

Visit 21 Form Changes

CORE: Clinical Outcome Reporting Form (10/01/04)

1. Add question C6i: “Enter the total number of underlying cause(s) of death recorded in question C6.”
2. Add question C6ii: “Enter the total number of other significant conditions recorded in question C6.”

CV01: Carotid Ultrasound Tracking Form (10/1/04)

1. Delete field in which to record technologist ID#.

CV29: Fasting Blood Specimen Collection Form (04/02/04a)

1. Delete text from question B3 “within one hour of collection,” so question asks only if tube was centrifuged prior to sending to lab for processing. Skip question B4 if tube was not centrifuged prior before being sent to lab.
2. Delete text from question B5 “within 30 minutes of collection,” so question asks only if tube was centrifuged prior to sending to lab for processing. Skip question B6 if tube was not centrifuged prior before being sent to lab.

DRUG FORM 1: Antiretroviral Medications (10/1/04)

1. Delete option to select whether form is completed for “WIHS Core Visit” vs. “3 Month VRS Visit.” Three-month VRS visits are no longer completed.
2. Add new ART: Truvada, drug code = 253. Truvada is taken as one pill, once per day, and consists of 300 mg tenofovir plus 200 mg emtricitabine.
3. Add new ART: Epzicom, drug code = 254. Epzicom is taken as one pill, once per day, and consists of 600 mg abacavir plus 300 mg lamivudine.
4. Add three new response categories to question 1C: prescription changes by physician (7), I’m having a baby (8), resistance to other medications (9).

DRUG FORM 2: Non-antiviral Medications (10/1/04)

1. Delete option to select whether form is completed for “WIHS Core Visit” vs. “3 Month VRS Visit.” Three-month VRS visits are no longer completed.
2. Add new medication to OI prophylaxis list: 247, Vfend (voriconazole).

DRUG FORM 3: Hepatitis Medications (10/1/04)

1. Delete option to select whether form is completed for “WIHS Core Visit” vs. “3 Month VRS Visit.” Three-month VRS visits are no longer completed.
2. Add new medication: Truvada, drug code = 253. Truvada is taken as one pill, once per day, and consists of 300 mg tenofovir plus 200 mg emtricitabine.

F07: Physical Examination (10/1/04)

1. Measure height once per year only, at even-numbered visits. Add question A1b, “even-numbered visit?” If yes, measure height and record in question A1c (previously A1b). If no, skip to question A3b.
2. Delete question A2, which asked about general health/overall appearance.

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3. Revise prompt following question A6 to clarify when body measures, skinfolds and BIA should be performed post-partum.
4. Perform breast exam once per year only, at even-numbered visits. Add question D1a, “even-numbered visit?” If yes, perform breast exam and record results in questions D1b (previously D1). If no, skip to Section E.
5. Add instructions to question E1 to measure and record blood pressure three times (instead of two) using a Dinamap monitor. Additionally, require that pulse measurements (3) be recorded on F07.
6. Due to problems with the footer, the entire form had to be redone. In this process, some sections were reformatted in order to shorten the form.

F08: Gynecological Examination (10/1/04)

1. Perform rectal exam once per year only, at even-numbered visits. Add question A17a, “even-numbered visit?” If yes, perform rectal exam and record results in question A17c (new question). If no, skip to question A18.
2. Add new skip pattern to question A17b (old A17). If rectal exam not done or declined, skip to question A18.
3. Add new question A17c, results of rectal exam. If exam is abnormal, participant should be referred as appropriate to medical provider.

F22HX: Follow-up Health History (10/1/04)

1. Delete option to select whether form is completed for “WIHS Core Visit” vs. “3 Month VRS Visit.” Three-month VRS visits are no longer completed.

F22MED: Medication History (10/1/04)

1. Delete option to select whether form is completed for “WIHS Core Visit” vs. “3 Month VRS Visit.” Three-month VRS visits are no longer completed.
2. Add new ART to question B2a: Truvada, drug code = 253. Truvada is taken as one pill, once per day, and consists of 300 mg tenofovir plus 200 mg emtricitabine.
3. Add new ART to question B2a: Epzicom, drug code = 254. Epzicom is taken as one pill, once per day, and consists of 600 mg abacavir plus 300 mg lamivudine.
4. Add new question B2c: “Enter the total number of antiretroviral medications the participant reported taking in Question B2a.”
5. Add new medication to OI prophylaxis list in question C1c: 247, Vfend (voriconazole).
6. Add new question C1d: “Enter the total number of non-antiretroviral medications the participant reported taking in Questions C1a, C1b and C1c.”
7. Add new hepatitis medication to question D1a: Truvada, drug code 253.
8. Add new question D1c: “Enter the total number of hepatitis medications the participant reported taking in Question D1a.”
9. Add new question E3l, to determine use of recently approved statin medication, Crestor (rosuvastatin).

