Mass General Brigham

Title:	Proposed Changes in IRB Approved Research and Exceptions
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:	June 4, 2007
Original Effective Date:	June 4, 2007
Revision Approval Date(s):	September 8, 2010; March 7, 2014; May 1, 2017
Current Revision Effective Date:	October 1, 2021
Next Review Date:	October 1, 2022
Contact Person:	Director, Human Research Office

KEYWORDS:

IRB, Institutional Review Board

PURPOSE:

The purpose of this policy is to define the procedures the Mass General Brigham IRB follows to ensure prompt reporting to the IRB of proposed changes, including single subject or other limited exceptions, in approved non-exempt human-subjects research and for ensuring that changes are not initiated without IRB review and approval, except where necessary to eliminate apparent immediate hazards to subjects. [45 CFR 46.108(a)(3)(iii) and 21 CFR 56.108(a)(4)]

DEFINITIONS:

See Definitions in Human Subject Research

POLICY STATEMENT:

Investigators conducting human subject research approved by the Mass General Brigham IRB are required to submit proposed changes in approved research, including single subject or other limited exceptions, for review and approval prior to initiation of the change except where necessary to eliminate apparent immediate hazards to subjects.

PROCEDURES:

The procedures the IRB follows to ensure that investigators submit proposed changes in approved human subject research, including single subject or other limited exceptions, for approval prior to initiation are as follows:

1. The IRB reviews proposed changes, including exceptions, in non-exempt approved human

subject research according to the procedures described in the policies for initial and continuing review of non-exempt human subject research, and review of proposed changes in approved research.

2. Changes made without IRB approval to eliminate apparent immediate hazards to subjects must be reported to and reviewed by the IRB as described in the policy on *Reporting Unanticipated Problems including Adverse Events*.

3. The IRB informs investigators via the written approval notification letters that they must submit changes in approved research for approval prior to initiation.

4. The Human Research Affairs Compliance & Education Office assesses compliance with applicable regulations and IRB requirements during onsite reviews. Such reviews may identify failure to obtain IRB approval of proposed changes in approved research prior to initiation. In such cases, investigators are required to complete and submit an Insight Other Event form to the IRB for review.

5. Educational programs, lectures, random audits, focus groups, and departmental Q/A sessions address this requirement.

OTHER APPLICABLE MASS GENERAL BRIGHAM IRB POLICIES:

Reporting Unapproved Deviations in IRB Approved Research

Reporting Unanticipated Problems including Adverse Events

REFERENCES:

45 CFR 46
21 CFR 56

DEVELOPMENT AND CONSULTATION:

Human Research Office