SPANISH VERSION

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

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

VISIT #: ___ ___

FORM COMPLETED BY: ___ ___ ___

VERSION DATE **04/01/05**

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

A2. ¿Se inyecta usted insulina o toma alguna de las siguientes medicaciones por boca: thiazolidinedione [incluido pioglitazone (Actos) o rosiglitazone (Arandia)] o metformin (Glucophage) para la diabetes, o para controlar el azúcar en su sangre?

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

A3. ¿Está usted tomando actualmente alguna otra medicina que le hubieran recetado para la diabetes, o para bajar el azúcar en su sangre?

YES.....1
NO.....2 **(A6)**

A4.	¿Incluyó alguna de las siguientes?	YES	NO		i. Fecha de la última vez que la tomó	ii. Hora de la última vez que la tomó	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	**(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.	Starlix (Nateglinide)	1	2	**(m)**	___ ___/___ ___/___ ___	|___|___| : |___|___|	AM.....1 PM.....2
m.	Other SPECIFY: _____	1	2	**(A5)**	___ ___/___ ___/___ ___	|___|___| : |___|___|	AM.....1 PM.....2

WIHS ID#

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 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.

Ahora le preguntaré acerca de cualquier medicamento que haya tomado en los últimos tres días para combatir el VIH/SIDA. Además de las medicinas recetadas, diga otros medicamentos que haya tomado como parte de un estudio, inluyendo estudios en los que no sabe si recibió el medicamento. En los últimos tres días, ha tomado usted...

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 __ Emtriva (Coviracil, emtricitabine, FTC)
253 __ Truvada (Viread + Emtriva)
254 __ Epzicom (Ziagen + Epivir)

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 __ Reyataz (atazanavir, BMS-232632)
238 __ Tipranavir (PNU – 140690)
249 __ Lexiva (fosamprenavir)

Entry Inhibitors

233 __ Fuzeon (T-20, enfuviratide, ENF)

Other

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

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

WIHS ID #

A7. **FOR EACH MEDICATION LISTED IN QUESTION A6a, ASK PARTICIPANT THE DATE AND TIME SHE LAST TOOK THAT MEDICATION AND COMPLETE COLUMNS a, b, c AND d.**

START MS01s1

	a. DRUG CODE	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 MS01s1

A8. ¿Cuándo fue la última vez que comió o bebió algo que no fuera agua?

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

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

A9. En los últimos tres días, ¿Ha usted tomado alguna otra medicina? Favor de incluir medicina que se le haya recetado, que NO hayamos mencionado antes, y medicinas que NO se le haya recetado (medicinas que se puede comprar SIN receta del doctor), y también hierbas, vitaminas, remedios caseros, u otros medicinas alternativas o complementarios.

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

WIHS ID #

A10. **ASK PARTICIPANT TO LIST ALL MEDICATIONS SHE HAS TAKEN IN THE LAST THREE DAYS, AND THE DATE/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 ___ ___ ___

	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/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 **(B6)**	2	|__|__| mls.
		IF NO, SPECIFY REASON		i. _____				

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

WIHS ID #

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 ___ ___ ___

	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. _____				

WIHS ID #

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 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.