PARTNERS HEALTHCARE | FOUNDED BY BRIGHAM AND WOMEN'S HOSPITAL AND MASSACHUSETTS GENERAL HOSPITAL

Title:	Proposed Changes in PHRC-Approved Research and Exceptions
Department:	Human Research Affairs
Policy Type:	☑ Partners System-wide ☐ Partners System-wide Template ☐ Partners Corporate ☐ Partners Corporate Departmental ☐ Entity
Applies to:	Employees, Professional Staff or Other Agents of the 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
Approval Date:	June 4, 2007
Effective Date:	June 4, 2007
Revision Date(s):	September 8, 2010; March 7, 2014
Next Review Date:	March 7, 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 to ensure prompt reporting to the PHRC of proposed changes, including single patient or other limited exceptions, in approved non-exempt human-subjects research and for ensuring that changes are not initiated without PHRC review and approval, except where necessary to eliminate apparent immediate hazards to the subject. [45 CFR 46.103(4)(iii) and 21 CFR 56.108(3)(4)]

DEFINITIONS:

See Definition of Human-Subjects Research

Exception means any change in the research or protocol requirements (e.g., eligibility criteria, laboratory tests, continuation on protocol) that is limited to a specific subject or situation and does not change the requirements for all subjects. Exceptions are approved by the PHRC prior to implementation.

POLICY STATEMENT:

Investigators conducting human-subjects research approved by the PHRC 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 the subject.

PROCEDURES:

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

1. The PHRC reviews proposed changes, including exceptions, in non-exempt approved human-subjects research according to the procedures described in the policies for initial and continuing review of non-exempt human-subjects research, and review of proposed changes in approved research.

2. Changes made without PHRC approval to eliminate apparent immediate hazards to the subjects must be reported to the PHRC as described in the policy on *Reporting Unanticipated Problems including Adverse Events*. The PHRC reviews changes made to eliminate apparent immediate hazards to the subjects as described in the policy on *Review of Unanticipated Problems in Human-Subjects Research.*

3. The PHRC informs investigators that they must submit changes in approved research to the PHRC for approval prior to initiation in PHRC written approval notification letters and in continuing review forms.

4. The Partners Human Research Quality Improvement Program (QI Program) assesses compliance with applicable regulations and requirements of the PHRC during onsite reviews. Such reviews may identify failure to obtain PHRC approval of proposed changes in approved research prior to initiation. In such cases, investigators are required to complete and submit an Insight/eIRB unanticipated problem form to the PHRC for review.

5. Educational programs, such as research coordinator orientation, lectures, random QI audits, roundtable discussions, focus groups, and departmental Q/A sessions held by the chairperson address this requirement.

OTHER APPLICABLE PARTNERS HEALTHCARE POLICIES:

Reporting Unapproved Deviations in PHRC-Approved Research
Reporting Unanticipated Problems including Adverse Events

REFERENCE:

45 CFR 46
21 CFR 56

DEVELOPMENT AND CONSULTATION

Human Research Office

Reviewed by:	Original Review Date:	Revision Approval Dates: