

WOMEN'S INTERAGENCY HIV STUDY

QUESTION BY QUESTION SPECIFICATIONS

FORM 22MED: MEDICATION HISTORY

General Instructions:

1. Before beginning this section, interviewers should make sure that they have one blank copy of the **Antiretroviral Dosage Form** and at least five blank copies each of **Drug Form 1**, **Drug Form 2** and **Drug Form 3** available in case they are needed.
2. All dates should be recorded in the MM/DD/YY format unless otherwise noted. For dates that must be completed on the form, if the participant cannot remember the exact month (and day), probe for the season. Use "15" for the day if the specific day cannot be recorded. Probe for the season and assign the month as follows:

Summer	=	July	=	07
Fall	=	October	=	10
Winter	=	January	=	01
Spring	=	April	=	04

Interviewers should have available an appropriate calendar to aid the participant in determining dates. Years in response to questions inquiring about occurrences "since last visit" should be 1995 and thereafter.

3. Times should be recorded in the HH:MM format. Remember to use leading zeros, e.g., 08:00.
4. For questions containing an open-ended specify box, interviewers should print responses exactly in the words of the respondent.
5. Obtain the date of the participant's previous visit from the **Visit Control Sheet (VCS)**. Enter the date of the participant's last completed core visit into **Question A6**. The month in this date should be used in the questions wherever (MONTH) appears.
6. Interviewers should ignore any markings related to data entry such as "START F22MEDS3." These indicators mark the beginning and end of all subforms; they have been added for data entry purposes only and will not affect how the form is completed.

General Instructions for Collection of Prescription Medication Data:

There are various methods by which WIHS participants can report prescription medication use at the WIHS core visit: (1) self report from memory, (2) self report with documentation (such as medication bottles, a pharmacy record, or a list of medications), or (3) medication records obtained directly from the pharmacy. Please follow the general instructions below regarding collection of prescription medication data based on these three methods for all sections of the F22MED that ask about medication usage.

- (1) If the participant does not bring any documentation to her visit (i.e., is recalling medication use by memory only), the interviewer should utilize the appropriate medication response card set to determine which medications the participant has used since her last study visit. For example, to determine ARV use, the interviewer would hand the participant the **Antiretroviral Photo Medication Cards**, and ask the participant, *"Since your (MONTH) study visit, have you taken (DRUG NAME)?"* for each medication.
- (2) If the participant brings documentation of medication use to her visit (e.g., brings a list of medications or brings pill bottles), it is not necessary for the interviewer to read aloud each medication listed on the F22MED. In this case, medication use data may be transferred directly from the list (or bottles) onto the F22MED. Please continue to ask **Question E12i**, *"Since your (MONTH) study visit, have you taken any other prescribed medications not previously mentioned?"* just to verify that her prescription medication data are complete.

- (3) If the site has obtained medication records directly from the participant's pharmacy, it is also not necessary for the interviewer to read aloud each medication listed on the F22MED. The interviewer can again transfer data directly from the pharmacy record to the F22MED. Please continue to ask **Question E12i**, *"Since your (MONTH) study visit, have you taken any other prescribed medications not previously mentioned?"* just to verify that her prescription medication data are complete.

Interviewers can ignore the three-digit numbers next to each medication in **Questions B2a, C1a – C1c and D1a**. These numbers are necessary for data entry, but can be ignored during the actual interview.

Detailed instructions on collection of the different types of prescription medications (e.g., ARV, OI prophylaxis, etc.) are included below by question number.

SECTION B: ANTIRETROVIRAL HISTORY

- B1. A vaccine against HIV-1 can include vaccines that prevent infection with HIV or therapeutic vaccines (those that prevent progression of the infection).

- B2. a. Record the antiretroviral medications used by the participant since her most recent study visit.

If the participant has brought medication bottles or a list of prescription medications you may transfer this information directly to the F22MED without asking the participant about use of each individual medication listed.

