

 JOHNS HOPKINS BLOOMBERG SCHOOL of PUBLIC HEALTH	Human Research Protection Program Policies & Procedures	
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Title: Institutional Review Boards	Date Effective 1/3/05	Supercedes P&P dated 6/15/04

Background

The Common Rule states that institutions holding an FWA and performing human subjects research must “certify that the research has been reviewed and approved by an IRB...and will be subject to continuing review by the IRB.” An IRB’s primary responsibility is to ensure that the rights and welfare of subjects are protected in the conduct of research. In doing so, the IRB ensures that the human subjects research is conducted ethically, and in compliance with Federal regulations, the requirements of applicable state law, the FWA (or other Assurance), and institutional policies and procedures. The JHSPH Institutional Review Boards are known as the Committees on Human Research (CHRs).

JHSPH Policy and Procedures

Committees on Human Research

The JHSPH IRBs act on behalf of the School to review all human subjects research regardless of the funding source, lack of funding or site of performance. The three JHSPH IRBs, CHR#1, CHR #2 and the Western IRB, review and approve human subjects research conducted or supported by JHSPH in accordance with Department of Health and Human Services regulations and Food and Drug Administration requirements, as well as applicable state and local laws and JHSPH policies and procedures.

CHR Authority

CHRs derive their authority from both regulatory and institutional sources. The CHRs function according to the JHSPH written Policies and Procedures, which comply with the obligations of the JHSPH FWA. The CHRs are required to review and have the authority to:

- Approve, require modifications in, or disapprove all JHSPH human subjects research, including proposed changes in ongoing, previously approved research, and
- Suspend or terminate the approval of ongoing, previously approved human subjects research that is not being conducted in accord with CHR requirements or that has been associated with unexpected or serious harm, or increased risk of harm, to subjects.

CHR Membership

The [membership](#) of each CHR is representative of the School's various scientific disciplines, community views and attitudes, and non-scientific perspectives, and has appropriate knowledge about the national and international institutions at which much of the School's research is performed. All of these resources are applied when reviewing human subjects research applications.

Each CHR is comprised of at least five JHSPH faculty members with expertise in diverse scientific areas, including two Co-Chairpersons. It also includes at least one member whose primary concerns are non-scientific, one member representing the community, a student representative, and a prisoner advocate. The Office for Research Subjects maintains records of the qualifications of all CHR members. Individuals with competence in special areas may be invited to assist in review of a study; these persons may not, however, vote on the proposal.

JHSPH faculty members are appointed to the CHRs by the Dean in coordination with the Institutional Official, the CHR Co-Chairs, the Director of the Office for Research Subjects, and chairpersons of the relevant departments. Community members are appointed by the Office for Research Subjects. Students interested in serving apply through the Student Assembly. Faculty members serve for three years, students for one to two years, and community members, indefinitely.

CHR meetings

CHR #1 and CHR #2 each meet twice per month for full committee reviews of new research applications, continuing review applications, amendment requests and adverse event reports. CHR #1 meets the second and fourth Wednesdays and CHR#2 meets the first and third Tuesdays. A schedule of the meetings can be found [here](#). Full committee meetings require that a majority of voting members be present, including at least one non-scientist. If the required number and type of voting members is lost during a meeting, no action may be taken until a quorum is restored. In order for research to be approved, it must receive the approval of a majority of the voting members present at the meeting. The CHR may, at its discretion, ask investigators to present their research at a convened CHR meeting. When this happens, the investigator is asked to leave prior to CHR deliberations and voting.

Attendance at convened full committee meetings is limited to CHR members, CHR staff, invited investigators, consultants and guests. Meeting proceedings are [confidential](#). Minutes are kept of each convened CHR full committee meeting. These include: a list of attendees at the meeting; actions taken by the CHR; the vote on these actions, including the number of members voting for, against, and abstaining; the basis for requiring changes in or for disapproving research; and a written summary of the discussion of controverted issues and their resolution.

CHR Review

The Director of the Office for Research Subjects is the institutional authority for determining whether certain research is [exempt](#) from the human subjects regulations. The CHR Director also works with the CHR Co-Chairs to determine whether individual studies constitute human subjects research. [Expedited reviews](#) are done by individual CHR members on an ongoing basis. Human subjects research that does not qualify for expedited review is [reviewed by the full committee](#) at a convened CHR meeting. The CHRs

conduct continuing reviews of ongoing approved research at intervals appropriate to the degree of risk, but not less than once per year.

The criteria for CHR approval of research must include determinations that:

- risks to subjects are minimized;
- risks are reasonable in relation to anticipated benefits;
- selection of subjects is equitable;
- informed consent is sought from each subject; and
- informed consent is appropriately documented;

and, where appropriate, may also include determinations that:

- data collection is monitored to ensure subject safety;
- privacy and confidentiality of subjects is protected; and
- additional safeguards are included for vulnerable populations.

When appropriate, research proposals are also reviewed by the Committees on Pharmacy and Therapeutics, Ionizing Radiation, Conflict of Interest, and Institutional Biosafety, and the Clinical Research Office. CHR may also coordinate reviews of research with the Johns Hopkins School of Medicine IRBs and may consult with various University offices and departments, such as the JHU General Counsel's Office, the Office of Graduate Education and Research and collaborating research institutions.

CHR Reports

CHR decisions as to whether to approve, request revision, or disapprove human subjects research are communicated to investigators in writing. The only persons authorized to discuss substantive aspects of the Committee's review or recommendations with the investigators are the Co-Chairs, CHR members who are designated reviewers for the study, invited consultants, the Director of the Office for Research Subjects, and the relevant CHR Research Subjects Specialist.

The CHR notifies officials of JHSPH of its actions each month by providing minutes and reports to the JHSPH Advisory Board. Research that has been approved by CHR may be disapproved by the Advisory Board, but the Advisory Board may not approve research that has been disapproved by CHR.

Conflict of interest

A CHR member may not participate in the review of any study in which the member has a conflicting interest, except to provide information requested by the CHR. At the beginning of each meeting members are reminded to recuse themselves if they have a conflict, financial or otherwise, in the research to be reviewed. [View JHSPH Conflict of Interest Policy](#). [View Conflict of Interest Form](#).

Oversight Activities

In collaboration with the Research Regulations Specialist, the CHRs are responsible for ensuring that investigators are monitored and that research is being conducted as approved by the CHR and in accordance with the JHSPH FWA. This includes ensuring that changes in approved research, during the period for which approval has been granted,

are not initiated without prior CHR approval. In cases of non-compliance by investigators CHR may authorize Co-Chairs to suspend enrollment in a study, withdraw approval for the study, or take other actions considered necessary to protect the rights and welfare of research subjects. Additionally, the CHRs, working with the Co-Chairs, are responsible for resolving grievances from research subjects, investigators or staff.