

HIV-1 Infection Report CRF

HVTN Ops Day

November 16, 2009

HIV-1 Infection is not an AE

- HVTN Network Memo #47, dated August 31, 2009 was notification that HIV infections are no longer reported as Adverse Experiences (AEs) using the Adverse Experience Log.
- Sections of the memo referring to HIV infection grading and EAE reporting have been further clarified.
 - HIV-1 infections will not be graded and will not be reported as EAEs.
 - This is incorporated into the new HIV-1 infection report CRF.

HIV Infection Reporting

- HIV-1 Infections will now be reported using the new CRF HIV-1 Infection Report for studies where HIV infection is not considered an endpoint.
 - If HIV infection is an endpoint, such as HVTN 503, 504, 505, there will be no changes.
- HIV-2 infections will continue to be reported as an AE.
- The form will be distributed on a per study basis via a bulletin.
- Some studies may include detailed instructions on what to do with HIV-1 infections previously reported as AEs.

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When to complete

- This form will be completed any time a HVTN –approved diagnosis lab distributes a test result of HIV-1 infected

OR

- A participant self-reports an HIV infection identified through outside testing and HVTN lab confirmatory testing is not performed.

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When NOT to complete

- The HVTN lab reports anything other than HIV-1 infected, such as redraw, unknown, indeterminate or final inconclusive

OR

- A participant reports he/she may be HIV infected but has not been tested

OR

- HIV-2 infections

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Item 1

- Item 1 asks what visit the infection was reported at.
 - If it is an HVTN confirmed infection, the visit code is the initial sample that resulted in a redraw request.
 - If it is a self reported infection, the visit code should be when the infection was reported to the site.

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Item 2

Item 2 -2b ask about if the infection was HVTN lab confirmed and what the date of diagnosis is.

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Item 2 – HVTN Lab confirmed

- If the infection was confirmed by the HVTN lab, item 2a should be completed using the date the initial sample that prompted the redraw was collected.
 - This date should not be updated if retrospective testing indicated the infection was earlier than this date.
- If a participant had an outside test done prior to the HVTN lab test, the date of diagnosis by self report can be put in the comments.
 - It should not be documented in item 2b.

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Item 2 – Self Report

- If the infection was diagnosed through outside testing only, the date of the diagnosis should be put in item 2b.
 - If there is not a diagnosis date, the date of the test can be recorded.
- Only 2a or 2b should be completed, not both.

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Item 3

- Item 3-3a ask about any AEs associated with the HIV-1 infection.
 - AEs associated with the HIV infection could be experiences such as acute retroviral syndrome, fevers, rash, URI, etc.
 - HIV-1 infection is no longer an AE and should not be reported here.
 - HIV-2 infection would still be considered an AE.
 - It would not be reported here since it would not be associated with the HIV-1 infection

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Item 4

- Item 4 asks about enrollment into a HVTN HIV infection protocol.
 - This item should be completed with information available at the time of initial form completion. It does not need to be updated at a later date.