



HPTN 052 (096)

IFU-1 (191)

Visit Code [][] . []

Visit Code

1

Index ID

Index Follow-up Visit [][][] - [][][] - 00 - []
Site Number Index Number Partner Chk

Visit Date

[][] [][][] [][]
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: _____

No LONGER APPLICABLE FOR THIS PROTOCOL.

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.

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 [] [] [] []

Visit Code

Index ID

Site Number [] [] [] - Index Number [] [] [] - Partner 0 0 - Chk []

Index Follow-up Visit

5. For this visit,...

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 ~~NO LONGER APPLICABLE FOR THIS PROTOCOL.~~ exam performed?

yes no

5b. did the participant receive HIV counseling? [] []

N/A (Index not on ART)

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.

- [] CD4+ ≤ 250 cells/mm³
[] AIDS-defining illness
[] pregnancy

Go to item 6.

If yes, complete Index Pill Count, Index Complete Chemistries, and Index Complete Hematology forms.

yes no

5g. was this the Post-ART Initiation visit? [] []

5h. were any abnormal hematology results reported?

5i. were any abnormal chemistries or LFTs reported?

yes no

6. Was this the partner seroconversion visit? [] []

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.