MTN-045: Protocol Deviation Report							
Site	❒ **MUJHU** ❒ **UZCHS**		**Female PTID**	☐ ☐☐☐☐		**Male PTID**	☐ ☐☐☐☐
PD #		**Staff Initials**		**Date form completed (DD/MMM/YYYY):**	☐☐/☐☐☐/☐☐☐☐		

Protocol Deviation (PD) Report		
Instructions: Complete this form each time a protocol deviation is identified. Consult the MTN-045 CUPID Protocol Team if you are unsure if an event requires reporting as a deviation.		
1.	Site awareness date	☐☐ ☐☐☐ ☐☐ dd MMM yy
2.	Deviation date	☐☐ ☐☐☐ ☐☐ dd MMM yy
3.	Has or will this deviation be reported to local IRB/EC?	☐$_1$ Yes ☐$_0$ No
4.	Type of deviation *(See back of form for code listing)*	☐☐ deviation code
5.	Description of deviation:	_____ _____ _____ _____ _____
6.	Plans and/or action taken to address the deviation	_____ _____ _____ _____ _____
7.	Plans and/or action taken to prevent future occurrences of the deviation	_____ _____ _____ _____ _____

Protocol Deviation Report (PD) Instructions

Purpose: This form documents and reports protocol deviations identified during the MTN-045study.

General Information/Instructions: Complete this form each time a protocol deviation is identified. Consult the MTN-045 protocol team if you are unsure if an event requires reporting as a deviation. Refer to the SSP for submission deadlines and procedures.

Overall instructions:

- At the top of this form, tick the box for the site where the PD occurred, enter the involved PTID(s), PD number, the initials of the staff member completing the form, and the date the form is completed (not the date of the deviation).
    - If the protocol deviation is identified for only one member of the couple, enter their PTID in the correct PTID field and leave the other PTID field blank.
    - If the PD is not related to a specific PTID, leave both PTID fields blank
- The PD numbers should be assigned sequentially at each site over the course of the study.
- 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 site became aware of the event.
2	Record the date the event occurred (start date).
3	Record whether this deviation has or will be reported to local IRB/EC.
4	Record the two-digit category code that best describes the type of deviation. Use "88" (other) if none of the listed categories match. Describe the specifics of the deviation in item 6
5	Briefly describe the deviation.
6	Briefly describe the specific details on actions taken to address the deviation.
7	Briefly describe the specific details on actions taken to prevent future occurrences of the deviation.

Code	Description
01	**Inappropriate enrollment:** The participant enrolled and not all eligibility requirements were met.
02	**Conduct of non-protocol procedure:** An administrative procedure was performed that was not specified in the protocol, and was not covered under local standard of care practice.
03	**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.
04	**Staff performing duties that they are not qualified to perform:** Use for any instance when any study procedure, including administrative procedures, is completed by a staff member who is not adequately qualified AND delegated to perform the procedure.
05	**Questionnaire administration deviation:** A required questionnaire was not completed according to protocol requirements. Include instances where the wrong questionnaire was completed.
06	**Counseling deviation:** Protocol-required counseling was not done and/or not documented correctly.
07	**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; also include use of documents after expiry period.
08	**Informed consent process deviation:** Examples include failure to accurately execute and/or document any part of the informed consent process.
88	**Other**