTIs

194 __ Rescriptor (delavirdine, U-90)
220 __ Sustiva (efavirenz, DMP266)
191 __ Viramune (nevirapine)

Protease Inhibitors

219 __ Agenerase (amprenavir, 141W94)
212 __ Crixivan (indinavir)
217 __ Kaletra (lopinavir/ritonavir, ABT-378/r)
216 __ Viracept (nelfinavir)
211 __ Norvir (ritonavir)
210 __ Invirase or Fortovase (saquinavir)
243 __ Atazanavir (BMS-232632)
238 __ Tipranavir (PNU-140690)

Entry Inhibitors

233 __ Fuzeon (T-20, enfuviratide)

Other

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

Name of Drug:	Drug Code: |__|__|__|
Name of Drug:	Drug Code: |__|__|__|

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

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

A7. **FOR EACH MEDICATION LISTED IN QUESTION A6a, ASK PARTICIPANT THE TIME SHE LAST TOOK THAT MEDICATION AND COMPLETE COLUMNS A, B AND C.**

START MS01s1

	A. DRUG CODE	B. TIME LAST TAKEN	C. 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 MS01s1

A8. When was the last date and time you had anything to eat or drink, other than water?

a. DATE: ___ ___ / ___ ___ / ___ ___
M D Y

b. TIME: |___|___| : |___|___| AM.....1
PM 2

A9. Did you take any other medications this morning? This could include prescription medications not named above, over the counter (non-prescription) medications, and/or alternative or complementary medications, like herbs or vitamins.

YES 1
NO ..... 2 **(SECTION B)**

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A10. **ASK PARTICIPANT TO LIST ALL MEDICATIONS SHE HAS TAKEN THE MORNING OF THE OGTT, AND THE TIME SHE LAST TOOK EACH MEDICATION. COMPLETE COLUMNS A, B AND C.**

START MS01s2

	A. DRUG NAME	B. TIME LAST TAKEN	C. 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

SECTION B. FIRST BLOOD DRAW (FASTING)

B1. TIME OF FIRST BLOOD DRAW: |__\|__\| : |__\|__\| AM.....1
PM 2

B2. PHLEBOTOMIST'S INITIALS ___ ___ ___

	TEST TYPE	TUBE TYPE	VOLUME	a.) SPECIMEN COLLECTED? YES	NO	b.) REQUIRED VOLUME COLLECTED? YES	NO	c.) ESTIMATED VOLUME COLLECTED?
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 **(B5)**	2	|__|__| mls.
		IF NO, SPECIFY REASON		i. _____				

PROMPT: PLEASE HAVE PATIENT DRINK 75G GLUCOSE LOAD WITHIN 5 MINUTES.

B5. DID THE PARTICIPANT FULLY DRINK GLUCOSE (75G GLUCOSE LOAD)?

YES.....1 **(B5a)**
NO.....2
SPECIFY REASON: _____ **(END FORM)**

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

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SECTION C. SECOND BLOOD DRAW (30 MINUTES)

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

C2. PHLEBOTOMIST'S INITIALS ___ ___ ___

	TEST TYPE	TUBE TYPE	VOLUME	a.) SPECIMEN COLLECTED?		b.) REQUIRED VOLUME COLLECTED?		c.) ESTIMATED VOLUME COLLECTED?
				YES	NO	YES	NO	
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 ___ ___ ___

	TEST TYPE	TUBE TYPE	VOLUME	a.) SPECIMEN COLLECTED?		b.) REQUIRED VOLUME COLLECTED?		c.) ESTIMATED VOLUME COLLECTED?
				YES	NO	YES	NO	
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 ___ ___ ___

	TEST TYPE	TUBE TYPE	VOLUME	a.) SPECIMEN COLLECTED?		b.) REQUIRED VOLUME COLLECTED?		c.) ESTIMATED VOLUME COLLECTED?
				YES	NO	YES	NO	
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 WILL BE BATCHED AND THEN SHIPPED TO QUEST DIAGNOSTICS. SEE THE WIHS MANUAL OF OPERATIONS, SECTION 25, FOR INSTRUCTIONS ON PROCESSING AND SHIPPING.