If the participant is recalling her antiretroviral medication use from memory, please hand the participant the current version of the **Antiretroviral Photo Medication Cards** and go through each card with the participant, asking for each medication, *"Since your (MONTH) study visit, have you taken (DRUG NAME)?"* (*"Desde su visita al estudio en (MES), ¿ha tomado usted..."*)

If the participant is HIV-negative, you do not need to read through the entire list of antiretroviral medications and should skip to **Question B2b**.

For all participants using antiretroviral medications, mark each drug the participant has taken since her last study visit by placing an "X" in the corresponding box. Ensure that, in addition to her prescribed antiretrovirals, the participant includes all antiretroviral medications that may have been taken as part of a research study, including those in which she may have been blinded (**PROBE: unaware of whether you were taking the actual medication or a placebo**) to the treatment.

If the participant reports using one of the four antiretroviral medications marked with "*" (i.e., Efavir, Viread, Emtriva, Truvada), the interviewer should ask, *"Do you take [EPIVIR, VIREAD, EMTRIVA, TRUVADA] (read name of appropriate medication only) to treat HIV only, hepatitis (B or C) only, or to treat both HIV and hepatitis?"*

- If use is for HIV treatment only, interviewer should mark the medication in **Question B2a** only and proceed with administration of the **Antiretroviral Dosage Form** and **Drug Form 1** (if participant has taken the medication in the past three days).
- If use is for hepatitis treatment only, interviewer should mark the medication in **Question D1a** only and complete **Drug Form 3** at the appropriate point in the interview.
- If use is for HIV and hepatitis treatment (or participant is unsure of reason for use), interviewer should mark medication in both **Questions B2a and D1a** and complete an **Antiretroviral Dosage Form**, a **Drug Form 1** (if participant has taken the medication in the past three days) and a **Drug Form 3**.

The antiretroviral drug listing in **Question B2a** is not complete. However, it does contain currently used medications to the best of our knowledge. This list is updated every six months. For any other antiretroviral medication used by the participant against HIV-1 that is not on the list in **Question B2a**, check *"Other antiretroviral(s)"* and print the name of the drug in the specify box. Check **Drug**

List 1 to see if it is on this list. If so, record the three-digit code in the space allotted next to the “Specify” box. If the drug is not on Drug List 1, check the drugs listed in **Questions C1a – C1c** to see if it is on one of these lists. If the drug is listed in **Questions C1a – C1c**, record its use there. Otherwise, bring this to the attention of the clinic coordinator/director. If the drug is not on the coding list, the center’s director should contact the coordinator at WDMAC to inquire about the applicability of getting a new drug code assigned. Use the drug code obtained from WDMAC.

If a participant indicates that she is taking an antiretroviral medication, but does not know or cannot remember the name of the medication, check **“Other antiretroviral(s)”** and print **“unknown”** in the specify box. Enter **“999”** in the space provided for the three-digit drug code. If the participant reports more than one unknown antiretroviral medication, please list them as **unknown1, unknown2**, etc., for tracking purposes.

If the participant indicates that she is taking a combination antiretroviral, for example, “Combivir,” you would mark only the “Combivir” box (code 227). The individual boxes for AZT and 3TC should not be checked. If, for example, the participant indicates that she is taking “Trizivir,” mark only the “Trizivir” box (code 240). The individual boxes for abacavir, AZT and 3TC should not be checked.

After marking all the antiretrovirals reported by the participant in **Question B2a**, review the participant’s **Visit Control Sheet (VCS)**. All antiretrovirals reported by the participant at her previous WIHS visit will be listed. If any antiretrovirals are included on the **VCS** as being used at her last visit, but are not reported as being used since the last visit in **Question B2a**, you will need to ask the participant to resolve this inconsistency. In this case, please ask the participant, **“Last visit you said you were taking [DRUG], have you stopped taking that since your (MONTH) study visit or are you still taking it?”** (“*En la última visita Ud. dijo que estaba tomando [DRUG], ¿ha dejado de tomarlo después de la última visita o todavía lo está tomando?*”) You should then amend the response to **Question B2a** as necessary based on the participant’s response and then proceed with the rest of the interview.

After completion of **Question B2a**, if the participant is taking any antiretroviral medications, complete the **Antiretroviral Dosage Form**. See the **Antiretroviral Dosage Form** and **QxQs** for detailed instructions on how to complete.

After completing the **Antiretroviral Dosage Form**, complete a **Drug Form 1** for all antiretroviral medications the participant reports that she has taken **in the past three days**. If the participant is taking multiple antiretrovirals, mark each drug on F22MED and complete a separate **Drug Form 1** for each medication. **NOTE:** Do not complete a **Drug Form 1** for any antiretroviral medications the participant has taken since her last study visit but has not taken in the last three days.

EXAMPLES for Participant “X”:

- X has taken AZT, 3TC and ritonavir in the past three days. On F22MED, mark the three boxes corresponding to AZT, 3TC and ritonavir. Complete the **Antiretroviral Dosage Form** and a separate **Drug Form 1** for each drug.
- X was taking AZT and ddI. One month before her study visit, she changed her regimen to AZT, ddC and saquinavir. On F22MED, mark the boxes corresponding to AZT, ddI, ddC and saquinavir. Complete an **Antiretroviral Dosage Form**, then a separate **Drug Form 1** for each drug she has taken in the past three days, i.e., AZT, ddC and saquinavir. Do not complete a **Drug Form 1** for ddI as she has not taken it in the last three days.
- X is currently in an AZT/ddI/nelfinavir trial, and knows that she is taking AZT and ddI, but is not sure whether she is receiving nelfinavir or a placebo (i.e., she is blinded to the treatment). Complete an **Antiretroviral Dosage Form** and a separate **Drug Form 1** for each drug. When filling out the drug form related to nelfinavir, be sure to follow the specific directions on **Drug Form 1** for blinded treatments.

- X reports taking lobucavir in the past three days in a research trial. Mark ***“Other antiretroviral,”*** and print ***“lobucavir”*** in the specify box. Go to **Drug List 1** and get the 3-digit code for lobucavir (222). Write code ***“222”*** in the boxes for 3-digit drug code. Fill out an **Antiretroviral Dosage Form** and a **Drug Form 1** for lobucavir.
- b. If the participant has not taken any antiretroviral medications since her (MONTH) study visit, check the box in this question and skip to **Question B10**.
- c. Enter the total number of antiretroviral medications the participant has taken from **Question B2a**.
- B3. The interviewer should review the participant’s **Visit Control Sheet (VCS)** and the **Antiretroviral Dosage Form (DSG)** to determine whether or not the participant has started taking any new antiretroviral medications since her last study visit. If she has not started any new medications, skip to **Question B4**.
- a. Ask the participant if this is the first time she has ever taken any antiretroviral medications. The participant should only answer “YES” if she has never before taken any antiretroviral medication. If she replies “NO,” skip to **Question B4**. If she replies “YES,” ask **Questions B3b – B3i** to determine why she decided to begin taking antiretroviral medications. Circle “YES” or “NO” for each question.
- B4. The interviewer should review the participant’s **Visit Control Sheet (VCS)** and the **Antiretroviral Dosage Form (DSG)** to determine whether or not the participant has changed or stopped any of her antiretroviral medications since her last study visit. If the participant has not changed or stopped any antiretroviral medications, skip to **Question B7**. If the participant has changed or stopped even one of her antiretroviral medications, ask **Questions B4a – B4m** to determine why she changed or stopped her antiretroviral medications. Circle “YES” or “NO” for each question.
- B7. a. This question is designed to assess the participant’s general level of adherence to all of her prescribed antiretroviral medications. If the participant responds that she took her antiretroviral meds 100% of the time, skip to **Section C**.
- b. Hand the participant **Response Card D1**. This question asks a series of potential reasons for missing medications and how often each reason applies. Read each reason to the participant and mark how frequently this reason causes her to miss her medications. At the end, ask the participant if there is any other reason that causes her to miss her medications. Print her response in the specify box and indicate how often this reason causes her to miss taking her medications.
- After asking **Question B7**, skip to **Section C** regardless of the participant's response.
- B10. Hand the participant **Response Card D3** before asking her **Question B10**.
- This question asks for the main reason a participant is not taking any antiretroviral medications. Read the responses to the participant and then circle the one answer that matches her response. If the participant’s main reason for not taking any antiretroviral medications is not listed as one of the responses, circle ***“any other reason”*** and print her response in the specify field.

