

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

ID LABEL
HERE --->

____ - ____ - ____ - ____

VISIT #:
____ - ____

FORM COMPLETED BY:
____ - ____ - ____

VERSION DATE **06/11/04**

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 **(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. Do these include any of the following? | <u>YES</u> | <u>NO</u> | i. <u>DATE LAST TAKEN</u> | ii. <u>TIME LAST TAKEN</u> | iii. <u>AM/PM INDICATOR</u> |
|--|------------|---------------|---------------------------|----------------------------|-----------------------------|
| 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: _____ | | | | | |

A5. PROMPT: IF PARTICIPANT HAS TAKEN ANY OF THE DIABETES MEDICATIONS LISTED IN QUESTIONS A4a – A4I 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 – A4I?

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.

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, 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)

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: |
| 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.

| |
|--|
| |
|--|

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. 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
PM2

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)**

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

A10d. 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 (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

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. _____ | | | | |

