The following information impacts the P1071 study and must be forwarded to your institutional review board (IRB)/ethics committee (EC) as soon as possible for their information and review. This must be approved by your IRB/EC before implementation.

The following information may also impact the sample informed consent. Your IRB/EC will be responsible for determining the process of informing subjects of the contents of this letter of amendment (LOA).

Upon receiving final IRB/EC and any other applicable regulatory entity (RE) approval(s) for this LOA, sites are required to submit an LOA registration packet to the DAIDS Protocol Registration Office (DAIDS PRO) at the Regulatory Compliance Center (RCC). Sites will receive a registration notification for the LOA once the DAIDS PRO verifies that all the required LOA registration documents have been received and are complete. Sites will not be able to implement this LOA until they have received an LOA registration notification from the DAIDS PRO. A copy of the DAIDS PRO LOA registration notification along with this letter and any IRB/EC correspondence should be retained in the site's regulatory files.

The purpose of this LOA is to incorporate use of Version 2.0 of the Manual for Expedited Reporting of Adverse Events to DAIDS (DAIDS EAE Manual) for subjects continuing follow-up after June 1, 2011, which is the final date for DAIDS support of Version 1.0 of the DAIDS EAE Manual. The following is updated language from DAIDS and will replace 7.0, Expedited Adverse Event Reporting section of P1071, Version 2.0, dated 6/5/09.

7.0 EXPEDITED ADVERSE EVENT REPORTING

7.1 Adverse Event Reporting to DAIDS

Requirements, definitions and methods for expedited reporting of Adverse Events (AEs) are outlined in Version 2.0 of the DAIDS EAE Manual, which is available on the RSC website at http://rsc.tech-res.com/safetyandpharmacovigilance/.

The DAIDS Adverse Experience Reporting System (DAERS), an internet-based reporting system must be used for expedited AE reporting to DAIDS. In the event of system outages or technical difficulties, expedited AEs may be submitted via the DAIDS EAE Form. For questions about DAERS, please contact DAIDS-ES at
DAIDS-ESSupport@niaid.nih.gov. Site queries may also be sent from within the DAERS application itself.

Where DAERS has not been implemented, sites will submit expedited AEs by documenting the information on the current DAIDS EAE Form. This form is available on the RSC website: http://rsc.tech-res.com/safetyandpharmacovigilance/. For questions about EAE reporting, please contact the RSC (DAIDS RSCSafetyOffice@tech-res.com).

7.2 Reporting Requirements for this Study

The SAE EAE Reporting Category, as defined in Version 2.0 of the DAIDS EAE Manual, will be used for this study.

The study agent for which expedited reporting is required is vicriviroc.

7.3 Grading Severity of Events

The most current Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events (DAIDS AE Grading Table), Version 1.0, December 2004, Clarification August 2009, must be used and is available on the RSC website at http://rsc.tech-res.com/safetyandpharmacovigilance/.

7.4 Expedited AE Reporting Period

The protocol-defined expedited event reporting period for this protocol is the entire study duration for an individual subject (from study enrollment until study completion or discontinuation of the subject from study participation for any reason) and for a period of 5 years after initiation of Stage II, if the subject continues on study drug.

After the protocol-defined AE reporting period, unless otherwise noted, only SUSARs as defined in Version 2.0 of the EAE Manual will be reported to DAIDS if the study staff become aware of the events on a passive basis (from publicly available information).

The above information will be incorporated into the next version of the protocol at a later time if it is amended.