

**COOPERATIVE AMENDMENT FOR FWA 00005834 –
THE JOHNS HOPKINS UNIVERSITY HOMEWOOD INSTITUTIONAL
REVIEW BOARD – AND FWA 00005752 –
THE JOHNS HOPKINS UNIVERSITY SCHOOL OF MEDICINE**

This Cooperative Amendment, to be effective July 1, 2005, is made by and between the Johns Hopkins University Homewood Institutional Review Board (HIRB) and the Johns Hopkins University School of Medicine (SOM).

As independent divisions of The Johns Hopkins University, the HIRB and the SOM maintain separate Institutional Review Boards (IRBs). The HIRB has one IRB under FWA 00005834. The HIRB is the IRB serving the University's Central Administration, Krieger School of Arts and Sciences, Whiting School of Engineering, School of Professional Studies in Business and Education, School of Advanced International Studies, Peabody Institute, and Applied Physics Laboratory. The HIRB is primarily responsible for reviewing behavioral and social sciences research. The SOM has six IRBs under FWA 00005752, five of which are Johns Hopkins Medicine (JHM) IRBs and one of which is Western IRB, reviewing protocols under a contractual arrangement with the SOM. The JHM IRBs are primarily responsible for reviewing biomedical research with testing and clinical care, and research subject to the Health Insurance Portability and Accountability Act of 1996 (HIPAA).

Given the interdisciplinary nature of many research projects, dual review of a project by the HIRB and the JHM IRBs would be required often. Given the particular expertise of the IRBs, HIRB in behavioral and social sciences research and the JHM IRBs in biomedical and HIPAA research, it often becomes necessary for one IRB to assign a research project to the other IRB for review. In order to facilitate the review process, the HIRB and the JHM IRBs have agreed to terms of a cooperative amendment to their respective Assurances.

This document is to confirm that the HIRB and the SOM agree to rely upon the review and determination of action of each Division's IRBs under the following circumstances:

1. Reviews of proposed research projects from the Divisions served by HIRB that are subject to HIPAA will be conducted by one of the JHM IRBs.
2. Reviews of proposed research projects from the Divisions served by HIRB involving biomedical or clinical research will be conducted by one of the JHM IRBs when the HIRB fails to have a member or consultant capable of reviewing the proposed research project.
3. Reviews of proposed research projects from the Divisions served by HIRB or SOM will be conducted by one of the IRBs at the Division of the Principal Investigator's primary appointment (class projects at the Homewood campus excepted). A consent form approved for a protocol by any of the JHM IRBs (or

the Johns Hopkins Bloomberg School of Public Health IRB acting for JHM) or HIRB will be accepted for any approved site of the research.

4. Principal investigators whose primary appointment is in one of the Divisions served by HIRB and who are proposing to conduct research at one of the sites served by the JHM IRBs may request that the JHM IRB serve as the IRB of record for that study.
5. Each Division reserves the right to determine on a case-by-case basis that review of a protocol should be conducted by one of the Division's own IRBs, regardless of the terms of this amendment. Such decisions are to be conveyed in writing by the undersigned, respectively, or their successors and provided to the Dean of Research and Graduate Education for the Krieger School of Arts and Sciences or the Vice Dean for Clinical Investigations for the JHM IRBs, respectively. Protocol reviews of the HIRB and JHM IRBs will be conducted in compliance with the Office of Human Subjects Research Protections (OHRP) regulatory requirements on membership and voting. Each Division will retain the responsibility for providing changes in voting membership to the OHRP. The HIRB and the SOM agree to abide by each cooperating Division's IRBs' decisions made under the terms of this cooperative amendment. Approval of a research project reviewed under this amendment may be administratively overruled by the Institutional Official ("I.O.") of either cooperating Division. Disapproval of a research project reviewed under this amendment may not be administratively overruled by either cooperating Division.
6. The JHM IRBs shall be responsible for receiving and handling all issues of non-compliance and termination for every research project in which the JHM IRBs review on behalf of Divisions served by the HIRB.

Reviewed and Accepted by:

Eaton E. Lattman

Eaton E. Lattman
Dean of Research and Graduate Education
The Johns Hopkins University
Krieger School of Arts and Sciences

Date: 3/1/06

D E Ford

Daniel E. Ford, M.D., M.P.H.
Vice Dean for Clinical Investigation
The Johns Hopkins University
School of Medicine

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