

PARTNERS HUMAN RESEARCH COMMITTEE POLICIES AND PROCEDURES

Reporting to Institutional Officials and Regulatory Agencies

1.0 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 *Prompt Reporting of Unanticipated Problems*, *Adverse Event Reporting Policy*, *Review of Unanticipated Problems*, *Suspension or Termination of Research*, and *Noncompliance Policy*.

2.0 SCOPE

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

3.0 DEFINITIONS

Human-subject research means activities that meet the DHHS definition of *research* and involve a *human subject* as defined by DHHS or meet the FDA definition of *clinical investigation* and involve a *human subject* or *subject* as defined by FDA. The DHHS definition for *research* and *human subject* and the FDA definition for *clinical investigation*, *human subject*, and *subject* are provided below:

Research as defined by DHHS means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. [45 CFR 46.102(d)]

Human subject as defined by DHHS means a living individual about whom an investigator (whether professional or student) conducting research obtains (1) Data through intervention or

interaction with the individual, or (2) Identifiable private information. *Intervention* includes both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes. *Interaction* includes communication or interpersonal contact between investigator and subject. *Private information* includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record). Private information must be individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects. [45 CFR 46.102(f)(1)(2)]

Clinical investigation as defined by FDA means any experiment that involves a test article and one or more human subjects and that either is subject to requirements for prior submission to the Food and Drug Administration under section 505(i) or 520(g) of the act, or is not subject to requirements for prior submission to the Food and Drug Administration under these sections of the act, but the results of which are intended to be submitted later to, or held for inspection by, the Food and Drug Administration as part of an application for a research or marketing permit. The term does not include experiments that are subject to the provisions of part 58 of this chapter, regarding nonclinical studies. The terms *research*, *clinical research*, *clinical study*, *study*, and *clinical investigation* are deemed to be synonymous... [21 CFR 50.3(c) and 21 CFR 56.102(c)]

Human subject as defined by FDA means an individual who is or becomes a participant in research, either as a recipient of the *test article* or as a control. A subject may be either a healthy human or a patient. [21 CFR 50.3(g) and 21 CFR 56.102(g)]

Test article as defined by FDA means any drug (including a biological product for human use), medical device for human use, human food additive, color additive, electronic product or any other article subject to regulation under the act or under sections 351 and 354-360F of the Public Health Service Act (42 U.S.C. 262 and 263b-263n).

Subject as defined by FDA means a human who participates in an investigation, either as an individual on whom or on whose specimen an

investigational device is used or as a control. A subject may be in normal health or have a medical condition or disease [21 CFR 812.3(p)].

4.0 POLICY

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 Brigham and Women's Hospital, Inc. (BWH) and of The General Hospital Corporation d/b/a Massachusetts General Hospital (MGH) 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 BWH and MGH 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.

5.0 PROCEDURES

- 5.1 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.

5.2 The Director and Chair of the PHRC is responsible for review and approval of the final incident report.

5.3 The report is sent to the following:

5.3.1 PHRC

5.3.2 Institutional officials

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

5.3.3 Regulatory Agencies

- 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 is effective for studies approved (or approved with modifications) on or after February 5, 2009.]
- Food and Drug Administration (FDA), if the study is subject to FDA regulations

5.3.4 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 in 5.3.2

5.4 The Director and Chair of the PHRC or designee will ensure that all steps of this policy will be completed 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.