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| **SITE AND PARTIPANT INFORMATION** | | | | | |
| Site Name: |  | | Query Date: | |  |
| Staff Name: |  | | Staff Email Address: | |  |
| PTID: |  | | Participant Age: | |  |
| **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 | | | | | |
| Request for consultation on AE management  Yes. Complete Section A and B, as appropriate  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 on a SCHARP AE Log form? | | | | Yes  No | |
| Has this AE been reported as an SAE/EAE? | | | | Yes  No | |
| Has this AE been evaluated more than once? | | | | Yes. Complete Section B  No. Skip to Narrative Summary | |
| **ADVERSE EVENT (AE) RE-ASSESSMENT INFORMATION: SECTION B** | | | | | |
| Date of Most Recent Evaluation: | |  | | | |
| Status of AE at Most Recent Evaluation: | | Continuing, stabilized (severity grade unchanged)  Continuing, improving → severity grade decreased to:  Continuing, worsening → severity grade increased to:  Resolved | | | |
| **NARRATIVE SUMMARY** | | | | | |
| *Describe the sequence of the signs and/or symptoms, relevant past medical history, diagnosis, intervention and/or treatment, relevant lab tests and results and status of participant:* | | | | | |
| *Proposed course of action:* | | | | | |

End of Form for Site Staff. Email completed form to the MTN-030/IPM 041 Protocol Safety Physicians [mtn030safetymd@mtnstopshiv.org](mailto:mtn030safetymd@mtnstopshiv.org) If an email response is not received from the PSRT within 3 business days, re-contact the Protocol Safety Physicians, copying the MTN-030 Management Team ([mtn030mgmt@mtnstopshiv.org](mailto:mtn030mgmt@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 | |