SECTION C. OI MEDICATION HISTORY

- C1. Record the non-antiretroviral (i.e., OI prophylaxis) medications used by the participant since her most recent study visit.
- If the participant has brought medication bottles or a list of prescription medications you may transfer this information directly to the F22MED without asking the participant about use of each individual medication listed.

If the participant is recalling her prescription medication use from memory, please hand the participant the current version of the **Response Card D4** and go through the card with the participant, asking for each medication, *“Since your (MONTH) study visit, have you taken (DRUG NAME)?”*

For all participants using OI prophylaxis medications, mark each drug the participant has taken since her last study visit by placing an “X” in the corresponding box.

If the participant reports using one of the four OI medications marked with “*” (i.e., interferon alfa-2b, pegylated interferon, Famvir, Rebetrone), the interviewer should ask, *“Do you take [INTERFERON ALFA-2b, PEGYLATED INTERFERON, FAMVIR, REBETRON] (read name of appropriate medication only) to treat hepatitis (B or C) only, to treat or prevent another condition, or to both treat hepatitis and treat/prevent another condition?”*

- If use is for treatment or prevention of another condition only, interviewer should mark the medication in **Question C1b** or **C1c** only (as appropriate) and proceed with administration of **Drug Form 2**.
 - If use is for hepatitis treatment only, interviewer should mark the medication in **Question D1a** only and complete **Drug Form 3** at the appropriate point in the interview.
 - If use is for hepatitis treatment and to treat/prevent another condition (or participant is unsure of reason for use), interviewer should mark the medication in both **Questions C1b/C1c** and **D1a** and complete both a **Drug Form 2** and a **Drug Form 3**.
- a. Indicate if the participant has taken the inhaled medication listed in **Question C1a** since her last study visit. If she has not, check **Question C1ai** and skip to **Question C1b**.
 - b. Indicate if the participant has taken any of the injected or infused medications listed in **Question C1b** since her last study visit. If she has not, check **Question C1bi** and skip to **Question C1c**. See instructions above if participant is taking a medication marked with “*.”
 - c. Indicate if the participant has used any of the pills, liquids or creams listed in **Question C1c** since her last study visit. If she has not, check **Question C1ci** and proceed to read the prompt after **Question C1ci**. See instructions above if participant is taking a medication marked with “*.”

If the participant is taking any of the medications in **Questions C1a, C1b or C1c**, complete a **Drug Form 2** for each medication the participant reports that she has taken since her last study visit. If the participant is taking multiple OI medications, mark each drug on the F22MED and complete a separate **Drug Form 2** for each medication.

- d. Enter the total number of OI medications the participant reported taking in **Questions C1a, C1b and C1c**.

SECTION D. HEPATITIS MEDICATION HISTORY

- D1. a. Record the hepatitis (B and C) medications used by the participant since her most recent study visit.

If the participant has brought medication bottles or a list of prescription medications you may transfer this information directly to the F22MED without asking the participant about use of each individual medication listed.

If the participant is recalling her prescription medication use from memory, please hand the participant the current version of the **Response Card D4a** and go through the card with the participant, asking for each medication, *“Since your (MONTH) study visit, have you taken (DRUG NAME)?”*

For all participants using hepatitis medications, mark each drug the participant has taken since her last study visit by placing an "X" in the corresponding box.

