

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 eight 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). The month in this date should be used in the questions wherever (MONTH) appears. Enter the date of the participant's **last completed core visit**.
6. Interviewers SHOULD IGNORE the three-digit numbers listed next to each box in **Questions B2a, C1a–C1c, D1a and F1b**. These numbers are necessary for data entry, but should be ignored during the actual interview. Additionally, 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.

READ THE INTRODUCTION TO THE PARTICIPANT.

SECTION B: ANTIRETROVIRAL HISTORY

The time frame for questions (e.g., since your (MONTH) study visit, in last six months, in general) shifts a number of times throughout this section. The interviewer should pay particularly close attention to the time frame to which each question refers and stress this time frame to the participant while reading each question.

- 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. **HAND THE PARTICIPANT THE CURRENT ANTIRETROVIRAL PHOTO MEDICATION CARDS.**

Go through each card with the participant. For EACH medication, ask the participant "Since your (MONTH) study visit, have you taken (DRUG NAME)?" Ensure that, in addition to her prescribed antiretrovirals, she 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. However, if the participant is

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

Mark each drug to which the participant responds with a “YES” by placing an “X” in the corresponding box. Do not concern yourself with the three-digit numbers listed next to each box. These numbers are necessary for data entry purposes only.

If the participant reports using one of the three antiretroviral medications marked with “*” (i.e., Epivir, Viread, Emtriva), the interviewer should read the prompt at the bottom of page 2 to determine how to proceed with form completion. The interviewer should ask the participant if she takes [EPIVIR, VIREAD, EMTRIVA] (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 medication in **Question B2a** and proceed with administration of the **Antiretroviral Dosage Form** and **Drug Form 1** (if participant is **currently** taking the medication).
- **If use is for hepatitis treatment only**, interviewer should mark 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 is **currently** taking the medication) 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. If the drug is a complementary/alternative therapy, record its use in **Question F1b**. 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 “Combivir,” mark the “Combivir” box (code 227). The individual boxes for AZT and 3TC should not be checked. If the participant indicates that she is taking “Trizivir,” mark the “Trizivir” box (code 240). The individual boxes for abacavir, AZT and 3TC should not be checked.

After completion of **Question B2a**, 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 medications the participant reports that she is **currently taking** at the time of her visit. If the participant is taking multiple antiretrovirals, mark each drug and complete a separate **Drug Form 1** for each medication.

DO NOT COMPLETE A DRUG FORM 1 FOR ANY ANTIRETROVIRAL MEDICATIONS THE PARTICIPANT HAS TAKEN SINCE HER LAST STUDY VISIT BUT IS NO LONGER TAKING AT THE TIME OF HER VISIT.

EXAMPLES for Participant “X”:

- X is currently taking AZT, 3TC and ritonavir. 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 is currently taking, i.e., AZT, ddC and saquinavir. Do not complete a **Drug Form 1** for ddI as she is no longer taking it at the time of her visit.
 - 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 currently taking lobucavir in a research trial. Mark “*Other antiretroviral*,” 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 reports that she 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 reported taking in **Question B2a**.
- B3. If the participant has taken antiretroviral medications since her (MONTH) study visit, ask her if this is the first time she ever has 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 subquestions **B3a – B3h** to determine why she decided to begin taking antiretroviral medications. Circle “YES” or “NO” for each subquestion.
- B4. Ask the participant if she has changed or stopped any of her antiretroviral medications since her (MONTH) study visit. The participant should answer “YES” if she has changed or stopped even one of her antiretroviral medications. If she replies “NO,” skip to **Question B7**. If she replies “YES,” ask **subquestions B4a – B4m** to determine why she changed or stopped her antiretroviral medications. Circle “YES” or “NO” for each subquestion.

The remaining questions in this section focus on how the participant has taken her medications in the past six months.

- 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 **Question B8**.
- b. Hand the participant **Response Card D1**. This question asks a series of 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.
- B8. a. Hand the participant **Response Card D2** before asking her **Question B8**. All participants reporting use of antiretrovirals in **Question B2** should answer this question related to general adherence to their medication schedules.

- b. If the participant was never given special instructions for any of her antiretroviral medications, skip to **Question B9**.
- c. Hand the participant **Response Card D2** before asking her **Question B8c**.

B9. If the participant is currently taking at least two antiretroviral medications, circle “YES” to indicate that she is on combination therapy and proceed to ask her **Questions B9a – B9d**. If she is on mono therapy (currently taking only one antiretroviral medication), or she has taken more than one antiretroviral medication since her (MONTH) study visit but is not currently taking at least two antiretroviral medications, circle “NO” and skip to **Section C**.

