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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

20th February 2008

Dear Study Site Investigators:

Re: Consenting for incapacitated adult

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

As per international guidelines consent for an incapacitated adult to participate in a study MUST be from the next of kin/legal representative. That means the wife or husband of the patient (dependent upon the gender of the patient). If the subject is widowed or unmarried consent MUST be obtained from the parents. If both the parents are deceased consent MUST be obtained from the sibling, (normally the eldest sibling first)

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