NOTE: If the participant indicates that she has taken Epivir, Viread, Emtriva or Truvada, but is uncertain if it was taken for her HIV or hepatitis infection, please complete **Drug Form 3**, in addition to the **Antiretroviral Dosage Form** and **Drug Form 1** (if she has taken the medication in the past three days). If participant indicates that she has taken interferon alfa-2b, pegylated interferon, Famvir or Rebetron, but is uncertain if it was taken for her hepatitis infection or for another condition, please complete a **Drug Form 3**, in addition to **Drug Form 2**.

- b. If the participant has not taken any of the medications for hepatitis listed in **Question D1a**, check the box in **Question D1b** and go to **Section E**.
- c. Enter the total number of hepatitis medications the participant reported taking in **Question D1a**.

If the participant is taking any of the medications in **Question D1a**, complete a **Drug Form 3** for each medication the participant reports that she has taken since her last study visit. If the participant is taking multiple hepatitis medications, mark each drug on F22MED and complete a separate **Drug Form 3** for each medication.

SECTION E. OTHER PRESCRIPTION MEDICATION USE

- E1a-f. These questions ask about vaccinations that the participant may have received. For each, indicate "YES" or "NO" to indicate whether she has received it since her last study visit.
- E2. Ask the participant if she has had a routine flu vaccination in the past year. (*PROBE: A flu shot is injected. The FluMist vaccine is sprayed into the nose.*)
 - b. Indicate whether the participant received the flu shot or the nasal spray vaccination.
 - c. Ask the participant to give an estimate of the date (month and year only) that she last received a flu vaccination.
- E7. Ask the participant whether she has had an illness she thinks was the flu in the past year. The entire question should be read to the participant to help to differentiate between whether she has had influenza, a cold, or a stomach virus. We are interested only in collecting data regarding influenza infection. If the participant did not have the flu in the past year, skip to **Question E11**.
 - b. Ask the participant to give an estimate of the date (month and year only) that she had her most serious case of the flu in the past year.
- E8a-f. These questions ask about specific symptoms the participant may have experienced when she had the flu. Record "YES" or "NO" for each symptom.
- E11. Record the hormone replacement therapies used by the participant since her most recent study visit.

If the participant has brought medication bottles or a list of prescription medications you may transfer this information directly to the F22MED without asking the participant about use of each individual medication listed.

If the participant is recalling her prescription medication use from memory, please hand the participant the current version of the **Response Card D4h** and go through the card with the participant, asking for each medication, *"Since your (MONTH) study visit, have you taken (DRUG NAME)?"*

This question should be recorded as "YES" only if the participant took any of the listed therapies for more than one month since her (MONTH) study visit.

NOTE: Do not include medications the participant reports taking solely for birth control, as their use will be captured on WIHS Form F23 Obstetric, Gynecologic and Contraceptive History.

If the participant reports no use of hormone replacement therapy, skip to **Question E12a**.

- a. This question should not be read aloud to the participant. Based on the medications the participant reports taking in **Question E11**, the interviewer should record the type of hormone replacement therapy taken by the participant since her last study visit. Be sure to specify the therapy taken if **“other HRT”** was indicated in **Question E11**. If the participant reports use of both estrogen and progesterone hormone replacement therapies, record this as **“combination”** in **Question E11a**.
- b. Read to the participant each reason listed and circle “YES” for each reason she reports is the reason she is taking hormone replacement therapy. If she answers “other,” specify the reason where listed on the form.

E12. Record any other prescription medications used by the participant since her most recent study visit.

If the participant has brought medication bottles or a list of prescription medications you may transfer this information directly to the F22MED without asking the participant about use of each individual medication type listed. Record any reported medications in the specify boxes provided in **Question E13a**. In this case, **Questions E12a – E12h** may be skipped; however, the interviewer should ask **Question E12i** to ensure that the participant has not taken any prescription medications not mentioned during the interview.

