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|  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. 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) 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 |