Title: Safety and Immunogenicity of Sequential Rotavirus Vaccine Schedules with RotaTeq® and Rotarix®

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Synopsis:

The Safety and Immunogenicity of Sequential Rotavirus Vaccine Schedules with RotaTeq® and Rotarix® is a Phase 4 clinical trial. Rotavirus is the most common cause of severe gastroenteritis among very young children. Vaccine coverage for rotavirus became universal in the US in 2006. There are currently two FDA-approved vaccines for rotavirus: RotaTeq® and Rotarix®. Both are given as a series to young infants. RotaTeq is a series of 3 shots, Rotarix is 2 shots. Both have been shown to be safe and effective. However, in practice healthcare providers may “mix” these two types of vaccines. The effectiveness and safety of a mixed sequences has not been formally evaluated. The purpose of the study is to determine if the proportion of seroresponders in the sequential mixed rotavirus vaccine groups (RotaTeq® and Rotarix®) is non-inferior to the proportion of seroresponders in the recommended schedule of the single vaccine alone group.

The NHLBI-sponsored Vaccine Testing and Efficacy Units (VTEU) are a network of sites that conduct clinical trials and other studies related to vaccines and which are deemed to have national significance. The target population are healthy infants between 6 weeks and 14 weeks, 6 days of age at the first visit who meet the other inclusion criteria. The VTEU aims to recruit 1266 subjects throughout the network. Approximately 150 children will be recruited from the Children’s Hospital & Research Center Oakland Primary Care Clinic.

Children who are recruited will be randomized into one of five study groups, each with a different sequence of the two types of vaccines. Children will receive usual doses of the vaccines during routine visits and according to a standard vaccine schedule. Depending on study group, children will have either 3 or 4 on-site study visits plus 3 or 4 phone “visits”. For both groups, blood will be drawn 3-6 weeks after the final dose of vaccine. The two primary outcomes include: (1) Seroresponse rate (proportion of subjects developing serum anti-rotavirus immunoglobulin A (IgA) ≥20 units) at 3-6 weeks month after the last dose of vaccine, and (2) Geometric mean titer (GMT) serum anti-rotavirus immunoglobulin A (IgA) at 3-6 weeks after the last dose of vaccine.