PARTNERS HEALTHCARE | FOUNDED BY BRIGHAM AND WOMEN'S HOSPITAL AND MASSACHUSETTS GENERAL HOSPITAL

Title:	Human-Subject Protection Education and Training Requirements for Investigators and Study Staff
Department:	Human Research Affairs
Policy Type:	☑ Partners System-wide ☐ Partners System-wide Template ☐ Partners HealthCare ☐ Partners HealthCare Departmental ☐ Institution
Applies to:	Employees, Professional Staff or Other Agents of Brigham and Women's Hospital (BWH), Brigham and Women's Faulkner Hospital (BWFH), Massachusetts General Hospital (MGH), McLean Hospital (McLean), North Shore Medical Center (NSMC), Spaulding Rehabilitation Hospital (SRH), and MGH Institute of Health Professions (MGH IHP)
Approved by:	Chief Academic Officer
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Current Revision Effective Date:	May 1, 2017
Next Review Date:	May 1, 2020
Contact Person:	Director, Human Research Review and Compliance

KEYWORDS:

IRB, Institutional Review Board

PURPOSE:

The purpose of this policy is to ensure that individuals conducting non-exempt human-subjects research overseen by the Partners Human Research Committee (PHRC) understand the ethical principles and regulations related to the protection of human subjects of research.

DEFINITIONS:

See Definition of Human-Subjects Research

POLICY STATEMENT:

The applicable Partners-affiliated entities have a legal and ethical responsibility to protect the rights and welfare of human subjects participating in research conducted or sponsored by them or under the auspices of the applicable Partners-affiliated entities, or in which the entities are otherwise engaged regardless of the location of the research or source of funding. Consistent with these responsibilities, the applicable Partners-affiliated entities require every individual engaged in non-exempt human-subjects research overseen by the Partners Human Research Committee to complete the web-based

Collaborative IRB Training Initiative (CITI) CITI Basic Biomedical, CITI Basic Social and Behavioral, or CITI Good Clinical Practice (GCP) course prior to their involvement in the research. In addition, one of the applicable continuing education/refresher courses must be completed every three years. The PHRC may accept an equivalent human-subject protection education course on a case-by-case basis. Notwithstanding this policy, the PHRC may require an investigator to fulfill additional education and training requirements, such as training in Good Clinical Practice, based on the type of research (e.g., IND/IDE sponsor-investigator research) or as part of remedial education.

Sponsors, such as the National Institutes of Health (NIH) may have additional training requirements. For example, NIH requires individuals engaged in NIH-funded *clinical trials* to complete training in Good Clinical Practice (GCP) every three years. *Clinical trials* as defined by NIH are studies in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control; need not be randomized) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes.

PROCEDURES:

1. New non-exempt research involving human subjects will not be approved by the PHRC until all of the study staff listed on the protocol have completed the human-subject protection education requirements (CITI or equivalent education program) including, when applicable, continuing education requirements. Completion of the CITI or equivalent education programs will be recorded in the Insight User Profile Training tab and will display on the Staff & Access page of the protocol record.

2. The addition of new study staff will not be approved by the PHRC unless the individual(s) being added via amendment has completed the human-subject protection education requirements (CITI course) including, when applicable, continuing education requirements.

3. At continuing review, the research will not be re-approved by the PHRC unless all of the study staff listed on the protocol have completed the human-subject protection education requirements (the CITI program) including, when applicable, continuing education requirements.

4. The Principal Investigator may elect to remove individuals from the study staff who have not completed the education requirements so that the study may be re-approved; however these individuals may not continue to function as part of the study staff unless and until they have completed the education requirements and an amendment to add them to the study staff has been submitted and approved by the PHRC.

5. Principal Investigators are responsible for ensuring that the study staff listed on their protocols complete their continuing education requirements every three years. Completion of the required CITI human subject protection education courses can be verified in Insight on the Staff & Access page of the protocol record or by use of the Insight Training Lookup functionality. Failure on the part of the study staff to comply with the human-subject protection continuing education requirements will be considered noncompliance with PHRC policies and procedures and should be reported at continuing review as a minor protocol deviation/violation.

6. In addition to the mandatory human-subject protection education requirements, investigators and study staff are strongly encouraged to take advantage of the many education and training opportunities offered through the BWH Center for Clinical Investigation (CCI) and MGH Clinical Research Program (CRP).

DEVELOPMENT AND CONSULTATION

Human Research Office