Mass General Brigham

Title:	Human Subject Protection Education and Training Requirements for Investigators and Study Staff
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
Original Approval Date:	September 9, 2010
Original Effective Date:	September 9, 2010
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Current Revision Effective Date:	December 1, 2020
Next Review Date:	January 15, 2022
Contact Person:	Director, Human Research Office

KEYWORDS:

IRB, Institutional Review Board

PURPOSE:

The purpose of this policy is to ensure that individuals conducting human subject research overseen by the Mass General Brigham Institutional Review Board understand the ethical principles and regulations related to the protection of human subjects of research.

DEFINITIONS:

See Definitions in Human Subject Research

POLICY STATEMENT:

The applicable Mass General Brigham-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 Mass General Brigham-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 Mass General Brigham-affiliated entities require every individual engaged in human subject research overseen by the Mass General Brigham IRB to complete the web-based

Collaborative IRB Training Initiative (CITI) Basic Biomedical, Basic Social and Behavioral, or 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 Mass General Brigham IRB may accept an equivalent human subject protection education course on a case-by-case basis.

Notwithstanding this policy, the Mass General Brigham IRB may require an investigator to fulfill additional education and training requirements, such as training in Good Clinical Practice, based on the type of research they are conducting (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.

PROCEDURES:

1. New research involving human subjects will not be approved by the Mass General Brigham IRB 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 Study Staff Form page of the protocol record.

2. The addition of new study staff will not be approved by the Mass General Brigham IRB 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 Mass General Brigham IRB 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 Mass General Brigham IRB.

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 Study Staff Form 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 Mass General Brigham IRB policies and procedures and must 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