**Instructions**: Sites may use this optional MTN Critical Event (CE) Reporting Form to facilitate communication with their OCSO representative on determination of a critical event and to report critical events directly to DAIDS and to their local IRB/IEC, as desired. Upon initial identification of a possible critical event, site staff should complete **Sections I** and **II** of this form and submit to their assigned OCSO Program Officer (PO). **Section I** should include institution and study information. S**ection II** should provide a brief description of the event. The OCSO PO will review and return the form with a determination.

If determined to be a CE, site staff should complete **Section III** within three reporting days (Monday-Friday; beginning 12:00 AM [midnight] and ending at 11:59 PM local time) following receipt of acknowledgement from the OCSO PO. **Section III** should include the classification under which the CE falls per the CE Manual, and a detailed description of the event, including noting and/or attaching any available information to support the report (e.g., template informed consent form(s), IRB/EC approval letter, copies of applicable source documents, etc.) Site staff should also summarize the planned corrective and preventive actions (CAPAs) to be taken and return the completed form to their OCSO PO. The OCSO PO will review the CAPA to determine if additional corrective actions need to be taken. Once the proposed CAPA is finalized in consultation with the OCSO PO, the plan should be implemented. The completed CE Reporting Form should be signed/dated by the site IoR and filed, along with all supporting documentation, in study essential document files. The site IoR is ultimately responsible for ensuring the CAPA is implemented and the CE is reported to the local IRB/EC and other institutional officials per its institutional policy.

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| --- | --- | --- | --- | --- |
| **Section I: SITE INFORMATION** | | | | |
| **CRS Name/ Institution Name:** |  | **DAIDS Site Number:** | |  |
| **Name of IoR:** |  | **Form completed by:** | |  |
| **MTN Protocol Title:** |  | | | |
| **IRB/EC Reference #:** |  | | | |
| **Participant ID(s) *(if applicable):*** |  | | | |
| **Section II: CRITICAL EVENT DETERMINATION** | | | | |
| **Date event occurred:** |  | **Date of site awareness:** |  | |
| **Event Summary:**  *Click or tap here to enter text.* | | | | |

|  |  |  |  |
| --- | --- | --- | --- |
| **Office of Clinical Site Oversight (OCSO) USE ONLY**  ***(must be completed by assigned OCSO PO)***  **Was this determined to be a critical event per DAIDS policy?**  **YES *(If YES, site to complete section III)***  **NO (*If NO, end of form*)** | | | |
| **Determination made by:**  ***(OCSO PO Name)*** | *Click or tap here to enter text.* | **Date CE confirmed:** |  |

|  |  |  |  |
| --- | --- | --- | --- |
| **Section III: EVENT INFORMATION** | | | |
| **Date event reported:** |  | **Date reported to IRB/EC:** |  |
| **First submission**  **Update**  *Note: For updates, please attach any applicable supporting information such as IRB/EC notification and response memos/letters* | | | |
| **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, attached supporting documents (DO NOT send information with participant identifiers (such as name) other than PTID):***  Applicable Informed Consent Form Template  Source Document Template  Ethics Committee Letter  Other (list): *Click or tap here to enter text.* | | | |
| **Description of Event:**  *Click or tap here to enter text.* | | | |
| **Corrective action taken to respond to event (if any), including date(s) of action(s) and persons notified (include protocol team members and NIH):**  *Click or tap here to enter text.* | | | |
| **Preventative action taken to avoid future occurrence of event (if any):**  *Click or tap here to enter text.* | | | |

**Signature** *(to be completed once critical event report is finalized in agreement with OCSO Program Officer).*

Investigator of Record (printed name): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Investigator of Record (signature): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

***References:***

***DAIDS*** [***Critical Events Manual***](https://www.niaid.nih.gov/sites/default/files/criticaleventsmanual.pdf)

* ***[Appendix 1- Examples of Critical Events](https://www.niaid.nih.gov/sites/default/files/ceappendix1.pdf" \t "_blank)***
* [***Appendix 2- Determining Which Adverse Events are Unanticipated Problems***](https://www.niaid.nih.gov/sites/default/files/ceappendix2.pdf)
* ***[Appendix 3- Examples of Corrective Actions](https://www.niaid.nih.gov/sites/default/files/ceappendix3.pdf" \t "_blank)***
* ***[Appendix 4- Reporting Critical Events to DAIDS](https://www.niaid.nih.gov/sites/default/files/ceappendix4.pdf" \t "_blank)***

***DAIDS Critical Event Policy:*** [***Identification and Classification of Critical Events: Site Responsibilities***](https://www.niaid.nih.gov/sites/default/files/cesiteresp.pdf)

[***Microbicide Trials Network (MTN) Manual of Operational Procedures (MOP); Protocol Deviation Policy***](https://mtnstopshiv.org/sites/default/files/16_mtn_mop_study_oversight_2018_final_6.28.2018.pdf)