

**WOMEN'S INTERAGENCY HIV STUDY
ANTIRETROVIRAL MEDICATIONS - DRUG FORM 1**

COMPLETE THIS FORM FOR EACH MEDICATION LISTED IN FORM 22 MED B2A.

PARTICIPANT ID: - - -

WIHS STUDY VISIT #:

FORM VERSION: 1 0 / 0 1 / 0 4

FORM COMPLETED BY: DATE COMPLETED: / /

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

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, ddl)
- 240 Trizivir (abacavir + AZT + 3TC)
- 234 Viread (tenofovir, bis-POC-PMPA)
- 239 Emtriva (Coviracil, emtricitabine, FTC)
- 253 Truvada (Viread + Emtriva)
- 254 Epzicom (Ziagen + Epivir)

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 Hydrexa (hydroxyurea)
- Other anti-viral (from Drug List 1)

Non-Nucleoside RTIs

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

Name of Drug: <input style="width: 95%;" type="text"/>	→ Drug Code: <input style="width: 95%;" type="text"/>
--	---

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

- Self report 1
- Participant brought written list to visit 2
- Participant brought medication bottles to the visit 3
- Participant brought pharmacy record to visit 4
- Record obtained directly from pharmacy 5
- Other 6

SPECIFY: _____

[Empty box for WIHS ID#]

You said you have taken (DRUG) since your (MONTH) study visit:

1. A. Is this either a new medication you have started using since your last (MONTH) study visit, or a medication that you had stopped using for some time, but started again since your last (MONTH) study visit?

YES.....1
NO.....2 → **GO TO Q2**

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)?

CIRCLE ONE ANSWER.

- 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 reason:

2. A. Since your (MONTH) study visit, how did you get access to (DRUG)?

CIRCLE ONE ANSWER.

- Regular Prescription 1 → **GO TO Q3**
- Compassionate Use Program . 2 →
- 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 →
NO 2 **STOP HERE**

3. PROMPT: SHOW PARTICIPANT RESPONSE CARD E1.

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

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

4. A. Are you currently taking (DRUG)?

YES 1 → **GO TO Q5**
NO 2

B. Since your (MONTH) study visit, in what month and year did you most recently take (DRUG)?

___ / ___
MONTH YEAR

C. PROMPT: SHOW PARTICIPANT RESPONSE CARD E2.

What is the MAIN reason you stopped taking (DRUG)?

CIRCLE ONLY ONE RESPONSE.

- Prescription changes by physician 1
- My CD4+ was too high/viral load
 was too low 2
- I felt too healthy 3
- Medication not working 4
- I am taking alternative medications . . . 5
- It caused unpleasant side effects 6
- Fear of drug/drug too toxic 7
- Too hard to swallow 8
- Tired of taking medications 9
- Too complicated 10
- Food/water restrictions too hard
 to follow 11
- I can't afford it/have no insurance
 coverage 12
- I'm having a baby 13
- Personal decision 14
- Family comes first, I don't have
 time for both 15
- Family/friends thought I should not
 take it 16
- Alcohol/drug use 17
- Other reason 18

Specify reason:

STOP HERE

5. 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 are currently taking (DRUG). 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 are currently taking (DRUG).

CIRCLE ONE ANSWER EACH FOR 5A AND 5B.

A. According to your doctor, how many times a day are you **supposed** to take (DRUG)?

- Once per day 1
- Twice per day 2
- Three times per day 3
- Four times per day 4

B. In what dosage form do you take (DRUG)?

- Pills 1
- Packs 2
- Teaspoons / Drops 3
- Injection/ IV 4

C. How many total (PILLS/PACKS/ TEASPOONS/DROPS/INJECTIONS) are you **supposed** to take each day?

 |_|_| total

6. Now I'm going to ask about how you took (DRUG) over the past three days.

A. How many times a day did you take this medication as prescribed? If you took only a portion of a prescribed dose, please report that time(s) as being missed.

- i. Yesterday (DAY): |_|_| times
- ii. 2 days ago (DAY): |_|_| times
- iii. 3 days ago (DAY): |_|_| times

B. How many total (PILLS/PACKS/ TEASPOONS/DROPS/INJECTIONS) did you take each day:

- i. Yesterday (DAY): |_|_|
- ii. 2 days ago (DAY): |_|_|
- iii. 3 days ago (DAY): |_|_|

7. We are interested in finding out how your use of antiviral medications in the past 3 days compares to the way that you usually take your medications. In the past three days, did you take more, less, or about the same amount of (DRUG) as you usually do?

- More 1
- Less 2
- About the same 3

8. PROMPT: SHOW PARTICIPANT RESPONSE CARD E3.

How many doses of (DRUG) have you missed in the last 2 weeks? **CIRCLE ONE ANSWER.**

- None 0
- One 1
- Two 2
- Three to Five 3
- Six to Ten 4
- Eleven to Twenty 5
- Twenty-one to Forty 6
- More than Forty 7
- All of them 8
- Don't Know <-8>

9. PROMPT: SHOW PARTICIPANT RESPONSE CARD E4.

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. **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. PROMPT: SHOW PARTICIPANT RESPONSE CARD E5.

When was the last time you missed a dose of (DRUG)? **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
- DON'T KNOW <-8>

11. The following question is about the timing of your doses of (DRUG). We will use the words “correct time” for a dose. You indicated in a previous question that you are supposed to take (DRUG) (5A RESPONSE) times a day. The correct time to take it is every **(24, 12, 8, 6)** hours. We would like to know how many doses of (DRUG) you took within 2 hours of the correct time in the last month.

PROMPT: SHOW PARTICIPANT RESPONSE CARD E6.

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. We would be surprised if this was 100% for most people.

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: GO BACK AND COMPLETE FORM 22 MED.