DATE: July 8, 2013

RE: LETTER OF AMENDMENT #3 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”.

The purpose of this letter of amendment is to inform the sites that the study is closing to follow up on August 30th, 2013. The study team would like to request that all participants of the study come in for a final “Year 5” visit, as per the Schedule of Evaluations, before August 30th, 2013. Please find below the Letter to P1085 Study Participants.
P1085 Letter to Study Participants

To: Study Participants
From: P1085 Team
Date: July 8, 2013
Re: Study Closure to Accrual and Follow-up of P1085

Dear Study Participant,

Thank you for your participation in IMPAACT P1085, "Duration of Human Papilloma Virus (HPV) Type-Specific Antibody after Administration of Quadrivalent HPV Vaccine to HIV-Infected Children".

On August 30th, 2013 the study will be closing to follow-up study visits. This decision was due to concerns raised by the IMPAACT Leadership and IMPAACT’s NIH sponsors regarding the scientific priorities and limited resources of the Network. This decision was not driven by safety concerns.

You will be asked to come into the clinic for one final study visit before August 30th, 2013. The site will help you schedule this visit. This last visit provides critical information for the study, even if the visit is early. There may be other clinical trials available to you, and the research clinician will in this case discuss those with you as options.

We appreciate your efforts in this trial and thank you for being a part of this study.

Sincerely,

The P1085 Team