MTN-041 PTID: 4 1 ☐☐☐☐

PD#: ☐☐

Date of Form Completion: ☐☐ dd ☐☐☐ MMM ☐☐ yy

Protocol Deviation Report (PD)

Instructions: Complete this form each time a protocol deviation is identified. Consult the MTN Regulatory Team (mtnregulatory@mtnstopshiv.org) and the MTN-041 Management Team (mtn041mgmt@mtnstopshiv.org) if you are unsure if an event should be reported as a deviation.

1.	Site awareness date	☐☐ dd ☐☐☐ MMM ☐☐ yy
2.	Deviation date	☐☐ dd ☐☐☐ MMM ☐☐ yy
3.	Has or will this deviation be/en reported to the local IRB/EC?	☐1 Yes ☐2 No
4.	Has or will this deviation be/en reported to DAIDS as a critical event?	☐1 Yes ☐2 No
5.	Type of deviation *(See back of form for code listing)*	☐☐ deviation code
6.	Description of deviation	_____ _____ _____ _____ _____
7.	Plans and/or action(s) taken to address the deviation	_____ _____ _____ _____ _____
8.	Plans and/or action(s) taken to prevent future occurrences of the deviation	_____ _____ _____ _____ _____

_____
Staff Initials / Date

Protocol Deviation Report (PD) Instructions

Purpose: This form is used to document and report protocol deviations identified for study participants.

Overall instructions: Enter the PTID in the top left corner of this form and initial and date the bottom right corner of the page. The date the form is completed (not the date of the deviation) should be completed at the top of the page, as well as the deviation number. The PD number should be assigned sequentially for each individual PTID. Any information recorded or modified on this form after the original date of completion should be initialed and dated, per GCP.

Item-specific Instructions:

Item	Instruction
1	Record the date the site became aware of the deviation. If consultation with study management is required regarding PD determination, site awareness date is the date the team is notified the event constitutes a PD.
2	Record the date the deviation occurred (start date).
5	Record the two-digit category code that best describes the type of deviation. Use "99" (other) if none of the listed categories match.
6	Briefly describe the specific details of the deviation.

Code	Description
01	**Inappropriate enrollment:** The participant enrolled and not all eligibility requirements were met.
08	**Conduct of non-protocol procedure:** A clinical or administrative procedure was performed that was not specified in the protocol, and was not covered under local standard of care practice.
10	**Unreported UE/SH:** Site staff become aware of an UE/SH, but do not report it per protocol requirements.
12	**Breach of confidentiality:** Include potential and actual cases where participant confidentiality is breached. For example, a staff member puts a participant's name on a case report form.
16	**Staff performing duties that they are not qualified to perform:** Use for any instance when any study procedure, including clinical and administrative procedures, is completed by a staff member who is not adequately qualified AND delegated to perform the procedure.
17	**Questionnaire administration deviation:** A required questionnaire was not completed according to protocol requirements. Include instances where the wrong questionnaire was completed.
18	**Counseling deviation:** Protocol-required counseling was not done and/or not documented correctly.
19	**Use of non-IRB/EC-approved materials:** Include use of ANY study-related material that requires IRB or EC approval for use per site requirements.
21	**Informed consent process deviation:** Examples include failure to accurately execute and/or document any part of the informed consent process.
99	**Other**