



DEPARTMENT OF THE ARMY
WALTER REED ARMY INSTITUTE OF RESEARCH
WALTER REED ARMY MEDICAL CENTER
WASHINGTON DC 20307-5001

REPLY TO
ATTENTION OF:

Institutional Review Board (IRB) Authorization Agreement

Name of Institution or Organization Providing IRB Review (Institution A):

Walter Reed Army Medical Center (WRAMC)

IRB Registration #: IRB00000662

Federalwide Assurance (FWA) #: FWA00000477

DoD Multiple Project Assurance (MPA): #10013

Name of Institution Relying on the Designated IRB (Institution B):

Walter Reed Army Institute of Research (WRAIR)

IRB Registration #: IRB00000794

Federalwide Assurance (FWA) #: FWA00000015

DoD Multiple Project Assurance (MPA): #20126

The Officials signing below agree WRAIR may rely on the WRAMC Human Use Committee (HUC) for review and continuing oversight of its human subject research described below:

This agreement applies to all human subject research wherein the WRAMC Human Use Committee (HUC) is serving as the IRB of record, the subject population is at WRAMC hospital, and the Principal Investigator(s) are employees of WRAMC.

Please note: This agreement does not cover studies performed under the Tri-Service AIDS Clinical Consortium (TACC), as those studies involve multiple Military Treatment Facilities and outside agencies. Those are to be addressed in a separate agreement.

When The Surgeon General of the Army is the Sponsor of an investigational product or is funding a study, the Human Subjects Research Review Board, Medical Research & Materiel Command, may still be required to review the protocol, unless otherwise agreed upon with Clinical Investigation Regulatory Office (CIRO) in advance.

The review and continuing oversight performed by the designated IRB will meet the human subjects protection requirements of the Department of Defense (DoD) & Health & Human Services (HHS) regulations for the protection of human subjects at 45 CFR 46 & 32 CFR 219, as well as the requirements of Institution A's OHRP-approved FWA. The IRB at Institution A will follow written procedures for reporting its findings and actions to appropriate officials at Institution B. Relevant minutes of IRB meetings will be made available to Institution B upon request. Institution B remains responsible for ensuring compliance with the IRB's determinations and with the terms of its OHRP-approved Assurance. In addition, the IRB at Institution A will supply a copy of the continuing review report and approvals for continuation to Institution B upon request.

SUBJECT: IRB Authorization Agreement

WRAIR investigators are responsible for reporting their participation on a WRAMC protocol to the Office of Research Management (ORM) and still require WRAIR Commander approval prior to participation.

This document must be kept on file at both institutions and provided to OHRP upon request.

Signatures:

Authorized Official of (A): WRAMC

Authorized Official of (B): WRAIR

Signed

(signature) (date)

VIRGIL T. DEAL
COL, MC
Commander
Walter Reed Health Care System

Signed

(signature) (date)

KENNETH A. BERTRAM
COL, MC
Commander
Walter Reed Army Institute of Research