DATE: September 2, 2011

RE: CLARIFICATION MEMO #1 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

This is Clarification Memo #1 applies to 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”.

This Clarification Memo can be obtained from the P1085 protocol specific webpage (http://www.impaactgroup.org). The document is located under the tab “Current Protocol Related Documents”.

This clarification memo is to clarify that there is no adverse event reporting or collection of adverse events in the P1085 protocol. Thus, for consistency, the text in the Schedule of Evaluations (Appendix I), footnote #1 has been removed as follows:

Footnote #1:
“A targeted history will be obtained at each visit. The first visit will record: baseline diagnoses (including pregnancy, significant medical conditions, CDC HIV Clinical Stage, medications, and vaccinations within 2 weeks of the visit. Subsequent visits: record new diagnoses (including pregnancy, change in CDC HIV Clinical Stage, medications), and significant adverse events since the preceding study visit”

The above information will be incorporated into the next version of the protocol when it is amended. Please contact the protocol team at actg.teamp1085@fstrf.org with any questions about this correspondence.

Thank you for your participation in IMPAACT P1085.