Mass General Brigham

Title:	Requirements for Ancillary Committee Approval of Human Subject Research
Department:	Human Research Affairs
Policy Type:	Mass General Brigham System-wide
Applies to:	Employees, Professional Staff or Other Agents of Mass General Brigham
Approved by:	Chief Academic Officer
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Contact Person:	Director, Human Research Office

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 subject research reviewed by the Mass General Brigham IRB.

DEFINITIONS:

See Definitions in Human Subject Research

POLICY STATEMENT:

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

1. Pharmacy Review

   The applicable Mass General Brigham research pharmacy committee 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 Mass General Brigham 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 Mass General Brigham IBC.

3. Biomedical Engineering Review

   The applicable Mass General Brigham Biomedical Engineering department 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 Mass General Brigham 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 Mass General Brigham 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 Mass General Brigham Nursing department must review and approve human research that will be conducted in the Emergency Department or on Inpatient Care Units (except the Translational and Clinical Research Center), 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. Embryonic Stem Cell Research 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*.

8. CMS Coverage Analysis
   Any protocol that involves potential medical billing activity must be reviewed through a hospital or Mass General Brigham central financial office to conduct a coverage analysis. Protocols are referred to the appropriate financial office through the Insight system by HRO staff. Approval or a determination that no coverage analysis is needed must be provided before IRB-approved protocols are released to investigators.

9. Research Information Security Office
   The applicable Mass General Brigham Information Security & Privacy Office must review and approve human research that meets the following criteria:
   - Research activities involve certain technology that will collect, process and store Protected Health Information (PHI), Personally Identifiable Information (PII) or other Confidential data. Technology includes, but is not limited to, internally developed applications, wearable devices, wireless devices, cloud-based systems, mobile and web-based applications, mobile/medical devices connecting to Mass General Brigham network
   - Research activities involve collecting, processing and storing data that is protected by federal or foreign privacy laws and regulations (i.e. FISMA, GDPR)

   For more information, visit the Research Information Security Office page.

10. Office for Interactions with Industry
    Ancillary review of protocols with research staff who have individual financial interests that may create a conflict of interest are reviewed as described in the Human Research Affairs policy "Individual Financial Conflicts of Interest. Protocols in which an institutional conflict of interest may exist are reviewed as described in the Human Research Affairs policy "Institutional Conflicts of Interest."

PROCEDURES:

1. Investigators who rely upon the IRB for review of human subject research are required to complete Insight application forms and provide all required information and documents to the IRB for review as described in the Protocol Submission Instructions and forms for continuing review and amendments.

2. The IRB notifies the relevant ancillary committee(s) of new human subject 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 IRB via Insight, and when approved, for notifying investigators and the Mass General Brigham IRB of approval.

4. The IRB 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 IRB approves the research and the ancillary committee requests modifications, the reviewing IRB Chairperson or designee follows the policies and procedures for review of proposed changes during the period of approval. Minor changes may be approved by expedited review. Changes that are not minor are referred for review by the IRB 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 (IRB, ESCRO Committee, and when applicable, Institutional Biosafety

Committee). The Human Research Office is responsible for notifying the IO when all approvals are completed.

DEVELOPMENT AND CONSULTATION:

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