

Title:	Reporting to Institutional Officials, Regulatory Agencies and Accrediting Organizations
Department:	Human Research Affairs
Policy Type:	<input checked="" type="checkbox"/> Partners System-wide <input type="checkbox"/> Partners System-wide Template <input type="checkbox"/> Partners HealthCare <input type="checkbox"/> Partners HealthCare Departmental <input type="checkbox"/> Institution
Applies to:	Employees, Professional Staff or Other Agents of Brigham and Women's Hospital (BWH), Faulkner Hospital (FH), Massachusetts General Hospital (MGH), McLean Hospital (McLean), and North Shore Medical Center (NSMC)
Approved by:	Chief Academic Officer
Original Approval Date:	December 6, 2007
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Current Revision Effective Date:	August 1, 2014
Next Review Date:	August 1, 2017
Contact Person:	Director, Human Research Review and Compliance

KEYWORDS:

IRB, Institutional Review Board

PURPOSE:

The purpose of this policy is to define the procedures the Partners Human Research Committees (PHRC) follow 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 FDA regulations or the requirements or determinations of the PHRC; or (3) any suspension or termination of PHRC-approved human-subjects research.

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

Non-exempt human-subjects research and clinical investigations that require PHRC review are subject to this policy.

DEFINITIONS:

See Definition of Human-Subjects Research

POLICY STATEMENT:

Consistent with federal regulations, the PHRC 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 with Department of Health and Human Services (DHHS) or FDA regulations or the requirements or determinations of the PHRC; or (iii) any suspension or termination of PHRC-approved non-exempt human-subjects research to the applicable institutional officials and, as required or appropriate, to the applicable regulatory agencies.

The Federalwide Assurances (FWAs) of the applicable Partners-affiliated entities are designated to apply to federally supported or conducted human-subjects research. In general, the same criteria and process for the conduct and oversight of human-subjects research, for determinations about reportable events, and for actions taken in response to such events will apply to all human-subjects research in which the applicable Partners-affiliated entities are engaged, regardless of funding source. However, if such an event involves human-subjects research that is not federally conducted or supported, the 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 Food and Drug Administration (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, the PHRC 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 and Chair of the PHRC or designee is responsible for preparing incident reports, which include the following information:

- The nature of the event (unanticipated problem involving risks to subjects or others, serious or continuing noncompliance, suspension or termination of approval of research);
- Name of the institution conducting the research;
- Number of the research project assigned by the PHRC and the number of any applicable federal award(s)(grant, contract, or cooperative agreement);
- A detailed description of the problem including the findings of the institution and the reasons for the decision;
- Actions 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.
- 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 Director and Chair of the PHRC is responsible for review and approval of the final incident report. The report is sent to the following:

1. PHRC
2. Institutional officials

- Signatory of the FWA
- Director, Human Research Affairs
- Director, Human Research Review and Compliance
- Director, Partners Research Compliance

3. 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.]
- Food and Drug Administration (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, and FDA Restrictions Placed on IRBs or Investigators; or
 - Any lawsuits related to human research protection.

4. Others

- Principal investigator
- Supervisor of the principal investigator
- 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 Director and Chair of the PHRC or designee will ensure that all steps of this policy will be completed generally within 30 days of the date when:

- The PHRC determines that an incident is an unanticipated problem involving risks to subjects or others;
- The PHRC determines that an incident is serious or continuing noncompliance with Department of Health and Human Services (DHHS) or FDA regulations or the requirements or determinations of the PHRC; or
- The PHRC or Institutional Official suspends or terminates PHRC-approved research.

OTHER APPLICABLE PARTNERS HEALTHCARE POLICIES:

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

REFERENCE:

45 CFR 46
 21 CFR 56

DEVELOPMENT AND CONSULTATION

Human Research Office

Office of the General Counsel

Reviewed by:	Original Review Date:	Revision Approval Dates:
Dennis A. Ausiello, MD, Chief Scientific Officer	December 16, 2010	
Anne Klibanski, MD, Chief Academic Officer		May 5, 2015