YOU MAY NEED TO REFER TO THE ANTIRETROVIRAL DOSAGE FORM COMPLETED AFTER QUESTION B2A IN ORDER TO DETERMINE WHETHER THE PARTICIPANT IS CURRENTLY TAKING AT LEAST TWO ANTIRETROVIRAL MEDICATIONS.

- a–d: Hand the participant **Response Card 12** before asking her **Questions B9a – B9d**. These questions ask about the participant’s attitude towards transmission of HIV while on combination therapy. For each question, record whether she strongly agrees, agrees, is uncertain, disagrees or strongly disagrees. If the participant is hesitant to answer, **PROBE** for a response by saying, “We are interested how you feel on this question,” or, “Which choice do you think is closest to how you feel?” If the participant has difficulty choosing a category, the interviewer should re-focus the participant by re-asking the question. If the participant has questions about the question you are asking, respond with, “Whatever you think the question means,” or, “However you understand it.” If the participant remains hesitant, **PROBE** further by saying, “Remember, there are no right or wrong answers. We are interested in your feelings on this.” These questions will only be asked of women on combination antiretroviral therapy.

As **Question B10** is asked only of women not currently taking any antiretroviral therapy, skip to **Section C** after asking **Question B9d** 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. Hand the participant **Response Card D4**. In **Questions C1b** and **C1c**, 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 read the appropriate prompt in **Question C1b/C1c** to determine how to proceed with form completion. The interviewer should ask the participant if she takes [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 hepatitis treatment only**, interviewer should mark medication in **Question D1a only** and complete **Drug Form 3** at the appropriate point in the interview.
- **If use is for treatment or prevention of another condition only**, interviewer should mark medication in **Question C1b/C1c (as appropriate)** and proceed with administration of **Drug Form 2**.
- **If use is for hepatitis treatment and to treat/prevent another condition (or participant is unsure of reason for use)**, interviewer should mark medication in both **Questions C1b/C1c** and **D1a** and complete both a **Drug Form 2** and a **Drug Form 3**.

- C1. a. Ask the participant if she has taken the inhaled medication listed in **Question C1a** since her (MONTH) study visit. If “YES,” mark an “X” in the appropriate box; if “NO,” check the box in **Question C1ai** indicating that the participant has not taken the medication listed in **Question C1a** since her (MONTH) study visit and skip to **Question C1b**.
- b. Ask the participant if she has taken any of the injected or infused medications listed in **Question C1b** since her (MONTH) study visit. If “YES,” mark an “X” in the appropriate box(es); if “NO,” check the box in **Question C1bi** indicating that the participant has not taken ANY of the medications listed in **Question C1b** since her (MONTH) study visit and skip to **Question C1c**. See instructions above if participant is taking a medication marked with “*.”
- c. Ask the participant if she has used any of the pills, liquids or creams listed in **Question C1c** since her (MONTH) study visit. If “YES,” mark an “X” in the appropriate box(es); if “NO,” check the box in **Question C1ci** indicating that the participant has not taken ANY of the medications listed in **Question C1c** since her (MONTH) study visit and go to **PROMPT**. See instructions above if participant is taking a medication marked with “*.”
- d. Enter the total number of OI medications the participant reported taking in **Questions C1a, C1b and C1c**.

PROMPT: COMPLETE A DRUG FORM 2 FOR EACH MEDICATION MARKED IN QUESTIONS C1a THROUGH C1c. IF NO MEDICATIONS ARE MARKED, GO TO SECTION D.

SECTION D. HEPATITIS MEDICATION HISTORY

- D1. a. Hand the participant **Response Card D4a**. Ask the participant if she has ever taken any of the listed medications for hepatitis (B or C). If “YES,” mark an “X” in the appropriate box(es).
- NOTE:** If the participant indicates that she has taken Epivir, Viread or Emtriva, 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 is currently taking the medication). 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**.

PROMPT: COMPLETE A DRUG FORM 3 FOR EACH MEDICATION MARKED IN QUESTION D1a.

SECTION E. OTHER PRESCRIPTION MEDICATION USE

- E1a–e: 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 (MONTH) study visit.
- E8. Hand the participant **Response Card D4h** before asking her **Question E8**. 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.

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 E2**.

- a. This question should not be read aloud to the participant. Based on the medications the participant reports taking in **Question E8**, the interviewer should record the type of hormone replacement therapy taken by the participant since her (MONTH) study visit. Be sure to specify the therapy taken

if “other HRT” was indicated in **Question E8**. If the participant reports use of both estrogen and progesterone hormone replacement therapies, record this as “combination” in **Question E8a**.

- b. Read the participant each reason listed and circle “YES” for each reason she reports that she is taking hormone replacement therapy. If she answers “other,” specify the reason where listed on the form.

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.

