

Title:	Review of Operations Centers or Coordinating Centers for Multi Site Research
Department:	Human Research Affairs
Policy Type:	Mass General Brigham System-wide
Applies to:	Employees, Professional Staff or Other Agents of Mass General Brigham
Approved by:	Chief Academic Officer
Original Approval Date:	September 9, 2010
Original Effective Date:	September 9, 2010
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Current Revision Effective Date:	October 1, 2021
Next Review Date:	October 1, 2022
Contact Person:	Director, Human Research Office

KEYWORDS:

IRB, Institutional Review Board

PURPOSE:

The purpose of this policy is to define the requirements and procedures the Mass General Brigham IRB follows for review of operations centers or coordinating centers for multi- site human subject research.

DEFINITIONS:

See Definitions in Human Subject Research

POLICY STATEMENT:

When employees or agents of Mass General Brigham are responsible for the operations center or coordinating center for multi-site human subject research, the IRB 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 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 IRB 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 IRB 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 Mass General Brigham, the protocol must be submitted separately to the IRB for approval.

The IRB 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 and/or FDA regulations, as applicable.

During the period of approval, investigators are required to report to the IRB 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 IRB until continuing review.

OTHER APPLICABLE MASS GENERAL BRIGHAM POLICIES:

None.

REFERENCE:

OHRP Guidance on Engagement of Institutions in Human Subjects Research

DEVELOPMENT AND CONSULTATION:

Human Research Office