

PARTNERS HUMAN RESEARCH COMMITTEE POLICIES AND PROCEDURES

Requirements for Ancillary Committee Approval

1.0 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 and clinical investigations reviewed by the Partners Human Research Committees (PHRC).

2.0 SCOPE

Non-exempt human-subjects research and clinical investigations reviewed by the PHRC are subject to this policy.

3.0 DEFINITIONS

As used in this document, human-subjects research encompasses activities that meet the DHHS definitions of *research* and *human subject* and/or the FDA definitions of *clinical investigation* and *human subject*. The DHHS definition for *research* and *human subject* and the FDA definition for *clinical investigation* and *human subject* are provided below.

Research means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. [45 CFR 46.102(d)]

Human subject means a living individual about whom an investigator (whether professional or student) conducting research obtains (1) Data through intervention or interaction with the individual, or (2) Identifiable private information. *Intervention* includes both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject’s environment that are performed for research purposes. *Interaction* includes communication or interpersonal contact between investigator and subject. *Private information* includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example,

a medical record). Private information must be individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects. [45 CFR 46.102(f)(1)(2)]

Clinical investigation means any experiment that involves a test article and one or more human subjects and that either is subject to requirements for prior submission to the Food and Drug Administration under section 505(i) or 520(g) of the act, or is not subject to requirements for prior submission to the Food and Drug Administration under these sections of the act, but the results of which are intended to be submitted later to, or held for inspection by, the Food and Drug Administration as part of an application for a research or marketing permit. The term does not include experiments that are subject to the provisions of part 58 of this chapter, regarding nonclinical studies. The terms *research*, *clinical research*, *clinical study*, *study*, and *clinical investigation* are deemed to be synonymous... [21 CFR 50.3(c) and 21 CFR 56.102(c)]

Human subject means an individual who is or becomes a participant in research, either as a recipient of the test article or as a control. A subject may be either a healthy human or a patient. [21 CFR 50.3(g) and 21 CFR 56.102(g)]

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)]

4.0 POLICY

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

4.1 Investigational Drug Service/ Pharmacy Committee

The BWH Investigational Drug Service and/or the MGH 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 and not for clinical care of the patient.

4.2 Harvard Committee on Microbiological Safety

The Harvard Committee on Microbiological Safety (COMS) must review and approve human research that involves recombinant DNA, microbiological agents (bacteria/viruses), gene therapy or animal to human transplantation. All such uses must be registered with COMS.

4.3 Biomedical Engineering

The Partners Department of Biomedical Engineering must review and approve human research that meets the following criteria:

- Research activities involving electrically (line or battery) powered investigational devices;
- 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.

4.4 Radiation Safety Committee

The BWH Radiation Safety Committee and/or the MGH Radiation Safety Committee must review and approve human research that meets the following criteria:

- Research activities involving exposure to ionizing radiation for research purposes; or
- Research activities involving exposure to nonionizing radiation for research purposes.

4.5 Radioactive Drug Research Committee (RDRC)

The 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).

4.6 Nursing

The Department of Nursing must review and approve research activities that involve facilitation by nurses or other members of Patient Care Services, such as:

- 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.

4.7 Partners Embryonic Stem Cell Oversight Committee (ESCRO)

The ESCRO Committee must review and approve research activities that meet the following criteria:

- Derivation of human embryonic stem cells (hESC) from an embryo created via fertilization, via somatic cell nuclear transfer or via parthenogenesis; or
- The use of hESCs that retain any identifiable information that links them to gamete or somatic cell donors.

5.0 PROCEDURES

Investigators who rely upon the PHRC for IRB review of human-subjects research are required to complete 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.

5.1 The Human Research Office provides the relevant ancillary committee(s) with a copy of all 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.

5.2 The ancillary committees are responsible for communicating issues and/or concerns to the investigators and to the PHRC and when approved, for providing written notification of approval to the investigator and Partners Human Research Office.

- 5.3 The PHRC may approve the research, but activation of the research by the Human Research Office is subject to receipt of written documentation of approval from all applicable ancillary committee(s).
- 5.4 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.
- 5.5 Investigators proposing hESC research 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.