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10. Add new trade name (Fortamet) for extended release metformin to question E4g.
11. Add Menostar and Estrasorb to list of Estrogen HRT in question E8.
12. Add Norplant, Ortho Evra and NuvaRing to list of Other HRT in question E8.
13. Add note to QxQs for question E8: “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.”
14. Add new question E10d: “Enter the total number of other prescription medications the participant reported taking in Question E10.”
15. Add new question F1c: “Enter the total number of alternative/complementary medications the participant reported taking in Question F1b.”
16. Delete question F5: “In the last six months, have you eaten powdered cornstarch for your health?” This question was added for visit 20 only.
17. Delete question F5a: “On average, how often do you eat cornstarch?” This question was added for visit 20 only.
18. Delete question F5b: “When you eat cornstarch, how much do you consume?” This question was added for visit 20 only.
19. Add new question G1z: “Enter the total number of other symptoms the participant reported in Questions G1s and G1t.”

F23: Obstetric, Gynecological and Contraceptive History (10/1/04)

1. Add probe containing definition of hysterectomy to question B5: “A partial hysterectomy includes removal of the uterus, or womb, only. A total hysterectomy includes removal of the cervix in addition to the uterus or womb.”
2. Change wording of prompt after question B6 to clarify skip pattern. Prompt now reads: “If participant has had both ovaries removed (B2 = 3) or a tubal ligation (B3 = 1) or a partial or total hysterectomy (B5 = 1), skip to question B8. Otherwise, proceed to question B7.”
3. Add prompt after question B7: “If participant is currently pregnant (B7 = 1), then participant is eligible for enrollment into the Pregnancy Protocol. Please notify the proper WIHS staff at your site.”
4. Add prompt after question B8: “If participant has been pregnant since her last study visit (B8 > 0), then participant is eligible for enrollment into the Pregnancy Protocol. Please notify the proper WIHS staff at your site.”
5. Delete questions C4b (In the past 6 months, have you used an IUD for birth control?) and C4c (In the past 6 months, have you used an IUD for any other reason?).
6. Delete questions C5a (In the past 6 months, have you used Ortho Evra for birth control?) and C5b (In the past 6 months, have you used Ortho Evra for any other reason?).
7. Delete questions C6a (In the past 6 months, have you used NuvaRing for birth control?) and C6b (In the past 6 months, have you used NuvaRing for any other reason?).

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8. Delete questions C7b (In the past 6 months, have you used emergency contraception for birth control?) and C7c (In the past 6 months, have you used emergency contraception for any other reason?).
9. Delete questions C10a (In the past 6 months, have you used the rhythm method or withdrawal for birth control?) and C10b (In the past 6 months, have you used the rhythm method or withdrawal for any other reason?).
10. Delete questions E10 – E14 (Did you use (vaginal cream or suppository / a pill or oral medication / a douche / acidophyllis, yogurt or tablets / other) for your most recent yeast infection?
11. Delete questions E10a – E14a (Are you currently using this?)
12. Add new question E9c: “Have you taken any medication(s) (either by mouth or in a cream or lotion) for a vaginal yeast infection?”
13. Add new question E9d: specify field to record medication(s) taken for vaginal yeast infection.

F24: Alcohol, Drug Use and Sexual Behavior (10/1/04)

1. Add new question B7: Does your use of alcohol affect how you take your HIV medications?
2. Add new question B7a: How does your use of alcohol affect how you take your HIV medications?
3. Reorganize Section C: Drug Use per recommendations of the Drug Use WG.
4. Add questions C1b i-vi: Of the marijuana or hash that you consumed, did you use it: i. to relax or reduce stress; ii. to better appreciate a social situation; iii. to relieve HIV-related symptoms, such as nausea; iv. to increase appetite because of weight loss; v. to relieve symptoms related to eye disease, such as glaucoma; or vi. for other reasons.
5. Add questions C1c i-vi: Of the times you used marijuana or hash, how often did you use it for [the reason stated in C1b i-vi]?
6. Add question C1d: Does your use of marijuana or hash affect how you take your HIV medications?
7. Add question C1e: How does your use of marijuana or hash affect how you take your HIV medications?
8. Add question C2: Since your (MONTH) study visit, have you smoked crack?
9. Add question C2a: On average, how often have you smoked crack since your (MONTH) study visit?
10. Add question C2b: Does smoking crack affect how you take your HIV medications?
11. Add question C2c: How does smoking crack affect how you take your HIV medications?
12. Add question C3: Since your (MONTH) study visit, have you injected crack by itself?
13. Add question C3a: On average, how often have you injected crack since your (MONTH) study visit?

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14. Add question C3b: Does injecting crack affect how you take your HIV medications?
15. Add question C3c: How does injecting crack affect how you take your HIV medications?
16. Move old question C5c to C4 on new version. (“Since your (MONTH) study visit, have you sniffed or snorted cocaine?”)
17. Add question C4a: On average, how often have you sniffed or snorted cocaine since your (MONTH) study visit?
18. Add question C4b: Does sniffing or snorting cocaine affect how you take your HIV medications?
19. Add question C4c: How does sniffing or snorting cocaine affect how you take your HIV medications?
20. Add question C5: Since your (MONTH) study visit, have you injected cocaine by itself?
21. Add question C5a: On average, how often have you injected cocaine since your (MONTH) study visit?
22. Add question C5b: Does injecting cocaine affect how you take your HIV medications?
23. Add question C5c: How does injecting cocaine affect how you take your HIV medications?
24. Move old question C6c to C6 on new version. (“Since your (MONTH) study visit, have you sniffed or snorted heroin?”)
25. Add question C6a: On average, how often have you sniffed or snorted heroin since your (MONTH) study visit?
26. Add question C6b: Does sniffing or snorting heroin affect how you take your HIV medications?
27. Add question C6c: How does sniffing or snorting heroin affect how you take your HIV medications?
28. Move old question C6d to C7 on new version. (“Since your (MONTH) study visit, have you smoked heroin?”)
29. Add question C7a: On average, how often have you smoked heroin since your (MONTH) study visit?
30. Add question C7b: Does smoking heroin affect how you take your HIV medications?
31. Add question C7c: How does smoking heroin affect how you take your HIV medications?
32. Add question C8: Since your (MONTH) study visit, have you injected heroin by itself?
33. Add question C8a: On average, how often have you injected heroin since your (MONTH) study visit?
34. Add question C8b: Does injecting heroin affect how you take your HIV medications?
35. Add question C8c: How does injecting heroin affect how you take your HIV medications?

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36. Add question C9: Since your (MONTH) study visit, have you injected heroin and cocaine together?
37. Add question C9a: On average, how often have you injected heroin and cocaine together since your (MONTH) study visit?
38. Add question C9b: Does injecting heroin and cocaine together affect how you take your HIV medications?
39. Add question C9c: How does injecting cocaine and heroin together affect how you take your HIV medications?
40. Add question C10: Since your (MONTH) study visit, have you sniffed or smoked methamphetamine (crank, crystal, tina)?
41. Add question C10a: On average, how often have you sniffed or smoked methamphetamine since your (MONTH) study visit?
42. Add question C10b: Does sniffing or smoking methamphetamine affect how you take your HIV medications?
43. Add question C10c: How does sniffing or smoking methamphetamine affect how you take your HIV medications?
44. Add question C11: Since your (MONTH) study visit, have you injected methamphetamine (crank, crystal, tina) by itself?
45. Add question C11a: On average, how often have you injected methamphetamine since your (MONTH) study visit?
46. Add question C11b: Does injecting methamphetamine affect how you take your HIV medications?
47. Add question C11c: How does injecting methamphetamine affect how you take your HIV medications?
48. Move old question C2 to C12 on new version. (“Since your (MONTH) study viit, have you used methadone when it was not prescribed to you by a doctor?”)
49. Move old question C2a to C12a on new version. (“On average, how often have you used methadone when it was not prescribed to you by a doctor since your (MONTH) study visit?”)
50. Add question C12b: Does your use of methadone when it was not prescribed to you by a doctor affect how you take your HIV medications?
51. Add question C12c: How does your use of methadone when it wasn’t prescribed to you by a doctor affect how you take your HIV medications?
52. Add question C12d: Does your use of HIV medications affect how you take methadone?
53. Add question C12e: How does your use of HIV medications usually affect how you take methadone?
54. Add question C13: Since your (MONTH) study visit, have you used amphetamines (speed, uppers)?

