



FOUNDED BY BRIGHAM AND WOMEN'S HOSPITAL
AND MASSACHUSETTS GENERAL HOSPITAL

Title:	Review of Operations Centers or Coordinating Centers for Multi Site Research
Department:	Human Research Affairs
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), Massachusetts General Hospital (MGH), McLean Hospital (McLean), and North Shore Medical Center (NSMC)
Approved by:	Chief Academic Officer
Approval Date:	September 9, 2010
Effective Date:	September 9, 2010
Revision Date(s):	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 requirements and procedures the Partners Human Research Committees (PHRC) follow for review of operations centers or coordinating centers for multi site human-subjects research.

DEFINITIONS:

See Definition of Human-Subjects Research

POLICY STATEMENT:

When employees or agents of the applicable Partners-affiliated entities are responsible for the operations center or coordinating center for multi site human-subjects research, the PHRC will review the standard operating procedures of the center to ensure that there are appropriate mechanisms in place to protect the rights, safety and welfare of the subjects participating in the research at the collaborating sites.

PROCEDURES:

Investigators must specify in the Insight/eIRB application what operations center or coordinating center activities they are engaged in and provide a copy of the center’s standard operating procedures. Although the PHRC does not need to approve the protocol as part of the operations center or coordinating center protocol, the investigator is asked to submit the protocol and model consent form and, when applicable, provide information about drugs, biologics, dietary supplements or devices being investigated so that the PHRC can ensure that the operations center or coordinating center’s standard operating procedures are appropriate for the study. Note that when subjects will be enrolled in the study at the applicable Partners-affiliated entities, the protocol must be submitted separately to the PHRC for approval.

The PHRC will review the center’s standard operating procedures and determine whether the operations center or coordinating center has sufficient mechanisms in place to ensure that, where applicable:

- (1) management, data analysis, and data safety and monitoring plan is adequate, given the nature of the research involved;
- (2) sample protocols and informed consent documents are developed and distributed to each collaborating institution;
- (3) each collaborating institution holds an applicable approved Federal Wide Assurance (FWA);
- (4) each protocol is reviewed and approved by the IRB at the collaborating institution prior to the enrollment of subjects;
- (5) any substantive modification by the collaborating institution of sample consent information related to risks or alternative procedures is appropriately justified; and
- (6) informed consent is obtained from each subject in compliance with HHS regulations.

During the period of approval, investigators are required to report to the PHRC any changes in the center’s standard operating procedures that are related to the six criteria above. Changes to the protocol and/or consent form do not need to be reported to the PHRC until continuing review.

At continuing review, investigators are required to report any unanticipated problems involving risks to subjects or others, protocol modifications, and interim findings.

OTHER APPLICABLE PARTNERS HEALTHCARE POLICIES:

Review of Multi Site Human-Subjects Research: Investigator-Initiated Collaborative Research

REFERENCE:

OHRP Guidance on Engagement of Institutions in Human Subjects Research

DEVELOPMENT AND CONSULTATION

Human Research Office

Reviewed by:	Original Review Date:	Revision Approval Dates:
