



HPTN 052 (096)

IFU-1 (191)

Visit Code [][][] . []

1

Index ID

Index ID form: [][][] - [][][] - 00 - []

Index Follow-up Visit

Visit Date

Visit Date form: [][] dd [][][] MMM [][] yy

Instructions: Complete this form at every follow-up and interim visit.

Items 1-3 are for females only. Male participants go to item 4.

- 1. Result of pregnancy test: [] negative [] positive [] not done. If not done, specify reason: [] Not of reproductive potential [] Pregnant [] Other, specify: _____

1a. Date of last menstrual period:

1b. Estimated date of delivery:

2. Since the last visit, were any pregnancy outcomes reported?

3. Is the participant currently breast feeding? [] yes [] no

4. Since the participant's last visit,...

4a. have any previously reported Adverse Events Grade 3 or above resolved or have any new adverse events started? [] yes [] no -> Complete or update Index Adverse Event Log.

4b. have any previously reported HIV/AIDS associated events or other targeted medical conditions resolved or have any new events started? [] yes [] no -> Complete or update Index When to Start form.

4c. were any previously reported antiretrovirals stopped or modified, or were any new antiretrovirals started? [] yes [] no -> Complete or update Index Antiretroviral Treatment Log.

4d. were any other non-ART medications stopped or were any new medications started? [] yes [] no -> Complete or update Index Concomitant Medications Log.

[] [x] [] [] 16-JAN-13

Language form: [0] [1]

Language

Staff Initials / Date

Index Follow-up Visit (IFU-1)

- At the Post-ART Initiation visit, record the visit code as an interim visit. For example, if a participant began ART for the first time at visit “010.0,” and their next visit is the Post-ART Initiation visit, the visit should be coded “010.1.”

Item-specific Instructions:

- **Item 1:** Pregnancy testing may be stopped after three consecutive positive pregnancy tests. Monthly pregnancy testing must resume one month after a pregnancy outcome is reported.
- **Item 4b:** Refer to the Code Lists for HIV/AIDS-related Illnesses, WHO Stage 2 and 3 Clinical Events, and Other Targeted Medical Conditions on the Index When to Start form.



HPTN 052 (096)

IFU-2 (192)

Visit Code [][][] . []

[1]

Index ID

Site Number [][][] - Index Number [][][] - Partner 00 - Chk []

Index Follow-up Visit

5. For this visit,...

5a. NO LONGER APPLICABLE FOR THIS PROTOCOL. ~~Was a physical exam performed?~~

5b. did the participant receive HIV counseling? yes no [] []

5c. did the participant receive ART adherence counseling? [] [] []

5d. did the participant report symptoms of a sexually transmitted disease without being tested? Complete Index Symptomatic STD form.

5d1. was the participant tested for STDs? yes no [] [] Complete Index Sexually Transmitted Diseases form.

5e. was a CD4/Viral Load test performed? Complete Index CD4/Viral Load Results form.

5f. was ART dispensed or returned? If no, go to item 5g.

5f1. If yes, is this the first visit at which pills were dispensed (delay arm initiation)? If no, complete Index Pill Count and Index Treatment Adherence form.

5f2. If yes to 5f1, indicate the reason(s) for ART initiation. Mark only primary reason. Go to item 6. If yes, complete Index Pill Count, Index Complete Chemistries, and Index Complete Hematology forms.

- CD4+ <= 250 cells/mm3
AIDS-defining illness
pregnancy

5g. was this the Post-ART Initiation visit? yes no [] []

5h. were any abnormal hematology results reported?

5i. were any abnormal chemistries or LFTs reported?

6. Was this the partner seroconversion visit? yes no [] []

[] [x] [] [] 16-JAN-13

Language [0] [1]

Staff Initials / Date

Index Follow-up Visit (IFU-2)

- At the Post-ART Initiation visit, record the visit code as an interim visit. For example, if a participant began ART for the first time at visit “010.0,” and their next visit is the Post-ART Initiation visit, the visit should be coded “010.1.”

Item-specific Instructions:

- **Item 5c:** Mark “N/A” if the index is not currently receiving study medications.
- **Items 5b–5c:** HIV counseling and ART adherence counseling may be conducted as a couple or individually.
- **Item 5f1:** Mark “yes” if this is the first time study medication has been dispensed, for either the peripartum or initial regimen. Mark “yes” if a participant was previously on a peripartum regimen but switches to an initial regimen.
- **Item 5g:** The Post-ART Initiation visit occurs 2 weeks after the first time study medication is dispensed, for either the peripartum or initial regimen.
- **Item 6:** This visit is the visit at which the required procedures for partner seroconversion are completed. See Schedule of Procedures in the protocol.