MTN-035/DESIRE Operational Guidance #01: SAE Reporting Requirements

MTN-035 is a non-IND study and therefore, there is no requirement to report serious adverse events (SAEs) expediently to the Division of AIDS (DAIDS) via the DAIDS Adverse Experience Reporting System (DAERS) mechanism. The purpose of this Operational Guidance document is to outline the process for reporting serious adverse events (SAEs) in MTN-035/DESIRE.

In the event an SAE occurs, sites should notify the Protocol Safety Review Team (PSRT). A PSRT query form, marked "Other: SAE Notification" should be completed and submitted to the MTN-035 Protocol Safety Physicians (mtn035safetymd@mtnstopshiv.org) as soon as the site becomes aware of the SAE.

Sites should also report the SAE to their local regulatory authorities (IRBs/ECs) in accordance with local guidelines and polices. If Immediate IRB/EC reporting is required, a copy of the IRB/EC report should be submitted along with PSRT notification. If notification to the local IRB/EC is not immediately made, a copy of the IRB report should be submitted to the PSRT for their information when available; initial notification to the PSRT should not be delayed.

As always, clinical management of study product should follow guidance in Protocol Section 9.4 and SSP Manual Section 8 (Adverse Event Reporting and Safety Monitoring).

All Operational Guidance documents must be printed and filed with regulatory documentation.

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