

 JOHNS HOPKINS BLOOMBERG SCHOOL of PUBLIC HEALTH	Human Research Protection Program Policies & Procedures	
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Title: Responsibilities	Date Effective May 18, 2005	Supersedes P&P dated December 1, 2004

The work of the JHSPH Human Research Protection Program to protect the rights and welfare of research subjects is shared by the individuals, committees and offices described below. This document outlines the responsibilities and functions of these individuals and groups. For an overview of the roles and responsibilities of the key components of the HRPP, please see the following chart: [Responsibilities Chart](#)

HRPP Institutional Official

The Dean of the School has ultimate responsibility for the institutional commitment made in the School's Federal Wide Assurance (FWA). The Institutional Official is appointed by, and reports to, the Dean, who authorizes him or her to act for JHSPH and assume, on behalf of the Dean and the School, the obligations of its FWA and of the Federal regulations. Accordingly, the Institutional Official is authorized to assure that JHSPH complies with the terms of the FWA and is ultimately responsible for the review and conduct of human subjects research conducted or supported by JHSPH. The Institutional Official also serves as the central authority for the JHSPH HRPP.

The Institutional Official is directly responsible for:

- Ensuring compliance with all applicable provisions of the Federal regulations, state laws and the JHSPH FWA,
- Serving on the HRPP Executive Committee and chairing its meetings,
- Serving as a knowledgeable contact for OHRP,
- Reporting to OHRP any serious or continuing noncompliance with Federal regulations concerning human subjects research,
- Reporting to OHRP any suspension or termination of CHR approval for research,
- Identifying and recommending to the Dean (together with the Director, Office for Research Subjects) appropriate faculty members to serve as Co-Chairs of the CHRs,
- Setting the "tone" for the institution's culture of respect for human research subjects,
- Ensuring School-wide communication and guidance on human subject research,
- Possessing knowledge about the requirements of Federal regulations, applicable state law, the institution's Assurance, and institutional policies and procedures for the protection of human subjects,
- Completing the OHRP training module,

- Having authority to speak on behalf of the School with regard to the CHRs and their functions,
- Serving as a non-voting member of the CHRs, and
- Supporting the authority and decisions of the CHRs.

The Institutional Official also has oversight responsibility for:

- Educating the School's research community (faculty, students and staff) in order to establish and maintain maximum compliance with Federal regulations and institutional policies relevant to the protection of human research subjects,
- Identifying appropriate members to serve on the CHRs,
- Monitoring compliance with Federal regulations and state laws,
- Developing and updating of HRPP policies and procedures, and
- Ensuring that personnel reviewing, conducting or supporting human research demonstrate sufficient knowledge of protection of research participants.

HRPP Executive Committee

The HRPP Executive Committee (EC) is the coordinating and policy-making body for the various components of the HRPP, including the CHRs, the Office for Research Subjects, the Office of Research Administration, the Institutional Official, the Research Regulations Specialist and the HRPP Legal Counsel. Members of the EC include the Institutional Official, who serves as chairperson, the CHR Co-Chairs, the Director, Office for Research Subjects and the Research Regulations Specialist. Ex officio members include the Assistant Dean for Research Administration and the HRPP Legal Counsel. The EC meets every two weeks.

The EC is directly responsible for:

- Identifying appropriate persons to serve as members of the CHRs,
- Setting standards for performance of CHR members, identifying those whose performance does not meet the standards, and recommending appropriate actions,
- Ensuring that the HRPP has and follows written policies and procedures,
- Advising Co-Chairs on efforts to resolve issues concerning investigator non-compliance or complaints, including actions to suspend or terminate previously approved research or other corrective actions, and to protect the rights and welfare of research participants,
- Ordering for-cause audits of JHSPH research projects when these are requested by CHR Co-Chairs,
- Establishing procedures for receiving and reviewing grievances from all elements of the HRPP, including investigators and research subjects,
- Monitoring grievances to determine whether there is a systematic pattern that requires attention and recommending appropriate corrective actions, and

- Providing comments on national, state and local policy announcements on the protection of human subjects.

The EC also has oversight responsibility for:

- Ensuring that elements of the HRPP comply with relevant Federal regulations and state laws, and all applicable provisions of the JHSPH FWA,
- Ensuring institution-wide communication and guidance on human subjects research,
- Reviewing Co-Chair or CHR review of, and Co-Chair or CHR recommended actions with regard to, reports of adverse or unexpected events,
- Providing the CHRs with appropriate resources and staff; and
- Monitoring and improving performance of the Office for Research Subjects.

CHR Co-Chairpersons

The Co-Chairs of the Committees on Human Research are appointed by The Dean in collaboration with the Institutional Official and the Director, Office for Research Subjects. Their responsibilities include:

- Completing the OHRP Training Module for IRB Chairpersons,
- Presiding over and facilitating full committee CHR meetings,
- Presenting the primary reviewer's findings and recommendations if the reviewer is unable to attend full committee CHR meetings,
- Reviewing reports of adverse events and unanticipated problems,
- Reviewing new research applications, amendments and continuing review reports,
- Designating CHR members as expedited reviewers,
- Signing CHR letters of approval, deferral for revision, disapproval, suspension or termination to investigators,
- Investigating, consulting with the full committee and the HRPP Executive Committee, and developing appropriate corrective actions with regard to investigator non-compliance or study complaints,
- Participating in meetings of the HRPP Executive Committee,
- Participating in the development and review of HRPP policies and procedures, and
- Composing non-routine correspondence with investigators on behalf of the CHRs, as required.

