To: Principal Investigators and Study Coordinators of DAIDS-sponsored Clinical Trial Sites, Network Leadership, and Operations Offices

Date: October 19, 2009

Subject: Updated Contact Information for the memo "Required Documentation of Risk/Benefit Category and Approval of Clinical Studies for Inclusion of Children by Institutional Review Boards/Ethics Committees Based on 45 CFR 46, Subpart D" dated July 8, 2005

The contact information contained in the memo has changed as a result of the DAIDS reorganization. For any questions regarding this memo and its contents, please contact NIAIDDAIDSHSPB@niaid.nih.gov and copy Liza Dawson, Branch Chief, HSPB at dawsonl@mail.nih.gov

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Division of AIDS
National Institutes of Health
National Institute of Allergy
and Infectious Diseases
Bethesda, Maryland 20892

To: Principal Investigators and Study Coordinators of DAIDS-sponsored Clinical Trial Sites, Network Leadership, and Operations Offices

Date: July 8, 2005

Subject: Required Documentation of Risk/Benefit Category and Approval of Clinical Studies for Inclusion of Children by Institutional Review Boards/Ethics Committees Based on 45 CFR 46, Subpart D

As you know, Institutional Review Boards (IRBs)/Ethics Committees (ECs) have specific responsibilities to review all research supported by the U.S. Department of Health and Human Services (DHHS) involving children as subjects and to approve only those research projects satisfying conditions stated in U.S. Code of Federal Regulations (CFR) Title 45 Part 46, Subpart D: "Additional DHHS Protections for Children Involved as Subjects in Research."

For research projects including children or adolescents, the Division of AIDS (DAIDS), National Institute of Allergy and Infectious Diseases (NIAID) requires documentation of the IRB/EC designation of a risk/benefit category from 45 CFR 46.404-407* and IRB/EC approval for involvement of children based on the determinations specified in that category. The documentation may be in the IRB/EC approval letter or in other official correspondence from the IRB/EC to the investigator.

This documentation will be required to complete DAIDS protocol registration for all clinical studies enrolling children or adolescents that are reviewed by an IRB/EC after **July 24, 2005**. This requirement applies to the initial and annual IRB/EC reviews of research protocols and to any subsequent reviews of amendments or Letters of Amendment involving potential study risks or benefits. Protocol registration will not be approved if this documentation is not received.

*As per CFR 45 Part 46, Subpart D, below are the allowable risk/benefit categories for involving children and adolescents as subjects. Please see http://rcc.tech-res-intl.com/DAIDS%20RCC%20Forms/45CFR46SubpartD.pdf for the criteria to make the determinations required for IRB approval, including the criteria set forth in 45 CFR 46.408 (c) for the waiver of parental permission for adolescent participation when applicable.

45 CFR §46.404	Research not involving greater than minimal risk.
45 CFR §46.405	Research involving greater than minimal risk but presenting the prospects of direct benefit to the individual subjects.
45 CFR §46.406	Research involving greater than minimal risk and no prospect of direct benefit to individual subjects but likely to yield generalizable knowledge about the subject's disorder or condition.

45 CFR §46.407	Research not otherwise approvable which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children. (This category requires a special level of Department of Health and Human Services review beyond that provided by the IRB/EC). Please see http://www.hhs.gov/ohrp/children/guidance_407process.html May 26, 2005 Guidance, "Children Involved as Subjects in Research: Guidance on the HHS 45 CFR 46.407 ("407") Review Process."

If you have any questions, please feel to contact the Human Subjects Protection team in the Regulatory Affairs Branch at +1 (301) 435-3741 or DAIDSRABHSP@niaid.nih.gov.

Sincerely,

Richard Hafner

Richard Hafner, MD
Acting Director
Office for Policy and Clinical Research Operations

RH:sdw

cc: Edmund C. Tramont, MD, Director, Division of AIDS
Sandra Nusinoff Lehrman, MD, Director, Therapeutics Research Program
Peggy Johnston, Ph.D., Director, Vaccine Research Program
Carl Dieffenbach, Ph.D., Director, Basic Sciences Program
Mary Fanning, MD, Ph.D., Director, Transition Office of International Research Integration
Mary Anne Luzar, Ph.D., Chief, Regulatory Affairs Branch