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| **SITE AND PARTIPANT INFORMATION** |
| Site Name: |  | Query Date: | DD/MM/YY. |
| Staff Name: |  | Staff Email Address: |  |
| Participant ID: |  | Participant Age: |  |

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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: Click or tap here to enter text. |
| *Study product in use by participant:* ☐ Tenofovir VR ☐ Placebo VR 🡪 Date inserted: DD/MM/YY.☐ N/A, prior to any study product use |

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| **SECTION A: ADVERSE EVENT (AE) INFORMATION** |
| Primary AE of Concern: |  |
| Onset Date: | DD/MM/YY. |
| 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/MM/YY.[ ]  Permanently Discontinued, as of DD/MM/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 [ ]  No. Skip to Narrative Summary |
| **SECTION B: ADVERSE EVENT (AE) RE-ASSESSMENT INFORMATION** |
| Date of Most Recent Evaluation: | DD/MM/YY. |
| 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 |

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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:* |
| Click or tap here to enter text. |
| *Proposed course of action:* |
| Click or tap here to enter text. |

**END OF FORM FOR SITE STAFF.**

Email completed form to the MTN-038 Protocol Safety Physicians mtn038safetymd@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-038 Management Team distribution list (mtn038mgmt@mtnstopshiv.org) for assistance.

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| **PSRT USE ONLY** |
| PSRT Responding Member Name:  |  |
| PSRT Response Date: |  |
| PSRT Comments: |
| Click or tap here to enter text. |