

DATE: October 21, 2011

RE: CLARIFICATION MEMO #3 for P1096 "Phase 1 Study to Determine the Safety, Infectivity, Immunogenicity and Tolerability of 2 Doses of Live Attenuated Recombinant Cold-passaged (cp) 45 Human Parainfluenza Type 3 Virus Vaccine, rHPIV3cp45, Lot PIV3#102A, Delivered as Nose Drops to HPIV3-Seronegative Infants and Children 6 to 36 Months of Age, at a 6 Month Interval"

TO: IMPAACT Principal Investigators & Study Coordinators at Sites Participating in IMPAACT P1096

FROM: P1096 Protocol Team

This is Clarification Memo #3 for P1096: "Phase 1 Study to Determine the Safety, Infectivity, Immunogenicity and Tolerability of 2 Doses of Live Attenuated Recombinant Cold-passaged (cp) 45 Human Parainfluenza Type 3 Virus Vaccine, rHPIV3cp45, Lot PIV3#102A, Delivered as Nose Drops to HPIV3-Seronegative Infants and Children 6 to 36 Months of Age, at a 6 Month Interval" Version 1.0, dated October 17th, 2010.

This Clarification Memo can be obtained from the P1096 protocol specific web page (<http://www.impaactgroup.org>). The document is located under the section titled "Current Protocol Related Documents".

The purpose of this memo is to clarify the following sections in the protocol:

1. HPIV3 Dose #2 should be administered between 24 and 30 weeks following Dose #1.

This will affect Section 4.2.9, Section 8.3 and Appendix IB, footnote #2.

These clarifications and additions will be included in the next version of the protocol when it is amended. Please contact the P1096 Protocol Team at impaact.teamhpiv3@fstrf.org with any questions about this correspondence.

Thank you for your participation in IMPAACT P1096.