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Wellcome Trust London UK
National Institute of Allergy and Infectious Diseases (NIAID) Bethesda USA
Center for International Research Assistance and Support (CIRAS)
World Health Organization

12th February 2008

Dear Study Site Investigators:

Re: Consenting for children

The purpose of this letter is to provide clarification on the issue of who is able to give consent for a child participating in the SEA001 study.

As per international guidelines consent for a child to participate in a study MUST be from the parent(s). Only if both parents are deceased can a legal representative/guardian give consent.

The Network has chosen the international standard as a guideline for giving consent in order to keep the process clear and to satisfy regulatory requirements.

If further information, or clarification, is required about this subject please contact your local NCC or CTSS.

With best wishes,

Steve Wignall MD
Chief Operations Officer