[The text in brackets (also highlighted in yellow) is intended to provide instructions or text options for the user. Make the appropriate selection of text, and delete the instructions prior to placement of this section in the protocol.]

# X.0 EXPEDITED ADVERSE EVENT (EAE) REPORTING

X.1 EAE Reporting to DAIDS

Requirements, definitions and methods for expedited reporting of adverse events are outlined in Version 2.0 of the DAIDS EAE Manual, which is available on the DAIDS RSC website at <https://rsc.niaid.nih.gov/clinical-research-sites/manual-expedited-reporting-adverse-events-daids>.

[If the manual of operations (MOP) contains a copy of the current DAIDS EAE Manual, note here.]

The DAIDS Adverse Experience Reporting System (DAERS), an internet-based reporting system, must be used for EAE reporting to DAIDS. In the event of system outages or technical difficulties, EAEs may be submitted using the DAIDS EAE Form. This form is available on the DAIDS RSC website at <https://rsc.niaid.nih.gov/clinical-research-sites/paper-eae-reporting>.

For questions about DAERS, please contact NIAID CRMS Support at CRMSSupport@niaid.nih.gov. Please note that site queries may also be sent from within the DAERS application itself.

For questions about expedited reporting, please contact the DAIDS RSC Safety Office at (DAIDSRSCSafetyOffice@tech-res.com).

X.2 EAE Reporting Requirements for the Study

[The protocol document must include the information listed below.]

* The [SAE or SUSAR] Reporting Category, as defined in Version 2.0 of the DAIDS EAE Manual, will be used for this study.
* The study products for which expedited reporting are required are: [Insert generic or non-proprietary names of study products here. Note that all placebos/controls administered as study products must be listed, and only products listed in this section will have expedited reporting. For example, “The study products for which expedited reporting are required are abacavir/lamivudine and placebo for abacavir/lamivudine."].

[In this section, clarify if an abbreviation is used. For example: zidovudine (zdv) or VRC hivadv014-00-vp (vrcrad5)].

* In addition to the [SAE or SUSAR] Reporting Category identified above, other adverse events that must be reported in an expedited manner are:[Insert additional AEs here. For example, “all cancers,” “all myopericarditis events,” “all hepatic failures,” “all autoimmune diseases,” etc.].

X.3 Grading Severity of EAEs

[Specify that the most current Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events (DAIDS AE Grading Table) is used and is available on the DAIDS RSC website at <https://rsc.niaid.nih.gov/clinical-research-sites/daids-adverse-event-grading-tables>.]

[If the study MOP contains a copy of the current DAIDS AE Grading Table, note here.]

[Protocol teams which have developed protocol-specific EAE grading criteria not found in the DAIDS AE Grading Table should define those additional or modified parameter(s) here or in an appendix noted here. For example, “non-fasting lipid levels will be graded according to the values for fasting triglycerides provided in this protocol.”]

X.4 EAE Reporting Period

* The EAE reporting period for this study is [insert reporting period here. For example, “as per the DAIDS EAE Manual.” If additional reporting is required beyond that specified in the DAIDS EAE Manual, then state the additional reporting period, the (SAE or SUSAR) reporting category and the study products (using generic/non-proprietary names)].
* After the protocol-defined EAE reporting period, unless otherwise noted, only SUSARs as defined in Version 2.0 of the DAIDS EAE Manual will be reported to DAIDS if the study staff become aware of the events on a passive basis (from publicly available information).