

WOMEN'S INTERAGENCY HIV STUDY
DRUG FORM 1 – ANTIRETROVIRAL MEDICATION USE

COMPLETE THIS FORM FOR EACH ANTIRETROVIRAL THE PARTICIPANT REPORTS SHE HAS TAKEN **IN THE PAST THREE DAYS** ON THE ANTIRETROVIRAL DOSAGE FORM. DO NOT COMPLETE DRUG FORM 1 FOR ANY ANTIRETROVIRAL THE PARTICIPANT HAS TAKEN SINCE HER LAST STUDY VISIT BUT HAS NOT TAKEN IN THE PAST THREE DAYS.

PARTICIPANT ID: |_|_|-|_|_|_|_|-|_|_|_|_|_|-|_|_|

WIHS STUDY VISIT #: |_|_|_|

FORM VERSION: **1 0 / 0 1 / 0 5**

FORM COMPLETED BY: |_|_|_|_|

DATE COMPLETED: |_|_|_| / |_|_|_| / |_|_|_|

PROMPT: SELECT THE SPECIFIC ANTIRETROVIRAL FOR WHICH INFORMATION WILL BE CAPTURED ON THIS FORM.

Combination Medications

- 262 ___ Atripla (Sustiva + Viread + Emtriva)
227 ___ Combivir (AZT + 3TC)
254 ___ Epzicom (Ziagen + Epivir)
240 ___ Trizivir (abacavir + AZT + 3TC)
253 ___ Truvada (Viread + Emtriva)

Non-Nucleoside RTIs

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

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:

→ Drug Code: |_|_|_|_|

PROMPT: INTERVIEWER, PLEASE RECORD HERE HOW USE OF THIS MEDICATION WAS REPORTED.

- SELF-REPORT1
- PARTICIPANT BROUGHT WRITTEN LIST TO VISIT2
- PARTICIPANT BROUGHT MEDICATION BOTTLES TO VISIT3
- PARTICIPANT BROUGHT PHARMACY RECORD TO VISIT4
- RECORD OBTAINED DIRECTLY FROM PHARMACY5
- OTHER6

SPECIFY: _____

PROMPT: INTERVIEWER READ TO PARTICIPANT IF NECESSARY: “A medication you have taken “in the past 3 days” includes one you have taken at least one time today, yesterday, or the day before yesterday.”

1. a. You said that you have taken (DRUG) in the past three days. Is this either a new medication you have started using since your (MONTH) study visit, or a medication that you had stopped using for some time, but started again since your (MONTH) study visit?

- YES 1
- NO 2 (**Question 2**)

- b. What was the date you began taking (DRUG)? I just need the month and year. If this is a medication that you are re-using, please give me the most recent date that you began taking or re-using this medication.

|_|_|_| / |_|_|_|_|_|
 MONTH YEAR

- c. What was the **main** reason you had for starting to take (DRUG)?

- Medication was easier to take 1
- My viral load went up 2
- To alleviate side effects 3
- To make other drugs more effective 4
- My CD4 level went down 6
- Prescription changes by physician 7
- I'm having a baby 8
- Resistance to other medications 9
- Other reason 5

SPECIFY: _____

2. a. Since your (MONTH) study visit, how did you get access to (DRUG)? **CIRCLE ONE ANSWER.**

- Regular prescription 1 (**Question 3**)
- Compassionate use program 2 (**Question 3**)
- Research study 3

b. Was this study one in which you were blinded to the treatment (in other words, you did not know the specific medications you were taking)?

- YES 1 **(STOP HERE)**
- NO 2

3. Since your (MONTH) study visit, how long have you used (DRUG)?

SHOW PARTICIPANT RESPONSE CARD E1. CIRCLE ONE ANSWER.

- 1 week or less 1
- More than 1 week, but less than 1 month..... 2
- 1 – 2 months 3
- 3 – 4 months 4
- 5 – 6 months 5
- More than 6 months..... 6

PROMPT: IF THIS IS THE FIRST DRUG FORM 1 YOU ARE COMPLETING FOR THIS PARTICIPANT AT THIS VISIT, READ INTRODUCTION 1. OTHERWISE, READ INTRODUCTION 2.

INTRODUCTION 1: This section of the questionnaire asks about how you have taken (DRUG) in the past three days. Most people with HIV have many pills to take at different times during the day. Many people find it hard to always remember their pills. I need to understand how people with HIV are really doing with their medication doses. Please tell me what you are actually doing. Don't worry about telling me that you don't take all your doses. I need to know what is really happening, not what you think I want to hear.

