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
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Next Review Date:	April 3, 2024
Contact Person:	Director, IRB 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:

Mass General Brigham has a legal and ethical responsibility to protect the rights and welfare of human subjects participating in research it conducts or sponsors, or in which Mass General Brigham is otherwise engaged regardless of the location of the research or source of funding. Consistent with these responsibilities, Mass General Brigham requires every individual engaged in human subject research overseen by the Mass General Brigham IRB to have appropriate training in human subjects protections. Employees of Mass General Brigham and members of their research teams must complete the HRA Good Clinical Practice (GCP) and Clinical Research Boot Camp live webinar or online courses in HealthStream

prior to their involvement in the research. In addition, both courses must be completed every three years. For research conducted by sites for which Mass General Brigham is serving as the single IRB under an IRB reliance agreement, the reliance agreement obligates the site to require appropriate human subjects training according to their local policies and procedures.

Notwithstanding this policy, the Mass General Brigham IRB may require an investigator to fulfill additional education and training requirements based on the type of research they are conducting (e.g., IND/IDE sponsor-investigator research) or as part of remedial education. It is strongly recommended, in addition to the training requirements listed above, that individuals take one or more of the human subject research education courses offered by the Human Research Affairs Compliance and Education Office (Pages - Education Courses and Certifications (sharepoint.com).

Sponsors or funding entities may have additional training requirements that need to be met in addition to MGB's human subject protection education requirements.

PROCEDURES for Mass General Brigham Employees and Research Team Members:

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 including, when applicable, continuing education requirements. Completion of the 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 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 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 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 recorded as a minor protocol deviation/violation.