DATE: August 16th, 2010

RE: LETTER OF AMENDMENT #1 FOR P1085, Version 1.0, dated May 5, 2010

“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, Version 1.0 dated May 5, 2010 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.

1. Inclusion criterion 4.14 has been changed to: “Subjects should be between 1.5 and 2.5 years following their last HPV vaccination.

2. Appendix I – Schedule of Evaluations: The window for the 2 year visit has been changed from +/- 8 weeks to +/- 24 weeks, in order to better accommodate subjects quarterly clinic visits.

3. The title page of the protocol should state: “A Multi-Center, Domestic Trial of the International Maternal Pediatric Adolescent AIDS Clinical Trials Group (IMPAACT)”

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