INTRODUCTION 2: Now I'm going to ask you about how you have taken (DRUG) in the past three days.

7. Please indicate on the response card the point showing your best guess about how much (DRUG) you have taken in the **past 3 days**.

SHOW PARTICIPANT RESPONSE CARD E4. CIRCLE ONE ANSWER.

- | | |
|-------------------|--------------------|
| 0 – 5 %..... 1 | 51 – 55 %..... 11 |
| 6 – 10 %..... 2 | 56 – 60 %..... 12 |
| 11 – 15 %..... 3 | 61 – 65 %..... 13 |
| 16 – 20 %..... 4 | 66 – 70 %..... 14 |
| 21 – 25 %..... 5 | 71 – 75 %..... 15 |
| 26 – 30 %..... 6 | 76 – 80 %..... 16 |
| 31 – 35 %..... 7 | 81 – 85 %..... 17 |
| 36 – 40 %..... 8 | 86 – 90 %..... 18 |
| 41 – 45 %..... 9 | 91 – 95 %..... 19 |
| 46 – 50 %..... 10 | 96 – 100 %..... 20 |

8. Please indicate on the response card the point showing your best guess about how much (DRUG) you have taken in the **past 2 weeks**.

SHOW PARTICIPANT RESPONSE CARD E4. CIRCLE ONE ANSWER.

0 – 5 %.....	1	51 – 55 %.....	11
6 – 10 %.....	2	56 – 60 %.....	12
11 – 15 %.....	3	61 – 65 %.....	13
16 – 20 %.....	4	66 – 70 %.....	14
21 – 25 %.....	5	71 – 75 %.....	15
26 – 30 %.....	6	76 – 80 %.....	16
31 – 35 %.....	7	81 – 85 %.....	17
36 – 40 %.....	8	86 – 90 %.....	18
41 – 45 %.....	9	91 – 95 %.....	19
46 – 50 %.....	10	96 – 100 %.....	20

9. Please indicate on the response card the point showing your best guess about how much (DRUG) you have taken in the **past month**. We would be surprised if this was 100% for most people.

SHOW PARTICIPANT RESPONSE CARD E4. CIRCLE ONE ANSWER.

0 – 5 %.....	1	51 – 55 %.....	11
6 – 10 %.....	2	56 – 60 %.....	12
11 – 15 %.....	3	61 – 65 %.....	13
16 – 20 %.....	4	66 – 70 %.....	14
21 – 25 %.....	5	71 – 75 %.....	15
26 – 30 %.....	6	76 – 80 %.....	16
31 – 35 %.....	7	81 – 85 %.....	17
36 – 40 %.....	8	86 – 90 %.....	18
41 – 45 %.....	9	91 – 95 %.....	19
46 – 50 %.....	10	96 – 100 %.....	20

10. When was the last time you missed a dose of (DRUG)?

SHOW PARTICIPANT RESPONSE CARD E5. CIRCLE ONE ANSWER.

Today.....	1
Yesterday.....	2
Earlier this week.....	3
Last week.....	4
Less than a month ago.....	5
More than a month ago.....	6
Never.....	7

11. The following question asks about the timing of your doses of (DRUG). We will use the words “correct time” for a dose. We would like to know how many doses of (DRUG) you took within 2 hours of the correct time in the last month. That is, how many did you take 2 hours or less (early or late) away from the correct time?

PROBE: What do we mean by “correct time?” If you are taking (DRUG) three times per day, the “correct time” to take it would be exactly every 8 hours.

Please indicate on the response card the point showing your best guess about how often you took (DRUG) within 2 hours of the correct time in the **past month**.

SHOW PARTICIPANT RESPONSE CARD E6. CIRCLE ONE ANSWER.

0 – 5 %.....	1	51 – 55 %.....	11
6 – 10 %.....	2	56 – 60 %.....	12
11 – 15 %.....	3	61 – 65 %.....	13
16 – 20 %.....	4	66 – 70 %.....	14
21 – 25 %.....	5	71 – 75 %.....	15
26 – 30 %.....	6	76 – 80 %.....	16
31 – 35 %.....	7	81 – 85 %.....	17
36 – 40 %.....	8	86 – 90 %.....	18
41 – 45 %.....	9	91 – 95 %.....	19
46 – 50 %.....	10	96 – 100 %.....	20

PROMPT: AFTER A DRUG FORM 1 HAS BEEN COMPLETED FOR EACH ANTIRETROVIRAL MEDICATION THE PARTICIPANT REPORTS SHE HAS TAKEN IN THE PAST 3 DAYS, GO BACK AND COMPLETE F22MED.