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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. 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) 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 |