



Title:	Suspension or Termination of Human-Subjects Research
Department:	Human Research Affairs/Research Management
Policy Type:	<input checked="" type="checkbox"/> Partners System-wide <input type="checkbox"/> Partners System-wide Template <input type="checkbox"/> Partners Corporate <input type="checkbox"/> Partners Corporate Departmental <input type="checkbox"/> Entity
Applies to:	Employees, Professional Staff or Other Agents of Brigham and Women's Hospital (BWH). Faulkner Hospital (FH) and Massachusetts General Hospital (MGH)
Approved by:	Chief Scientific Officer
Approval Date:	June 4, 2007
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Next Review Date:	September 8, 2013
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 suspending or terminating PHRC-approved human-subjects research and clinical investigations.

This policy is established to comply with the regulatory requirement in 45 CFR 46.103(b)(5)(ii) and 21 CFR 56.108(b)(3) requiring IRBs to have written procedures ensuring prompt reporting to the IRB, appropriate institutional officials, Office for Human Research Protections, and, when applicable, the Food and Drug Administration (FDA), any suspension or termination of IRB approval.

DEFINITIONS:

See Definition of Human-Subjects Research

Suspension means to cause some aspect of the research to be stopped temporarily or permanently while the research continues under review or an investigation takes place.

Termination means to cause the research to be stopped permanently in its entirety. Of note, expiration of PHRC approval is not considered termination of research.

POLICY STATEMENT:

Consistent with federal regulations, the PHRC has the authority to suspend or terminate approval of research that is not being conducted in accordance with the requirements or determinations of the PHRC or that has been associated with unexpected serious harm to subjects. Additionally, the Institutional Official may suspend or terminate research approved by the PHRC for human subject protection, administrative, financial or other reasons.

When the Institutional Official suspends or terminates PHRC-approved research, s/he is responsible for promptly notifying the Principal Investigator, Department Chair/Chief of Service, and the PHRC of the suspension or termination and the reasons for doing so.

When the PHRC suspends or terminates approved research, the PHRC is responsible for promptly reporting the suspension or termination and the reasons for doing so in accordance with the policy *Reporting to Institutional Officials and Regulatory Agencies*.

PROCEDURES:

When research approved by the PHRC is suspended or terminated, the PHRC Chairperson/PHRC considers and determines whether:

- subjects currently on active treatment must be withdrawn from the study;
- subjects will be placed at risk of harm by withdrawing them from the study; and
- subjects must continue to be followed for safety reasons.

1. Early Withdrawal of Subjects

When the suspension or termination involves withdrawal of subjects from an interventional study, the PHRC Chairperson/PHRC considers and determines what, if any, termination procedures are required for the safety and welfare of those subjects. Termination procedures may include, but are not limited to the following:

- tapering of the drug;
- making a final study visit at which a physical exam and/or laboratory or other tests will be performed; or
- making arrangements for subjects to receive medical care by their primary care physician or specialist or through referrals to other healthcare providers.

2. When Subjects are at Risk of Harm

When the PHRC determines that the suspension or termination will place subjects at risk of harm, the PHRC must determine what subjects are to be told and the manner in which they are to be notified, e.g., in writing, in person, or by telephone.

3. Subject Follow-Up

When the PHRC requires or approves subject follow-up for safety reasons, the investigator is subject to continuing review and requirement to promptly report any unanticipated

problems involving risks to subjects or others, including adverse events, to the PHRC and, when applicable, the sponsor.

4. Notification of Subjects

Depending upon the reasons for the suspension or termination and the design of the protocol, the PHRC may require that the following subjects be notified of the suspension or termination:

- all subjects who have been or are enrolled;
- subjects currently on protocol; or
- subjects who participated in a certain aspect of the protocol.

5. Reporting Requirements

Whenever the Institutional Official or PHRC suspends or terminates a research protocol involving human subjects, the Director and Chair of the PHRC or designee shall be responsible for submitting a report of the suspension or termination of the research in accordance with the policy *Reporting to Institutional Officials and Regulatory Agencies*.

OTHER APPLICABLE PARTNERS HEALTHCARE POLICIES:

Reporting to Institutional Officials and Regulatory Agencies

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: