

DATE: May 3, 2011

RE: CLARIFICATION MEMO #2 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 #2 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. Temporary Exclusion Criteria (Section 5.3.3)
 - Any child presenting with rhinorrhea on the day of vaccination is considered to meet temporary exclusion criteria (see bullet #1, regarding upper respiratory illness) and should NOT be enrolled, or receive vaccine, until the rhinorrhea has resolved.
2. Informed Consent (Appendix V)
 - At the end of the study after all testing is completed, any leftover specimens will be destroyed. Specimens will NOT be stored for use in future research studies.

Additionally, the following additions to the protocol are being made to address FDA comments:

3. Subject Withdrawal / Termination Criteria (Section 5.6); Clinical Monitoring & Evaluation – Study Day 0 (Dose 2) (Section 8.3)
 - Children who have been hospitalized between dose 1 and dose 2 for any respiratory or respiratory related condition are excluded from receiving dose 2, but will continue to be followed until the condition resolves
4. Sick Visits (Section 8.7)
 - Any medically attended visit will be followed until resolution with appropriate clinical and laboratory evaluations

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 impact.teamhpiv3@fstrf.org with any questions about this correspondence.

Thank you for your participation in IMPAACT P1096.