DATE: March 29, 2011

RE: LETTER OF AMENDMENT #2 FOR P1085, Version 1.0, dated 05/05/10

“Duration of Human Papilloma Virus (HPV) Type-Specific Antibody after Administration of Quadrivalent HPV Vaccine to HIV-1 Infected Children Previously Enrolled in IMPAACT P1047”

DAIDS ES# 10826

TO: IMPAACT Principal Investigators and Study Coordinators at Sites Participating in IMPAACT P1085

FROM: IMPAACT P1085 Protocol Team

THE FOLLOWING INFORMATION IMPACTS THE P1085 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.

UPON RECEIVING FINAL IRB/EC AND ANY OTHER APPLICABLE REGULATORY ENTITY (RE) APPROVAL(S) FOR THIS LoA, SITES SHOULD IMPLEMENT THE LoA IMMEDIATELY. SITES ARE STILL REQUIRED TO SUBMIT A LoA REGISTRATION PACKET TO THE DAIDS PROTOCOL REGISTRATION OFFICE (PRO) AT THE REGULATORY SUPPORT CENTER (RSC). 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. A LoA REGISTRATION NOTIFICATION FROM THE DAIDS PRO IS NOT REQUIRED PRIOR TO IMPLEMENTING THE LoA. A COPY OF THE LoA REGISTRATION NOTIFICATION ALONG WITH THIS LETTER AND ANY IRB/EC CORRESPONDENCE SHOULD BE RETAINED IN THE SITE’S REGULATORY FILES.

This Letter of Amendment can be obtained from the P1085 protocol specific web page (http://www.impaactgroup.org/). The document is located under the section titled “Current Protocol Related Documents”.

1. Exclusion criterion 4.23 has been changed. The text below in bold has been added.

Receipit of an additional dose of Merck HPV vaccine other than that administered for the P1047 study. NOTE: An inadvertent 4th dose of HPV prior to enrollment to P1085, or receipt of the 4th dose that is not from the investigational lot provided for this dose, does not automatically exclude enrollment into P1085. Rather the circumstances involved should be discussed with the Protocol Chair (actg.teamp1085@strf.org) and a determination will be made by the team as to the value of future samples from such subjects and ultimately whether the subject may still be enrolled in the P1085 study.

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