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55. Add question C13a: On average, how often have you used amphetamines since your (MONTH) study visit?
56. Add question C13b: Does your use of amphetamines affect how you take your HIV medications?
57. Add question C13c: How does your use of amphetamines affect how you take your HIV medications?
58. Add question C14: Since your (MONTH) study visit, have you used hallucinogens (such as LSD, PCP, mushrooms, peyote)?
59. Add question C14a: On average, how often have you used hallucinogens since your (MONTH) study visit?
60. Add question C14b: Does your use of hallucinogens affect how you take your HIV medications?
61. Add question C14c: How does your use of hallucinogens affect how you take your HIV medications?
62. Add question C15: Since your (MOHTH) study visit, have you used any club drugs, such as ecstasy, ketamine or GHB?
63. Add question C15a: On average, how often have you used club drugs since your (MOHTH) study visit?
64. Add question C15b: Does your use of club drugs affect how you take your HIV medications?
65. Add question C15c: How does your use of club drugs usually affect how you take your HIV medications?
66. Add question C16: Since your (MONTH) study visit, have you used any other narcotic drugs, such as morphine, codeine, oxycodone or Demerol, that have not been prescribed by your doctor?
67. Add question C16a: On average, how often have you used narcotic drugs that have not been prescribed by your doctor since your (MONTH) study visit?
68. Add question C16b: Does your use of narcotic drugs that have not been prescribed by your doctor affect how you take your HIV medications?
69. Add question C16c: How does your use of narcotic drugs that have not been prescribed by your doctor affect how you take your HIV medications?
70. Add question C17: Since your (MONTH) study visit, have you used any tranquilizers, such as sleeping pills, barbiturates or valium, whether or not they were prescribed to you?
71. Add question C17a: On average, how often have you used tranquilizers since your (MONTH) study visit?
72. Add question C17b: Does your use of tranquilizers affect how you take your HIV medications?
73. Add question C17c: How does your use of tranquilizers usually affect how you take your HIV medications?

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74. Add question C18: INTERVIEWER, BASED ON RESPONSES TO QUESTIONS C3 (crack), C5 (cocaine), C8 (heroin), C9 (speedball) and C11 (methamphetamines), HAS PARTICIPANT INJECTED DRUGS SINCE HER (MONTH) STUDY VISIT?
75. Move old question C8f to C19 on new version. (“Since your (MONTH) study visit, what is the total number of times that you injected drugs of **any** kind?”)
76. Move old question C8a to C19a on new version. (“Were any of these times in a shooting gallery?”)
77. Move old question C8g to C20 on new version. (“Over the past **month**, what is the total number of times that you injected drugs of **any** kind?”)
78. Add question C21: Now let’s talk about reuse of injection equipment since your (MONTH) study visit. Since your (MONTH) study visit, how often have you used a needle or syringe that you are **absolutely sure** nobody else had used before you?
79. Add question C22: Since your (MONTH) study visit, how often did you use a cooker or cotton that you are **absolutely sure** nobody else had used before you?
80. Add question C23: Since your (MONTH) study visit, how often did you use rinse water that you are **absolutely sure** nobody else had used before you?
81. Add question C24: So far we’ve talked about you using equipment **after** someone else; now I’d like to ask you about using equipment **before** someone else. We will be asking about times you lent, rented or sold your equipment to someone else. Since your (MONTH) study visit, how often did someone else use a needle or syringe after you had used it?
82. Add question C25: Since your (MONTH) study visit, how often did someone else use a cooker or cotton after you had used it?
83. Add question C26: Since your (MONTH) study visit, how often did someone else use rinse water after you had used it?
84. Move old question C10 to C27 on new version and change response categories: Since your (MONTH) study visit, how often did you use bleach to clean your works?
85. Move old question C11 to C28 on new version. (“Since your (MONTH) study visit, have you participated in a needle exchange program?”)
86. Move old question C11 to C28a on new version and change response categories: Of the times you obtained needles, how often did you get them from a needle exchange?
87. Delete question C16: “We need to be certain that we have correct information about your history of injection drug use, ever in your lifetime. Did you ever, even once, use a needle or syringe after someone else had used it?” This question was added for visit 20 only.
88. Delete question C16a: “How old were you when you last used a needle or syringe after someone else had used it?” This question was added for visit 20 only.
89. Delete question C16b: “How often did you use a needle or syringe after someone else had used it?” This question was added for visit 20 only.

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F25: Health Care Utilization (10/1/04)

1. Add response category to question B3: Hospital (not emergency room).
2. Add subquestion B4g: Hospital (not emergency room).
3. Renumber old question B4g to B4h.

F29: Blood Specimen Collection Form (04/02/04a)

1. Change question number of C4a, “novel CVD assay,” to C4d. There already is a question C4a on the form.
2. Change question number of C12a, “NMR lipoprotein,” to C12d. There already is a question C12a on the form.

F29a: Drug Usage Assessment for Blood Draw (10/1/04)

1. Add new ART to question 1a: Truvada, drug code = 253. Truvada is taken as one pill, once per day, and consists of 300 mg tenofovir plus 200 mg emtricitabine.
2. Add new ART to question 1a: Epzicom, drug code = 254. Epzicom is taken as one pill, once per day, and consists of 600 mg abacavir plus 300 mg lamivudine.
1. Add question 1c: “Enter the total number of antiretroviral medications the participant reported taking in Question 1a.”

F31: Specimens Collected During the Physical Exam (10/1/04)

1. Delete question A5: Urine for LCR. WIHS has stopped collecting urine for repository storage.
2. Add response category (nape / base of neck) to question C1a.

INT: Interim Events Form

1. Protocol discontinued.

L03: Automated CBC/Differential (10/1/04)

1. Delete option to select whether form is completed for “WIHS Core Visit” vs. “3 Month VRS Visit.” Three-month VRS visits are no longer completed.

L03a: Hand/Manual Differential (10/1/04)

1. Delete option to select whether form is completed for “WIHS Core Visit” vs. “3 Month VRS Visit.” Three-month VRS visits are no longer completed.

L04: Flow Cytometry (10/1/04)

1. Delete option to select whether form is completed for “WIHS Core Visit” vs. “3 Month VRS Visit.” Three-month VRS visits are no longer completed.

MS01: Specimen Collection Form (06/11/04a)

1. Add new ART to question A4a: Truvada, drug code = 253. Truvada is taken as one pill, once per day, and consists of 300 mg tenofovir plus 200 mg emtricitabine.
2. Add new ART to question A4a: Epzicom, drug code = 254. Epzicom is taken as one pill, once per day, and consists of 600 mg abacavir plus 300 mg lamivudine.

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PK02: Current Antiretroviral Medication Use (10/1/04)

1. Add new ART to question B2: Truvada, drug code = 253. Truvada is taken as one pill, once per day, and consists of 300 mg tenofovir plus 200 mg emtricitabine.
2. Add new ART to question B2: Epzicom, drug code = 254. Epzicom is taken as one pill, once per day, and consists of 600 mg abacavir plus 300 mg lamivudine.
3. Add new question B3: “Enter the total number of antiretroviral medications the participant reported taking in Question B2.”

PK06: Dosing of Antiretroviral Medications (10/1/04)

1. Add new ART to question A6: Truvada, drug code = 253. Truvada is taken as one pill, once per day, and consists of 300 mg tenofovir plus 200 mg emtricitabine.
2. Add new ART to question A6: Epzicom, drug code = 254. Epzicom is taken as one pill, once per day, and consists of 600 mg abacavir plus 300 mg lamivudine.
1. Add new question A7: “Enter the total number of antiretroviral medications taken by the participant as indicated in Question A6.”

PR01: Pregnancy Form (10/1/04)

1. Delete question A1 (indication of who is completing form), as form will now only be completed by OB designee.
2. Delete questions A2 and A3 as these questions were completed only by clinicians.

PR02: Postpartum Form (10/1/04)

1. Delete question A1 (indication of person completing form), as form will now only be completed by OB designee.
2. Delete question A4 as it was completed only by clinicians.
3. Delete question C1, type and timing of membrane rupture.
4. Delete question C2, character of amniotic fluid.
5. Delete question C3, type and timing of labor onset.
6. Delete question C7, use of fetal scalp electrode.
7. Delete question C8, use of IUPC.
8. Delete question C9, collection of fetal scalp blood sample.
9. Change question C13 from “episiotomy” to “episiotomy or laceration.”
10. Delete question C14, extension of episiotomy or laceration of perineum.
11. Delete question C14a, specify degree of extension or laceration.
12. Delete question C15, lacerations (other).
13. Delete question C17, information on placenta delivery.
14. Delete questions C21 and C22, start and end times of Cesarean section.
15. Delete questions E3b, E3c, E3d, zidovudine usage information.

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SS01: Lab Report Form (10/01/03a)

1. Correct error in form header: change “WIHS Interagency HIV Study” to “Women’s Interagency HIV Study (WIHS).”

DRUG LIST 1 (10/01/04)

1. Add new ART: Truvada, drug code = 253. Truvada is taken as one pill, once per day, and consists of 300 mg tenofovir plus 200 mg emtricitabine.
2. Add new ART: Epzicom, drug code = 254. Epzicom is taken as one pill, once per day, and consists of 600 mg abacavir plus 300 mg lamivudine.

DRUG LIST 3 (10/01/04)

1. Add new alternative/complementary therapy: Colostrum, drug code = 653.
2. Add new alternative/complementary therapy: Tryptophan (L-Tryptophan, L-5-HTP, 5-hydroxy-tryptophan), drug code = 654.