Mass General Brigham

Title:	Reporting to Institutional Officials, Regulatory Agencies and Accrediting Organizations
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:	December 6, 2007
Original Effective Date:	December 6, 2007
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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 when reporting: (1) any unanticipated problem involving risks to subjects or others; (2) any serious or continuing noncompliance with Department of Health and Human Services (DHHS) or Food and Drug Administration (FDA) regulations or the requirements or determinations of the Mass General Brigham IRB; or (3) any suspension or termination of Mass General Brigham IRB-approved human subject research.

The policies and procedures for prompt reporting and Mass General Brigham IRB review of reports of unanticipated problems, noncompliance, and suspensions or terminations of Mass General Brigham IRB-approved human subject research are covered in separate Mass General Brigham IRB policies, which include *Reporting Unanticipated Problems including Adverse Events*, *Review of Unanticipated Problems in Human Subject Research*, *Suspension or Termination of Human Subject Research*, and *Noncompliance in Human Subject Research.*

Non-exempt human subject research and clinical investigations that require Mass General Brigham IRB review are subject to this policy.

DEFINITIONS:

See Definitions in Human Subject Research

POLICY STATEMENT:

Consistent with federal regulations, the Mass General Brigham IRB is responsible for reporting on behalf of the institutions: (i) any unanticipated problems involving risks to subjects or others; (ii) any serious or continuing noncompliance; or (iii) any suspension or termination of Mass General Brigham IRB-approved non-exempt human subject research to the applicable institutional officials and, as required or appropriate, to the applicable regulatory agencies.

The Federalwide Assurances (FWAs) of the applicable Mass General Brigham-affiliated entities are designated to apply to federally supported or conducted human subject research. In general, the same criteria and process for the conduct and oversight of human subject research, for determinations about reportable events, and for actions taken in response to such events will apply to all human subject research in which the applicable Mass General Brigham-affiliated entities are engaged, regardless of funding source. However, if such an event involves human subject research that is not federally conducted or supported, the Mass General Brigham IRB is not required to report the event to the Office for Human Research Protections (OHRP) or other relevant federal department or agency head (reporting to the FDA may still be required, if the research is subject to FDA regulations). The IRB may voluntarily report any such event to OHRP or other agencies in its discretion. All other reporting requirements described below apply regardless of funding source.

In addition to the above reporting requirements to institutional officials and regulatory agencies, Mass General Brigham Human Research Office (HRO) is responsible for reporting any major event to the Association for the Accreditation of Human Research Protection Programs (AAHRPP) to comply with AAHRPP's reporting requirements for accredited organizations.

PROCEDURES:

The Director, HRO or designee is responsible for preparing incident reports, which include the following information or for reports to the OHRP, the information required on the OHRP Incident Report Form:

- Name of the institution and the principal investigator conducting the research;
- Title of the research project and protocol number assigned by the Mass General Brigham IRB and the number of any applicable federal award(s)(grant, contract, or cooperative agreement);
- The nature of the event (unanticipated problem involving risks to subjects or others, serious or continuing noncompliance, suspension or termination of approval of research);
- A description of the problem including the findings of the Mass General Brigham IRB and the reasons for the decision;
- Actions the Mass General Brigham IRB and, if applicable, the institution is taking or plans to take to address the problem (e.g., revise the protocol, suspend enrollment, terminate the research, revise the informed consent document, inform enrolled subjects, increase monitoring of subjects, etc.); and
- Plans, if any, to send a follow-up or final report by the earlier of: (a) a specified date, or (b) when the investigation has been completed or a corrective action plan has been implemented.

The Vice President, Human Research Affairs is responsible for review and approval of the final incident report. The report is sent to the following:

1. Institutional officials
    - Signatory of the FWA
    - Director, Human Research Office
    - Director, Mass General Brigham Research Compliance

2. Regulatory Agencies and Accrediting Organizations
    - OHRP
      [Note: As reflected in Section 4.0 above, reporting to OHRP is not required unless the study is federally supported or conducted. This change was effective February 5, 2009.]
    - FDA, if the study is subject to FDA regulations
    - AAHRPP, if a major event, within 24 hours after the accredited Organization (or Researcher) becomes aware of any of the following:
        - Catastrophic event that results in an interruption or discontinuance in a component of or the entire Human Research Protection Program;
        - Sanctions taken by a government oversight office, including, but not limited to, OHRP Determination Letters, FDA Warning Letters, FDA 483 Inspection Reports with official action indicated, and FDA Restrictions Placed on IRBs or Investigators;
        - Any litigation, arbitration or settlements initiated related to human research protection; or
        - Any press coverage (including but not limited to radio, TV, newspaper, online publications) of a negative nature regarding the Organization's HRPP.

3. Others
    - Any Common Rule Federal Agency that is supporting the research, when applicable
    - The Privacy Officer of the institution, if the report involves unauthorized use, loss, or disclosure of individually identifiable patient information from the covered entity
    - Others, such as the Chief Medical Officer, Corporate Sponsor or Entity supporting the research, deemed appropriate by the Institutional Officials named above

The Human Research Office Director or designee will ensure that all steps of this policy are completed generally within 30 days of the date when:

- The Mass General Brigham IRB determines that an incident is an unanticipated problem involving risks to subjects or others;
- The Mass General Brigham IRB determines that an incident is serious or continuing noncompliance with DHHS or FDA regulations or the requirements or determinations of the Mass General Brigham IRB; or
- The Mass General Brigham IRB or Institutional Official suspends or terminates Mass General Brigham IRB-approved research.

OTHER APPLICABLE MASS GENERAL BRIGHAM POLICIES:

Reporting of Unanticipated Problems including Adverse Events
Review of Unanticipated Problems in Human Subject Research
Suspension or Termination of Human Subject Research
Noncompliance in Human Subject Research

REFERENCE:

45 CFR 46
21 CFR 56

DEVELOPMENT AND CONSULTATION

Human Research Office
Office of the General Counsel