

Revised Amendment
March, 2002

***COOPERATIVE AMENDMENT FOR FWA0000027 – THE JOHNS HOPKINS
UNIVERSITY BLOOMBERG SCHOOL OF PUBLIC HEALTH – AND MULTIPLE
PROJECT ASSURANCE (MPA) FOR M1011 – THE JOHNS HOPKINS UNIVERSITY
SCHOOL OF MEDICINE***

As independent divisions of The Johns Hopkins University, the Bloomberg School of Public Health (BSPH) and the School of Medicine (SOM) maintain separate Institutional Review Boards (IRBs). The BSPH has two IRBs under FWA 0000027, the Committee on Human Research (CHR) Continuing Review Committee and CHR New Application Committee (CHRs). The SOM has six IRBs under Assurance M1011, five of which are Johns Hopkins Medicine (JHM) IRBs and one of which is Western IRB, reviewing protocols under arrangement with the SOM. Four of the JHM IRBs meet at the East Baltimore Campus and one of the JHM IRBs meets at The Johns Hopkins Bayview Medical Center (JHBMC). Given the interdisciplinary nature of many research projects, dual review of a project by the BSPH and JHM IRBs would be required often. In order to facilitate the review process, the BSPH and JHM IRBs have agreed to terms of a cooperative amendment to their respective Assurances.

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

1. Reviews of proposed BSPH or SOM projects will be conducted by one of the IRBs at the Division of the Principal Investigator's primary appointment. A consent form approved for a protocol by any of the JHM IRBs or BSPH IRBs will be accepted for any approved site of the research.
2. Projects that originate with, or recruit from populations at the National Institute on Aging Gerontology Research Center at the JHBMC campus are not governed by this amendment. Such projects must be reviewed by the JHM IRB located at JHBMC.
3. 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 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 Associate Dean for Graduate Education and Research for the CHRs or the Vice Dean for Clinical Investigation for the JHM IRBs, respectively. Protocol reviews of the CHRs and JHM IRBs will be conducted in compliance with the Office of Human Subjects Research (OHRP) regulatory requirements on membership and voting. Each Division will retain the responsibility for providing changes in voting membership to the OHRP. The BSPH 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 Administrator of either cooperating

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Division. Disapproval of a research project reviewed under this amendment may not be administratively overruled by either cooperating Division.

Reviewed and Accepted by:

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Date: 3/25/02

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