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| --- | --- | --- | --- | --- |
| SITE AND PARTIPANT INFORMATION | | | | |
| Site Name: |  | | **Query Date:** |  |
| Staff Name: |  | | **Staff Email Address:** |  |
| Participant ID: |  | | **Participant Age:** |  |
| Enrollment Date: |  | |  |  |
| REASON FOR QUERY | | | | |
| Request for consultation on clinical/laboratory evaluations related to eligibility determination | | | | |
| Request for consultation on clinical/laboratory evaluations related to study product management  Should study product be continued?  Should study product be permanently discontinued? | | | | |
| Request for consultation on AE management  Yes. Complete Section A  No. Skip to Narrative Summary | | | | |
| Other: Please Describe | | | | |
| ADVERSE EVENT (AE) INFORMATION: SECTION A | | | | |
| Primary AE of Concern: | |  | | |
| Onset Date: | |  | | |
| Severity Grade at Onset: | | Grade 1 Mild  Grade 2 Moderate  Grade 3 Severe  Grade 4 Potentially Life-Threatening  Grade 5 Death | | |
| Relatedness to Study Product: | | Related  Not Related | | |
| Relatedness to Study Procedure: | | Yes. Record etiology or explanation in the Narrative Summary section.  No | | |
| Current Study Product Administration: | | Not Applicable  Continuing  Permanently Discontinued, as of ( DD-MMM-YY) | | |
| Has this AE been reported to SCHARP  (using an AE Log CRF)? | | Yes  No | | |
| Has this AE been reported as an SAE/EAE? | | Yes  No | | |

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| NARRATIVE SUMMARY |
| *In the space provided below, please note as much detail as possible regarding the participants’ condition. Provide the participants’ gender and describe the sequence of the signs and/or symptoms, whether the event is a reoccurrence or has been evaluated previously (if so, indicate the date and status of the most recent evaluation) and any additional relevant past medical history, diagnosis, intervention and/or treatment, relevant lab tests and results and current status of participant.*  *Proposed course of action:* |

End of Form for Site Staff. Email completed form to the MTN-026 Protocol Safety Physicians [mtn026safetymd@mtnstopshiv.org](mailto:mtn026safetymd@mtnstopshiv.org). If an email response is not received from the PSRT within 3 business days, re-contact the Protocol Safety Physicians, copying the following distribution list ([mtn026mgmt@mtnstopshiv.org](mailto:mtn026mgmt@mtnstopshiv.org)) for assistance.

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| --- | --- |
| PSRT USE ONLY | |
| PSRT Responding Member Name: |  |
| PSRT Response Date: |  |
| PSRT Comments: | |
| Query Outcome  Not Applicable  Approved  Not Approved | |