

Johns Hopkins University Institutional Review Boards (IRBs) Reciprocity Policy

The Johns Hopkins University (JHU) actively promotes interdisciplinary research activities across the Schools of JHU. Three Schools within the JHU system maintain a human research protection program (HRPP): School of Medicine (JHUSOM), Bloomberg School of Public Health (BSPH), and the Homewood Schools (Homewood). Each HRPP includes an administrative office and has appointed institutional review boards¹ to review proposed research applications² when one or more of a School's qualified employees or students meet the Department of Health and Human Services' definition of "engaged" in human subject's research. The review may determine when research may be exempt from the requirements for IRB review or that IRB review and approval is required.

Since 2002, the Schools have agreed to reduce the regulatory burden associated with multiple IRB reviews across the JHU system. This policy updates and replaces the original agreement executed between JHUSOM and BSPH in 2002, as revised in 2011, and the agreement between Homewood and JHUSOM,

¹ "IRBs" or "Boards" in this policy references the specific JHU School's administrative office and its associated internal and external Boards. The School of Medicine has seven internal IRBs; the Bloomberg School of Public Health has two internal IRBs and a review agreement with WIRB; and Homewood has one IRB. JHU enters into IRB Designation Agreements with external IRBs where appropriate.

² The JHUSOM IRB is the IRB of record for the following components of JHU and Johns Hopkins Health Systems:

The Johns Hopkins University School of Medicine, FWA00005752

- The Johns Hopkins School of Medicine
- The Johns Hopkins University School of Nursing

The Johns Hopkins Hospital and Johns Hopkins Health Systems, FWA00006087

- All Children's Health System, Inc.
- Howard County General Hospital
- Johns Hopkins All Children's Hospital, Inc.
- Johns Hopkins Bayview Medical Center
- Johns Hopkins Community Physicians
- Johns Hopkins Regional Physicians, LLC
- Johns Hopkins Hospital
- Sibley Memorial Hospital
- Suburban Hospital and Health System

In addition the JHU SOM IRB routinely serves as the IRB of record for the following external IRB entities:

- The Johns Hopkins University Applied Physics Laboratory, FWA 00018613
- Hugo W. Moser Research Institute at Kennedy Krieger, Inc., FWA00005719
- DoD – Air Force, F50459 (covers all DoD supported research)

The JHSPH IRB is the IRB of record for the following components of the University system:

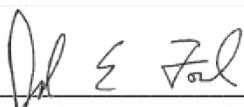
- Jhpiego, FWA00003428
- Johns Hopkins University Bloomberg School of Public Health, FWA00000287

The Homewood IRB is the IRB of record for the following Schools of the University system:

- Johns Hopkins University Homewood Schools, FWA00005834

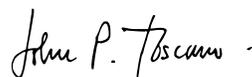
renewed in 2012, to confirm the JHUSOM, BSPH, and Homewood continue to agree to rely upon the reviews and determinations of each School's IRB(s) under the following conditions:

1. Principal Investigators (PI) must submit research applications to the IRB at the School of the PI's primary appointment, except as set forth in paragraphs 2 and 3 of this policy. An exception to this requirement may be made by written agreement between the Institutional Officials for the relevant Schools.
2. Reviews of proposed research projects from Homewood that: (a) involve the collection, transfer, or use of data subject to the Health Insurance Portability and Accountability Act of 1996 ("HIPAA"); (b) that take place in Johns Hopkins Health Systems (JHHS) space; (c) that is subject to the regulations of the Food and Drug Administration (FDA); or (d) involve biomedical or clinical research when Homewood lacks committee expertise to review the proposed research; shall be reviewed by the JHUSOM IRB.
3. For all proposed domestic research contemplating the use of a single IRB at JHU when single IRB review is mandated by the sponsor, the JHUSOM IRB shall serve as a single IRB in such cases, regardless of the PI's primary appointment. The Schools shall coordinate policies on use of a single IRB so that, to the extent possible, consistent standards are applied.
4. The reviewing IRBs agree to follow federal, state, and local laws and regulations, JHU policy, and the policies and procedures associated with the Schools' HRPP.
5. The Institutional Official that oversees the reviewing IRB has the authority to establish the qualifications required for an investigator from another School to serve as a PI for a human subject's research study reviewed by that IRB, and for establishing the terms for providing IRB review.
6. IRB approval of a research application does not constitute institutional permission to access a specific research site for research purposes. For example, an investigator from the BSPH or Homewood with approval to collect data from Johns Hopkins Hospital or a JHHS clinical site must obtain all permissions required by the clinical site.
7. Institutional Officials, both of the School that provides the IRB review and the PI's primary appointment, will be notified of an event or non-compliance that is reportable by law or policy to the institution, the sponsor, the Office for Human Research Protections (OHRP), and/or the FDA. Notification will apply to any internal audits, reports of investigations by oversight agencies, or sponsor or funding agencies actions.



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Vice Dean for Clinical Investigation
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3/8/2018
Date



John Toscano, Ph.D.
Vice Dean for Research
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3/8/2018
Date

Janet DiPietro

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Janet A. DiPietro, Ph.D.
Vice Dean for Research
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March 6, 2018
Date