- E2. This question asks if the participant has taken any medication for blood pressure or her heart. Hand the participant **Response Card D4b**. If she indicates that she has taken any blood pressure or heart medications in the past six months (whether they are included on the list or not), then also ask about use in the last five days. Record use of any blood pressure or heart medications in the specify boxes provided in **Question E11a**.
- E3. 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 indicates that she has taken any cholesterol, triglyceride or blood lipid medications in the past six months (whether they are included on the list or not), then also ask about use in the last five days. Record use of any cholesterol, triglyceride or blood lipid medications in the specify boxes provided in **Question E11a**.
- E4. This question asks if the participant has taken any medication to lower her blood sugar. Hand the participant **Response Card D4d**. If she indicates that she has taken any medications to lower her blood sugar in the past six months (whether they are included on the list or not), then also ask about use in the last five days. Record use of any blood sugar medications in the specify boxes provided in **Question E11a**.
- E5. This question asks if the participant has taken any medication to treat or prevent osteoporosis. Hand the participant **Response Card D4e**. If she indicates that she has taken any osteoporosis medications in the past six months (whether they are included on the list or not), then also ask about use in the last five days. Record use of any osteoporosis medications in the specify boxes provided in **Question E11a**.
- E6. This question asks if the participant has taken any medication for seizures. Hand the participant **Response Card D4f**. If she indicates she has taken any seizure medications in the past six months (whether they are included on the list or not), then also ask about use in the last five days. Record use of any seizure medications in the specify boxes provided in **Question E11a**.
- E7. This question asks if the participant has taken any medication for psychological conditions or depression. Hand the participant **Response Card D4g**. If she indicates that she has taken any psych medications in the past six months (whether they are included on the list or not), then also ask about use in the last five days. Record use of any psychological or depression medications in the specify boxes provided in **Question E11a**.
- E9. 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 indicates that she has taken any medications for lipodystrophy or body fat changes in the past six months (whether they are included on the list or not), then also ask about use in the last five days. Record use of any HIV lipodystrophy or body fat change medications in the specify boxes provided in **Question E11a**.
- E10. Ask the participant if she has taken any other **PRESCRIBED** medications not previously mentioned since her (MONTH) study visit. If she indicates she has taken any other prescription medications in the past six months, list those medications named in the specify fields provided in **Question E11a**. 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.”

- E11. Enter the total number of prescription medications the participant reports taking in **Questions E2** through **E10**.

IF E11=0, SKIP TO SECTION F. IF E11≥1, LIST MEDICATIONS IN E11a AND COMPLETE E11b AND E11c FOR EACH LISTED MEDICATION.

PHOTOCOPY PAGE 12 AND INSERT IF PARTICIPANT REPORTS USING MORE THAN 7 OTHER PRESCRIPTION MEDICATIONS.

- b. For each medication listed in **Question E11a**, ask the participant whether she has taken it within the last five days.
- c. For each medication listed in **Question E11a**, 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.

SECTION F. ALTERNATIVE/COMPLEMENTARY MEDICATION USE

- F1. a. Hand the participant **Response Card D5**. Ensure that the participant is aware that all enzyme therapies, flower remedies, herbs, homeopathic remedies and nutritional supplements such as vitamins or minerals should be reported in this question. If the participant has not taken any complementary or alternative medications since her last study visit, skip to **Question G3**.
- b. THIS LIST IN F1b IS NOT MEANT TO BE READ TO THE PARTICIPANT. Rather, the participant should read **Response Card D5**. If the participant cannot read or has problems with her vision, read the list of therapies and treatments. For each therapy the participant indicates that she has taken (since last visit), place an "X" in the corresponding box. Once you have placed an "X" in the corresponding box, ask the participant about her frequency of use, if she is currently taking the therapy, and her main reason for taking the therapy. For the participant's main reason, hand the participant **Response Card D6** and record the number the participant indicates in the box corresponding to the therapy under question.

If the participant names a therapy that is not listed in **Question F1b**, or if she knows that she is taking a particular class of alternative therapies but does not know the exact therapies, record her response in one of the specify fields at the end of the table. If the therapy is listed on **Drug List 3**, record the appropriate three-digit drug code in the corresponding boxes. If the therapy is not listed on **Drug List 3**, record the drug code as 699 (other alternative/complementary medication).

NOTE: Beginning with visit 20, codes 503 (other nutritional supplements, unspecified) and 539 (other herbs, unspecified) have been deleted from question **F1b** and **Drug List 3**. Henceforth, all alternative/complementary therapies that can not be classified using one of the specific codes on **Drug List 3** should be listed in one of the specify boxes with drug code 699 (other alternative/complementary medication). WDMAC will periodically review all therapies listed with code 699 to determine whether a new drug code is warranted.

- c. Enter the total number of alternative/complementary medications the participant reported taking in **Question F1b**.
- G3. Record the time module ended. Circle the code for AM (code 1) or PM (code 2).