Institutional Review Board Authority

Policy: GEN002
Responsible Executive: Provost and Senior Vice President for Academic Affairs
Responsible Office: Office of the Provost
Approved by: Senior Planning Group
Effective: 01/01/2019
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Policy Statement

As an institution committed to the creation of new knowledge through research, The Johns Hopkins University ("University" or "JHU") acknowledges the critical role of persons who participate in research studies and the need for the University to establish appropriate oversight structures to ensure that such research participants are provided the ethical and legal protections to which they are entitled. The protection of human research subjects involves the actions of multiple individuals, offices, and committees within the University, and this Policy outlines the authority granted to one of those committees, the Institutional Review Board ("IRB").

Oversight for the matters addressed in this Policy is the ultimate responsibility of the President of the University, who has delegated this oversight responsibility to the Vice Provost for Research. The primary oversight responsibilities for the functions of the IRB rests with the relevant Institutional Official ("IO").

Who Is Governed By This Policy

All units of the University, including the Applied Physics Laboratory.

Policy Purpose

This Policy vests the appropriate authority in each IO and IRB (as defined below) appointed under this Policy to review and approve (or not approve) any proposed human subject research conducted by any University faculty, staff or students, when acting in their University role. This Policy shall provide the structure to ensure that human subject research is compliant with the principles of the Belmont Report, and the requirements of all federal, state, and local laws that may apply to human subject research.

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Definitions

Belmont Report	The report issued April 18, 1979 by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, setting forth the Ethical Principles and Guidelines for the Protection of Human Subjects of Research. The Belmont Report sets forth the ethical principles of respect for persons, beneficence, and justice.
Clinical Investigation	Any experiment that involves a test article and one or more human subjects and that is either subject to requirements for prior submission to the United States Food and Drug Administration (“FDA”) under the United States Federal Food, Drug and Cosmetic Act or is not subject to requirements for prior submission to the FDA under the Act, but the results of which are intended to be submitted later to, or held for inspection by, the FDA as part of an application for research or marketing permit. The terms "research," "clinical research," "clinical study," "study," and "clinical investigations" are synonymous for purposes of this Policy.
Common Rule	The regulations applicable to all human subject research conducted by or supported by any federal agency, currently set forth at 45 CFR Part 46, and including all subparts.
Federal Wide Assurance (“FWA”)	An assurance that must be provided by an institution engaged in human subject research conducted or supported by the federal department of Health and Human Services. FWA terms and conditions are set by the Office of Human Research Protections, and only an IO appointed under this Policy may execute an FWA on behalf of any component of the University.
Institutional Official (“IO”)	The Institutional Official (IO) is the person appointed under this Policy, for the relevant component of the University governed by a particular federal wide assurance, who is responsible for ensuring that the human research protection program for that component functions effectively and to ensure that the necessary resources and support are provided to comply with all applicable regulations for research involving human subjects. The Institutional Official is the only person authorized to commit in a federal wide assurance on behalf of the University that federal requirements will be met. The Institutional Official is responsible for ensuring that the IRB under that Institutional Official’s responsibility operates independently.
Institutional Review Board (“IRB”)	A board comprised of one or more committees, each appointed by an IO under this Policy, with a composition that meets the requirements of 45 CFR Part 46, and for clinical investigations, 21 CFR Part 56. As used in this Policy, Institutional Review Board includes both IRBs appointed under this policy, and IRBs that are serving as the IRB of record under an executed IRB Reliance Agreement.
Research	A systematic investigation, including research development, testing and evaluations, designed to develop or contribute to generalizable knowledge

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Policy

The University IRBs will apply the provisions of the Common Rule to all non-exempt human subject research conducted by the University, regardless of funding source or site of the research.[1] For human subject research conducted in the State of Maryland, the University IRBs will apply the provisions of Health-General § 13-2001 through § 13-2004, commonly known as the Hubbard Bill, and any subsequent amendments thereto. For any clinical investigations, the University IRBs shall also apply the regulations promulgated under the federal Food, Drug and Cosmetic Act by the FDA.

The University investigators must submit all proposed human subject research applications to the IRB associated with the Principal Investigator's primary appointment, unless otherwise authorized by the relevant IRBs and IOs. The University IRB will review proposed applications and only the IRB may make regulatory determinations under the Common Rule, or other federal or state law, including making the determination as to whether the application meets the regulatory criteria for exemption, or qualifies for limited, expedited or convened review. As set forth below, an IRB may delegate certain of its duties, under its policies and procedures, including the process for determination of whether a project qualifies for exemption.

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[1]Where funding flows through the University for the conduct of human subject research at another site or organization, the University shall require that subrecipient organization to conduct the research in accordance with all applicable federal, state and local laws at that site, and in accordance with all requirements of the funding source. Where federal funding is supporting the proposed human subject research, the University shall require the subrecipient (or subcontractor, if engaged in the research) to file its own FWA.

A. Authority of the IRBs
   1. The University IRBs, and any IRB designed by the IO under an executed IRB Reliance Agreement to review research, have the authority to:
      a. Approve, require modifications to secure approval, or disapprove, all human subjects research activities overseen and conducted by the University.
      b. Make determinations, under procedures that the IO may approve, regarding whether proposed research activities meet the regulatory criteria for exemption.
      c. Suspend or terminate approval of research that is not being conducted in accordance with the IRB's requirements or that has been associated with unexpected serious harm to participants.
      d. Observe, or have a third party observe, the consent process.
      e. Observe, or have a third party observe, the conduct of the research.
      f. Require that research applications be subject to continuing review, even when not required by the Common Rule
   2. University officials, including the IOs, may not approve the conduct of human subject research if it has not been approved prospectively by an IRB that is authorized under this Policy (which may include an external IRB when the University has entered into a reliance agreement with such IRB.) An IO may disapprove the conduct of human subject research that has been approved by an IRB authorized as the

IRB of record under the purview of that IO under this Policy. University IRBs may delegate certain of their authority, where permitted under applicable regulations, to designated IRB office staff.

3. The University IRBs, or their designated staff, shall promulgate more specific policies and procedures to carry out their responsibilities under this Policy, the terms of their applicable FWA, and applicable law.

B. Authority of the Institutional Officials
   1. The Institutional Officials shall have the authority and responsibility under this Policy to take the following actions and carry out the following duties within their component of the University (Institutional Officials may delegate the duties set forth in subsections v and vi below, as appropriate):
      a. Appoint and evaluate IRB members;
      b. Negotiate budget and space allocations for the IRB;
      c. Assess workload of the IRBs and make adjustments in the size or composition of IRB committees to ensure that IRBs can carry out their duties effectively;
      d. Approve IRB policies;
      e. Approve programs for the training of faculty, staff and students in the ethical conduct of research that is sufficient to permit such faculty, staff or students to engage in human subject research within the component of the University for which the IO has authority;
      f. Enter into IRB Reliance Agreements to permit the University to rely upon the IRB review of an external, appropriately constituted IRB;
      g. Receive reports from the IRB of matters that may constitute serious or continuing noncompliance with federal regulations governing human subject research, or unanticipated events that may present a risk to subjects or others, assess such reports, and make any necessary determinations, including requiring additional corrective actions and communicate as necessary with the IRB on the matter. The IO makes all reports to federal agencies that may be required.
      h. Require the submission of progress reports for ongoing human subjects research activities at intervals as set forth in institutional policies.
      i. Approve the local context review procedures to be used when the University relies on an external IRB, including requirements for submission of progress reports.

C. Ethical Principles Applicable to All Human Subject Research Conducted by University Personnel
   1. Notwithstanding any provisions of the Common Rule or other applicable law that may not require review, the University requires all human subject research, whether exempt or non-exempt under the Common Rule and other state or federal regulations, to comply with the principles of the Belmont Report. The University IRBs have the authority to ensure compliance with this ethical requirement.

Exceptions/Exclusions

None.

Procedures

A. Appointment of IRB Members
   1. Appointment of IRB Members shall be the responsibility of the IO for each IRB. As required by federal regulations, each IRB shall have at least five members, who shall be chosen to reflect varied backgrounds, including a diversity of professional expertise, gender, race and culture, and who should

have understanding and sensitivity to the issues and attitudes of the research subject communities who may participate in University designed research. Members shall be chosen to ensure that the overall IRB composition reflects the expertise required to review specialized research and/or research involving vulnerable populations. In addition to these general requirements, each IRB under this Policy shall include:

a. An individual with a primary interest in science.
b. An individual with a primary interest that is nonscientific in nature.
c. At least one member who is not affiliated with the University or Johns Hopkins Medicine ("JHM") and who is not part of the immediate family of someone who is affiliated with the University or JHM.

B. RB Policies and Procedures

1. Each IO and IRB authorized under this Policy shall promulgate more specific policies and procedures as necessary under the Common Rule and other applicable federal or state laws or regulations to implement the requirements of such laws and to ensure compliance with the terms of the applicable FWA. No such policies and procedures may alter, increase or reduce the obligations set forth in this Policy. All IOs and IRBs authorized under this Policy shall, to the maximum extent possible, work to harmonize policies and procedures.

Policy Enforcement

Reporting Violations	All members of the University community have an obligation to report good faith concerns regarding violations of IRB protocols or policies within the scope of this Policy. Violations may be reported to the appropriate IRB Office, or through the Compliance Hotline.

Related Resources

University Policies and Documents
JHU Homewood IRB Policies: http://homewoodirb.jhu.edu/ JHM IRB Policies: https://www.hopkinsmedicine.org/institutional_review_board/index.html JHSPH IRB Policies: https://www.jhsph.edu/offices-and-services/institutional-review-board/index.html
External Documentation
The Belmont Report: https://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/read-the-belmont-report/index.html 45 CFR Part 46: https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html 21 CFR Part 50: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=50 The Maryland Hubbard Bill: http://mgaleg.maryland.gov/WEBMGA/frmStatutesText.aspx?article=ghg&section=13-2001&ext=html&session=2017RS&tab=subject5

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Contacts

Subject Matter	Office Name	Telephone Number	E-mail/Web Address
Policy Clarification and Interpretation	Institutional Review Board Offices		
Anonymous Reporting/ EthicsLine	Johns Hopkins University and Health System Compliance Line	1-844-SPEAK2US	https://johnshopkinsspeak2us.tnwreports.com/
Reporting violations of civil or criminal law	Office of the Vice President and General Counsel	410-516-8128	http://web.jhu.edu/administration/general_counsel/
Reporting allegations of research misconduct	Research Integrity Officer	410-516-6880	http://web.jhu.edu/administration/provost/bios/links