HPTN Critical Event Reporting Form

Instructions: This form is to be completed once an event is determined by NIH staff to qualify as a Critical Event (per DAIDS Critical Event Policy). Sites are also to follow the HPTN specific reportable protocol deviation process, if applicable.

|  |
| --- |
|  **EVENT INFORMATION** |
| **DAIDS Site Number:** | **Date event occurred:**[ddMMMyy] | **Date of site awareness that this was a CE:** [ddMMMyy] | **Form completed by:** |
| **CRS Name/ Institution Name:** |  | **Date event reported:** [ddMMMyy]**(*Must be within 3 days of awareness Monday through Friday 12 am to 11:59 PM; all holidays count as a reporting day*)** |  **First submission** **Update****Note: For updates, please attach any applicable supporting information such as IRB/EC notification and response letters.** |
| **Name of CRS Leader/ Study IoR:** |  |  |  |
|  |  | **Participant ID *(if applicable):*** |  |
| **HPTN Protocol Title (abbreviated):** |
|  **IRB/EC Reference #:***If applicable- This is the number your IRB uses to refer to your research.* |  | **Date reported to IRB/EC (if reported at time of report/update):***Note: All Critical Events must be reported to the applicable Ethics Committees as soon as possible.*  |  |

|  |
| --- |
| **Type of Critical Event (Mark all that apply):** Unanticipated Problems Serious or Continuing Noncompliance Suspension or Termination of IRB/EC Approval Suspected Research Misconduct\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**If Applicable**, supporting **Documents Attached (DO NOT send information with participant identifiers (such as name) other than PTID #):** Applicable Informed Consent Form Template Source Document Template Ethics Committee LetterCorrective and Preventative Action (CAPA) Plan Other:**Description of Event:****Action taken to respond to event (if any), including date(s) of action(s) and persons notified (include protocol team members and NIH):****Action taken to prevent future occurrence of event (if any):** |

|  |
| --- |
| **FWA Number:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_­­­­­­­­­­­­­­­­­**CRS award Number and title:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**Does the institution listed on the FWA require notification to OHRP?** **Yes** **No****If “Yes”, Has OHRP been notified?** **Yes** **No** |