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| **SITE AND PARTIPANT INFORMATION** | | | |
| Site Name: |  | Query Date: |  |
| Staff Name: |  | Staff Email Address: |  |
| Participant ID: |  | Participant Age: |  |
| Enrollment Date: |  |  |  |

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| **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 temporarily held?  Should study product be permanently discontinued?  Should study product be resumed? |
| Request for consultation on AE management  Yes. Complete Section A and B, as appropriate  No. Skip to Narrative Summary |
| Other: Please Describe |

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| **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  Temporarily Held, as of (DD-MMM-YY)  Permanently Discontinued, as of (DD-MMM-YY) |
| Has this AE been reported on the EDC AE Log form? | Yes  No |
| Has this AE been reported as an SAE? | Yes  No |
| Has this AE been evaluated more than once? | Yes. Complete Section B  No. Skip to Narrative Summary |

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| **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 |

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| **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 current status of participant:* |
| *Proposed course of action:* |

End of Form for Site Staff. Email completed form to the MTN-044 Protocol Safety Physicians [mtn044safetymd@mtnstopshiv.org](mailto:mtn044safetymd@mtnstopshiv.org). In case of an emergency, contact Dr. Jill Long at [jill.long@nih.gov](mailto:jill.long@nih.gov).

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