

SAMPLE. Do NOT FAX TO DATAFAX



DF Study 244 (244)

HIR-1 (479)

Participant ID

Unit ID - Protocol - Participant Number - Chk

HIV-1 Infection Report

Form Completion Date

dd MMM yy

Instructions: Complete this form when the HVTN-approved lab confirms that the participant's HIV-1 status is "infected"; or if the participant self-reports HIV-1 infection and confirmatory testing is not performed. Do not complete this form if the HVTN-approved lab reports the final HIV-1 infection status as "negative," "unknown," "indeterminate," or "final inconclusive."

1. At which visit was the HIV-1 infection reported? visit code

TD: Use the appropriate Visit Code format per study.

2. Was HIV-1 confirmatory testing performed by an HVTN-approved lab? yes no

If no, go to item 2b.

2a. What is the date of HIV-1 diagnosis by an HVTN-approved lab? dd MMM yy

Go to item 3.

2b. What is the date of HIV-1 diagnosis by self-report? dd MMM yy

3. Are there any adverse experiences (AEs) related to this HIV-1 infection? yes no

If no, go to item 4.

3a. Record AE Log Page(s) related to this HIV-1 infection:

AE Log Page # AE Log Page # AE Log Page # AE Log Page # AE Log Page #

4. Will the participant be enrolled in an HVTN HIV infection protocol? yes no don't know

Comments:

HIV-1 Infection Report (HIR-1)

Purpose: This form is used to document that a participant has become HIV-1 infected. Complete this form when the HVTN lab confirms that the participant's HIV-1 status is "infected;" or if the participant self-reports HIV-1 infection and confirmatory testing is not performed.

General Information/Instructions: Confirmatory testing must be done through an HVTN-approved HIV diagnostic lab.

Item-specific instructions:

- **Item 1:** Record either a regular or an interim visit code.
 - If the infection was confirmed by the HVTN lab, record the visit code associated with the initial diagnostic sample that prompted the "redraw."
 - If the participant self-reports a diagnosis of HIV-1 infection and confirmatory testing is not performed, record the visit code at which the infection was reported to the site.
- **Item 2a:** Date of HIV-1 diagnosis is the date when the initial diagnostic sample that prompted the "redraw" was collected. The date is provided by an HVTN-approved HIV diagnostic lab. A complete date is required. If additional testing performed retrospectively on stored samples indicates infection was earlier than this date, DO NOT UPDATE the HIV-1 diagnosis date.
 - If the participant self-reports a diagnosis date of HIV-1 infection that is earlier than the HVTN lab diagnosis date, document the self-reported date in the Comments (not in item 2b).
- **Item 2b:** If no date of diagnosis is available, record the test date.
- **Item 3:** Submit Adverse Experience Log page(s) for adverse experiences that are associated with HIV infection (e.g., acute retroviral syndrome, URI, fevers, rash, etc.) HIV-1 infection is not reportable as an adverse experience (AE). Do not report HIV-1 infection on an Adverse Experience Log or as an Expedited Adverse Experience. HIV-2 infection should be reported as an Adverse Experience.
- **Item 4:** This item does not need to be updated if the initial response changes.