



Note: Number pages sequentially (01, 02, 03) for each participant.

Page

Participant ID

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Site Number Participant Number Chk

Protocol Deviation Log

Form Completion Date

dd MMM yy

1. Site awareness date:	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>
2. Deviation date:	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>
3. Has or will this deviation be reported to local IRB/EC?	<input type="checkbox"/> <i>yes</i> <input type="checkbox"/> <i>no</i>
4. Has or will this deviation be reported to DAIDS as a critical event?	<input type="checkbox"/> <i>yes</i> <input type="checkbox"/> <i>no</i>
5. Type of deviation:	<input type="text"/> <input type="text"/> <i>deviation code (See back of form for code listing.)</i>
6. Description of deviation:	<hr/> <hr/>
7. Plans and/or action taken to address the deviation:	<hr/> <hr/>
8. Plans and/or action taken to prevent future occurrences of the deviation:	<hr/> <hr/>
9. Deviation reported by:	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <i>staff code</i>

## Protocol Deviation Log (PDL-1)

**Purpose:** This form documents and reports protocol deviations identified for study participants.

### General Information/Instructions:

Complete this form each time a protocol deviation is identified. Consult the MTN Regulatory Team (mtnregulatory@mtnstophiv.org) and the Study Management Team if you are unsure if an event requires reporting as a deviation.

### Item-specific Instructions:

**Page:** Number pages sequentially for each participant, starting with 01. Do not re-assign page numbers if a form is marked for deletion.

**Item 2:** Record the date the event occurred (start date).

**Item 5:** Record the two-digit category code that best describes the type of deviation. Use "99" (other) if none of the listed categories match. Describe the specifics of the deviation in item 6.

**Item 6:** Briefly describe the specific details of the deviation.

**Item 9:** Record staff code of the site staff person who completed the form. Sites will need to assign a four-digit staff code to each site staff person who will be completing this form. This list is created, maintained, and kept at the study site.

Code	Description	Code	Description
01	<b>Inappropriate enrollment:</b> The participant enrolled and not all eligibility requirements were met.	14	<b>Lab assessment deviation:</b> Include missed, or incomplete lab specimen collection.
02	<b>Failure to follow trial randomization or blinding procedures:</b> Include instances where randomization procedures were not followed by site staff, or product blinding procedures were not followed by pharmacy staff.	15	<b>Mishandled lab specimen:</b> Include errors in the labeling, physical handling, processing, testing, storage, or shipment of collected lab specimens.
08	<b>Conduct of non-protocol procedure:</b> A clinical or administrative procedure was performed that was not specified in the protocol, and was not covered under local standard of care practice.	16	<b>Staff performing duties that they are not qualified to perform:</b> 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.
09	<b>Improper AE/EAE follow-up:</b> Use when an AE or EAE is not followed per protocol. For example, a clinical finding/lab result is not re-assessed as outlined in the protocol.	17	<b>Questionnaire administration deviation:</b> A required questionnaire was not completed according to protocol requirements. Include instances where the wrong questionnaire was completed.
10	<b>Unreported AE:</b> Site staff become aware of an AE, but do not report it per protocol requirements.	18	<b>Counseling deviation:</b> Protocol-required counseling was not done and/or not documented correctly.
11	<b>Unreported EAE:</b> Site staff become aware of an EAE, but do not report it per protocol and DAIDS EAE Manual requirements.	21	<b>Informed consent process deviation:</b> Examples include failure to accurately execute and/or document any part of the informed consent process.
12	<b>Breach of confidentiality:</b> 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.	22	<b>Visit completed outside of window:</b> Use when visit procedures for a visit are done within the wrong window or not in a designated visit window. For example, use if Visit 3.0 procedures are done in the Visit 4.0 window.
13	<b>Physical assessment deviation:</b> Include missed or incomplete physical/pelvic/rectal exam assessments.	99	<b>Other</b>