If the participant is recalling her prescription medication use from memory, please ask each of **Questions E12a – E12i** and hand the participant the current version of the appropriate response card for each question.

- a. This question asks if the participant has taken any medication for blood pressure or her heart. Hand the participant **Response Card D4b**. If she has taken any blood pressure or heart medications since her last study visit (whether they are included on the list or not), then also ask about use in the last five days. Record use of blood pressure or heart medications in the specify boxes provided in **Question E13a**.
- b. This question asks if the participant has taken any medication to lower her cholesterol, triglyceride or blood lipid level. Hand the participant **Response Card D4c**. If she has taken any cholesterol, triglyceride or blood lipid medications since her last study visit (whether they are included on the list or not), then also ask about use in the last five days. Record use of cholesterol, triglyceride or blood lipid medications in the specify boxes provided in **Question E13a**.
- c. This question asks if the participant has taken any medication to lower her blood sugar. Hand the participant **Response Card D4d**. If she has taken any medications to lower her blood sugar since her last study visit (whether they are included on the list or not), then also ask about use in the last five days. Record use of blood sugar medications in the specify boxes provided in **Question E13a**.
- d. This question asks if the participant has taken any medication to treat or prevent osteoporosis. Hand the participant **Response Card D4e**. If she has taken any osteoporosis medications since her last study visit (whether they are included on the list or not), then also ask about use in the last five days. Record use of osteoporosis medications in the specify boxes provided in **Question E13a**.
- e. This question asks if the participant has taken any medication for seizures. Hand the participant **Response Card D4f**. If she has taken any seizure medications since her last study visit (whether they are included on the list or not), then also ask about use in the last five days. Record use of seizure medications in the specify boxes provided in **Question E13a**.
- f. This question asks if the participant has taken any medication for psychological conditions or depression. Hand the participant **Response Card D4g**. If she has taken any psych medications since her last study visit (whether they are included on the list or not), then also ask about use in the last five days. Record use of psychological or depression medications in the specify boxes provided in **Question E13a**.

- g. This question asks if the participant has taken any medication for HIV lipodystrophy or body fat changes related to HIV. Hand the participant **Response Card D4h**. If she has taken any medications for lipodystrophy or body fat changes since her last study visit (whether they are included on the list or not), then also ask about use in the last five days. Record use of HIV lipodystrophy or body fat change medications in the specify boxes provided in **Question E13a**.
 - h. This question asks if the participant has taken any medication for breathing or lung problems. Hand the participant **Response Card D4k**. If she has taken any medications for breathing or lung problems since her last study visit (whether they are included on the list or not), then also ask about use in the last five days. Record use of breathing or lung problem medications in the specify boxes provided in **Question E13a**.
 - i. This question should be asked of all participants. Ask the participant if she has taken any other prescribed medications not previously mentioned since her last study visit. If she has taken any other prescription medications, list those medications named in the specify fields provided in **Question E13a**. If possible, enter the exact name of the medication the participant is taking. However, if the participant knows that she is taking, for example, an anti-depressant or blood pressure medication, but can't remember the medications' specific name(s), record *"anti-depressant"* or *"blood pressure medication."*
- E13. Enter the total number of prescription medications the participant reports taking in **Questions E12a** through **E12i**.
- If **Question E13 = 0**, skip to **Question G3**. If **Question E13 ≥ 1**, list in Column "a" all the medications taken by the participant and complete Columns "b" and "c" for each medication.
- b. For each medication listed in **Question E13a**, ask the participant whether she has taken it within the past five days.
 - c. For each medication listed in **Question E13a**, the interviewer should record how use of the medication was reported by the participant, i.e., self report, participant brought written list to visit, participant brought medication bottle to visit, participant brought pharmacy record to visit, record obtained directly from pharmacy, or other.
- G3. Record the time module ended. Circle the code for AM (code 1) or PM (code 2).