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:	10/01/04				
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)
- $227 \quad _ \text{Combivir} (\text{AZT} + 3\text{TC})$
- 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)

<u>Other</u>

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

Name of Drug:

→ Drug Code: |__|_|

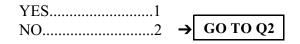
PROMPT: INTERVIEWER, PLEASE RECORD HERE HOW USE OF THIS MEDICATION WAS REPORTED.

Self report 1	
Participant brought written list to visit	1
Participant brought medication bottles to the visit)
Participant brought pharmacy record to visit	ļ
Record obtained directly from pharmacy5	í
Other)

SPECIFY:

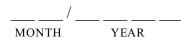
You said you have taken (DRUG) since your (MONTH) study visit:

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?



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.



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

CIRCLE ONE ANSWER.

- 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 → 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 $1 \rightarrow$ NO2STOP 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)?

$YES \ldots 1 \rightarrow$	GO TO Q5
NO 2	

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

MONTH YEAR

GO TO O3

C. **PROMPT: SHOW PARTICIPANT RESPONSE CARD E2.**

What is the <u>MAIN</u> reason you stopped taking (DRUG)?

CIRCLE ONLY ONE RESPONSE.

Prescription changes by physician 1
My CD4+ was too high/viral load
was too low
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
Too hard to swallow 8
Tired of taking medications
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
Alcohol/drug use 17
Other reason

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 <u>actually</u> 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 day2
Three times per day
Four times per day 4

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

Pills 1
Packs
Teaspoons / Drops 3
Injection/ IV

WIHS ID#

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 <u>portion</u> of a prescribed dose, <u>please report that</u> <u>time(s) as being missed</u>.
 - i. Yesterday (DAY):
 - ii. 2 days ago (DAY):
 - iii. 3 days ago (DAY):
- 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	th	e :	sa	m	le	•	•			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
Two2
Three to Five
Six to Ten 4
Eleven to Twenty 5
Twenty-one to Forty 6
More than Forty7
All of them
Don't Know

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.**

Today1
Yesterday
Earlier this week
Last week
Less than a month ago 5
More than a month ago 6
Never
DON'T KNOW

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.