Principal Investigators

Principal Investigators are responsible for how human subjects research is both planned and conducted. This includes primary responsibility for ensuring the safety and well-being of study participants. This responsibility starts with protocol design and continues through interactions with the CHRs and the actual conduct of research.

The Principal Investigator (PI) is directly and primarily responsible for ensuring the protection of every subject who takes part in his or her research. All proposed human subjects research for which a JHSPH faculty member is PI must be submitted for CHR review and approval. JHSPH full-time or adjunct faculty are eligible to serve as PI; faculty with other appointments may only serve as PI when approved by CHR on a case-by-case basis. A PI whose primary appointment is in another Johns Hopkins institution should submit his or her research for review in that institution.

JHSPH Principal Investigators who conduct human subjects research are directly responsible for:

Conduct of the Research

- Obtaining CHR approval prior to commencing any human subjects research; this includes consulting with the Office for Research Subjects if there is any doubt as to whether the activity qualifies as human subjects research;
- Disclosing all actual or perceived conflicts of interests with regard to their research;
- Conducting the research according to the CHR-approved protocol;
- Providing sufficient oversight throughout the research to ensure that research staff are appropriately qualified, trained and supervised.
- Complying with all applicable provisions of the JHSPH FWA;
- Ensuring that risks to subjects are minimized, risks are reasonable in relation to anticipated benefit, and the selection of subjects is equitable;
- Ensuring that informed consent is sought from each subject, using a CHR-approved consent form or procedure, and that the consent is appropriately documented, unless the requirement for consent is waived by CHR;
- Ensuring that data collection is monitored to ensure subject safety, the protection of privacy and confidentiality of subjects, and that additional safeguards are included for vulnerable populations; and
- Submitting to CHR all changes in protocol(s) previously approved by CHR, and ensuring that changes in approved research are not initiated without prior CHR approval.

Recordkeeping and Reporting

- Ensuring that all research records and correspondence are maintained appropriately and are available upon request to authorized Federal officials and JHSPH auditors;
- Ensuring prompt reporting of proposed changes in a research activity;
- Ensuring prompt reporting to CHR and appropriate agencies of adverse events or unanticipated problems that harm, or create risks for, the research subjects;
- Maintaining copies of all research proposals reviewed, scientific evaluations, approved sample consent documents, progress reports submitted by investigators, reports of injuries to subjects, DSMB or Safety Monitor reports, records of continuing review activities, and correspondence between investigators and local IRBs or CHR;
- Maintaining all signed consent documents in the manner approved by CHR;
- Reporting progress to the CHR on an annual basis, at a minimum, or more frequently if required by CHR; and
- Accounting for any disclosure of protected health information.

Monitoring and Oversight

- Monitoring compliance with Federal human subjects protection regulations;
- Ensuring that all cooperating performance sites have appropriate OHRP-approved assurances; and
- Ensuring that all research performance sites have, and can document, appropriate mechanisms to protect research subjects.

Communication

- Complying with all research recordkeeping and reporting requirements,
- Ensuring that each potential research subject understands the nature of the research and of the subject's participation, taking all necessary steps to achieve that understanding, including communication of associated risks and benefits, and ensuring that participation is voluntary; and
- Providing a copy of the signed CHR-approved informed consent document to each subject at the time of consent, unless the requirement is waived by CHR.

Education and Training

- Ensuring that all personnel conducting or supporting human research demonstrate sufficient knowledge of protection of research participants; this includes all investigators and research staff completing the training required by JHSPH on the protection of human subjects prior to their taking part in the research;

- Ensuring that investigator(s) and the research team have sufficient scientific expertise to conduct the proposed human subjects research;
- Possessing knowledge about Federal regulations, applicable state law, the JHSPH FWA, and institutional policies and procedures for the protection of human subjects; and
- Being sufficiently educated in order to establish and maintain maximum compliance with Federal regulations and institutional policies relevant to the protection of human subjects.

Human Protections Administrator (Director, Office for Research Subjects)

The JHSPH Human Protections Administrator directs the Office for Research Subjects, is the administrative coordinator of the CHR review process, serves as OHRP's primary contact at JHSPH for issues related to CHR review, and plays an important role in communicating HRPP policies and practices to faculty, students and staff. The Director is responsible for ensuring that administrative policies and procedures related to the ethical review of human subjects research at JHSPH are consistently carried out. Additionally, the Director is the central point in the Office for Research Subjects for compliance with Federal and regulations and state laws.

