



FOUNDED BY BRIGHAM AND WOMEN'S HOSPITAL
AND MASSACHUSETTS GENERAL HOSPITAL

Title:	Requirements for Ancillary Committee Approval of Human-Subjects Research
Department:	Human Research Affairs
Policy Type:	<input checked="" type="checkbox"/> Partners System-wide <input type="checkbox"/> Partners System-wide Template <input type="checkbox"/> Partners Corporate <input type="checkbox"/> Partners Corporate Departmental <input type="checkbox"/> Entity
Applies to:	Employees, Professional Staff or Other Agents of Brigham and Women's Hospital (BWH), Faulkner Hospital (FH), Massachusetts General Hospital (MGH), McLean Hospital (McLean), and North Shore Medical Center (NSMC)
Approved by:	Chief Academic Officer
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Contact Person:	Director, Human Research Review and Compliance

KEYWORDS:

IRB, Institutional Review Board

PURPOSE:

The purpose of this policy is to define the requirements and procedures for obtaining approval of various institutional committees, departments, groups or individuals ("ancillary committees") of non-exempt human-subjects research reviewed by the Partners Human Research Committees (PHRC).

DEFINITIONS:

See Definition of Human-Subjects Research

Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. [45 CFR 46.102(i)][21 CFR 56.102(i)]

POLICY STATEMENT:

Non-exempt human-subjects research approved by the PHRC are subject to additional review by institutional committees, departments, groups or individuals as follows:

1. Pharmacy Review

The applicable institutional research pharmacy committees must review and approve human research that meets the following criteria:

- Research activities that direct drug administration, whether the drug is FDA-approved or not; or
- Research activities in which ancillary drugs are given for any procedure/test required by protocol (not for clinical care of the patient).

2. Biosafety Review

The Partners Institutional Biosafety Committee (IBC) must review and approve human studies involving recombinant DNA, RNA inhibition (RNAi), microbiological agents (bacteria/viruses), gene transfer or animal to human transplantation. Additionally, research laboratories utilizing unfixed human materials (tissues, blood, cells) must be registered with the PIBC.

3. Biomedical Engineering Review

The applicable institutional Biomedical Engineering departments must review and approve human research that meets the following criteria:

- Research activities involving electrically (line or battery) powered devices, whether the device is FDA-approved or not;
- Research activities involving the non-standard use of hospital electrically (line or battery) powered devices; or
- Research activities involving the use of non-hospital inventory electrically (line or battery) powered devices.

The use of any commercially available medical device in research must meet the same hospital safety standards as medical devices being used for patient care and as such is subject to the institution's medical equipment management program.

4. Radiation Safety Review

The applicable institution's radiation safety committee must review and approve human research that meets the following criteria:

- Research activities involving exposure to ionizing radiation for research purposes (e.g., x-rays, fluoroscopy, CT)
- Research activities involving exposure to nonionizing radiation for research purposes (e.g., magnetic resonance imaging, ultrasound, and the use of lasers or other optical devices); or
- Research to determine the safety and/or effectiveness of a radioactive drug.

5. Radioactive Drug Review

The applicable institution's Radioactive Drug Research Committee (RDRC) must review and approve human research that involves the use of radiopharmaceuticals to obtain basic information regarding the metabolism (including kinetics, distribution, and localization) or basic information about human physiology, pathophysiology, or biochemistry. The RDRC does not review the use of radiopharmaceuticals intended for immediate therapeutic,

diagnostic or similar purposes or to determine the safety and/or effectiveness of the drug in humans (i.e., to carry out a clinical trial).

6. Nursing Review

The applicable institution's Nursing department must review and approve human research that will be conducted in the Emergency Department or on Inpatient Care Units (except the GCRC), or human research that involves the use of nurses as subjects; for example, surveys or interviews on nursing practice or observation of nurses in the performance of employment-related duties. Investigators must indicate whether nursing staff may be asked to perform any of the following research-related activities:

- Administering and monitoring of investigational medications and devices;
- Procuring of any research-related specimens;
- Insertion of additional research-required intravenous catheters;
- Accompanying subjects to research-required tests;
- The use of research technology and equipment; or
- Collection of data for research purposes.

7. Partners Embryonic Stem Cell Oversight Committee (ESCRO)

The ESCRO Committee must review and approve research activities that involve the derivation and/or use of human embryonic stem cells (hESC). The Committee must also review and approve research activities that involve certain sensitive uses of other human pluripotent stem cells (hPSCs), as described in the *Investigator Guidance: Derivation and Use of Human Induced Pluripotent Stem (iPS) Cells and Other Human Pluripotent Stem Cells (hPSCs) Derived from Non-Embryonic Sources*.

PROCEDURES:

1. Investigators who rely upon the PHRC for IRB review of human-subjects research are required to complete Insight/eIRB application forms and provide all required information and documents to the Partners Human Research Office for review as described in the Protocol Submission Instructions and forms for continuing review and amendments.
2. The Human Research Office notifies the relevant ancillary committee(s) of new human-subjects research applications and related documents that require their review as well as all proposed changes in approved research that require their review.
3. The ancillary committees are responsible for communicating issues and/or concerns to the investigators and to the PHRC via Insight, and when approved, for notifying investigators and the Partners Human Research Office of approval.
4. The PHRC may approve the research, but activation of the research by the Human Research Office is subject to documentation in Insight of approval by all applicable ancillary committee(s).
5. When the PHRC approves the research and the ancillary committee requests modifications, the reviewing PHRC Chairpersons follow the policies and procedures for review of proposed changes during period of approval. Minor changes may be approved by expedited review. Changes that are not minor are referred for review by the PHRC at a convened meeting.

6. Investigators proposing hESC research to derive new hESCs must receive final sign-off from the Institutional Official (IO) before they commence their research. The ESCRO Office receives all relevant approvals (PHRC, ESCRO Committee, and when applicable, Institutional Biosafety Committee). The ESCRO Office is responsible for notifying the IO when all approvals are completed.

DEVELOPMENT AND CONSULTATION

BWH Investigational Drug Service
 MGH Clinical Trials Pharmacy
 Partners Institutional Biosafety Committee
 BWH/MGH Radiation Safety Committee
 BWH/MGH Radioactive Drug Research Committee
 Partners Biomedical Engineering
 BWH/MGH Department of Nursing
 Partners Embryonic Stem Cell Oversight Committee (ESCRO)

Reviewed by:	Original Review Date:	Revision Approval Dates: