|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| SITE AND PARTIPANT INFORMATION | | | | |
| Site Name: |  | | **Query Date:** |  |
| Staff Name: |  | | **Staff Email Address:** |  |
| Participant ID: |  | | **Participant Age:** |  |
| Enrollment Date: |  | | **Sequence:** |  |
| 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 use continue?  Should study product be temporarily held?  Should study product be resumed?  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 | | |
| Current Study Product Regimen | | Rectal Insert  Rectal Douche  Rectal Suppository | | |
| Relatedness to Study Product: | | Related  Not Related | | |
| Relatedness to Study Procedure: | | Yes. Record explanation in the Narrative Summary section.  No. Record etiology or explanation in the Narrative Summary section. | | |
| Current Study Product Administration: | | Not Applicable  Temporarily Held, as of DD/MM/YY.  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? | | Yes  No | | |
| Has this AE been evaluated more than once? | | Yes  No | | |
| Date of Most Recent Evaluation: | |  | | |
| Status of AE at Most Recent Evaluation: | | Continuing, stabilized (severity grade unchanged)  Continuing, improving → severity grade decreased to: Enter Grade.  Continuing, worsening → severity grade increased to: Enter Grade.  Resolved | | |
| NARRATIVE SUMMARY | | | | |
| *In the space provided below, please note as much detail as possible regarding the participants’ condition. Provide the participants’ gender, genital anatomy, describe the sequence of the signs and/or symptoms, 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-035 Protocol Safety Physicians [mtn035safetymd@mtnstopshiv.org](mailto:mtn035safetymd@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 ([mtn035mgmt@mtnstopshiv.org](mailto:mtn035mgmt@mtnstopshiv.org)) for assistance.

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