The Director of the Office for Research Subjects is directly responsible for:

- Managing policies and procedures of the Office for Research Subjects and monitoring Office performance;
- Complying with all applicable provisions of the JHSPH FWA;
- Serving as a knowledgeable point of contact for OHRP;
- Ensuring that all cooperating performance sites have appropriate OHRP-approved assurances;
- Acting on behalf of the School to certify research that is exempt from Federal regulations;
- Serving as a voting non-scientist member of both CHRs,
- Serving as a voting member of the HRPP Executive Committee;
- Ensuring institution-wide communication and guidance on human subjects research;
- Possessing knowledge about the requirements of Federal regulations, applicable state and local laws, the JHSPH FWA, and JHSPH policies and procedures for the protection of human subjects; and
- Educating JHSPH faculty, students and staff on behalf of CHR on issues related to human subjects protection.

The Director of the Office for Research Subjects has oversight responsibility for:

- Coordinating full committee CHR meetings and ensuring that a majority of the CHR members are present, including at least one non-scientist;

- Ensuring that CHR records and correspondence are maintained appropriately and are available upon request to authorized Federal officials;
- Ensuring that changes in approved research, during a period in which approval has been granted, are not initiated without prior CHR approval;
- Ensuring the prompt reporting to CHR and appropriate agencies of any breaches of protocol or Federal regulations, or unanticipated injuries or problems involving risks to the research subjects;
- Maintaining copies of all research proposals reviewed, scientific evaluations, approved sample consent documents, progress reports submitted by investigators, reports of injuries to subjects, records of continuing review activities, correspondence between CHR and investigators; and
- Maintaining file copies of all CHR meeting minutes.

Office for Research Subjects

The Office for Research Subjects requires trained staff who possess knowledge of the Federal regulations, applicable State laws, the JHSPH Assurance, and the School's policies and procedures for the protection of human research subjects. The Office staff are responsible for the administrative and regulatory review of all JHSPH research submissions that involve human subjects. Office staff are selected and supervised by the Director, CHR.

Staff of the Office for Research Subjects are directly responsible for:

- Maintaining a dialogue with faculty and student investigators to support their efforts to prepare and submit for review protocols that accord fully with ethical and regulatory requirements,
- Providing administrative support for full committee CHR meetings,
- Ensuring that a quorum of CHR members is present, including at least one non-scientist, for all convened meetings of the CHRs,
- Ensuring that CHR meeting minutes include: attendance at the meeting; actions taken by the CHR; the votes on these actions, including the number voting for, against, and abstaining; when members leave the meeting for conflict-of-interest; the basis for requiring changes in or disapproving research; documentation of specific findings required by regulations; and a written summary of the discussion of controversial issues and their resolution,
- Maintaining file copies of all CHR meeting minutes,
- Monitoring compliance with relevant Federal regulations,
- Screening protocols before CHR review,
- Assigning protocols to CHR members for expedited review,
- Ensuring CHR records and correspondence are maintained appropriately and available upon request to authorized Federal officials,
- Maintaining copies of all research proposals reviewed, scientific evaluations, approved sample consent documents, progress reports submitted by investigators, reports of adverse events and unanticipated problems,

certificates of confidentiality records of continuing review activities, and correspondence between the CHR and investigators,

- Ensuring that all cooperating performance sites have appropriate OHRP-approved Assurances,
- Preparing regular and periodic performance reports on CHR activities for the School's faculty and administration,
- Initiating and/or composing routine correspondence to investigators, and
- Possessing knowledge of and complying with the requirements of Federal regulations, applicable State law, the School's Assurance, and institutional policies and procedures for the protection of human subjects by engaging in professional development, such as certification, and by participating in professional associations.

Research Regulations Specialist

The Research Regulations Specialist coordinates and supports a program for ensuring HRPP compliance with the Federal regulations involving human subjects research and other ethical and research-related compliance issues. The specific roles and responsibilities of the Research Regulations Specialist are as follows:

- Possessing knowledge about the requirements of Federal regulations, applicable state and local laws, the JHSPH FWA, and JHSPH policies and procedures for the conduct of human subjects research;
- Serving as a resource for CHR members and Co-Chairs, the Executive Committee, Office for Research Subjects staff and investigators on regulatory issues that arise in the review and conduct of human subjects research,
- Promoting understanding of, and compliance with, all elements of the HRPP with Federal, state and local regulations, by CHR members, staff and investigators,
- Identifying and addressing potential vulnerabilities in achieving compliance in research studies by working closely with various University offices, such as the Office of Research Administration, the Office for Research Subjects, Office of the General Counsel and the Department of Health, Safety and Environment, and preparing reports to the appropriate institutional officials and the Committees on Human Research,
- Ensuring that research performance sites have, and can document, appropriate mechanisms to protect research subjects,
- Providing consultation and administrative review on all human subjects research proposals covered by HIPAA,
- Performing for-cause audits of research projects at the instruction of the Executive Committee and/or the CHRs,

- Providing updates and on-going education to the JHSPH research community regarding changes in research-related regulations and legal requirements, and
- Planning, organizing and implementing a quality assessment and quality improvement program for the HRPP.

DEFINITIONS

RESOURCES & REFERENCES

OHRP Requirement _____
FDA Requirement _____
AAHRPP Element _____