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. Sites are to follow HPTN specific protocol deviation processes, if applicable.

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| **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 ofCRS 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.* |  |

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| **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):** |

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| **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** |