Mass General Brigham

Title:	Review of Human Subject Research Conducted Off-Site
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:	June 4, 2007
Original Effective Date:	June 4, 2007
Revision Approval Date(s):	September 8, 2010; March 7, 2014; August 16, 2015
Current Revision Effective Date:	December 1, 2020
Next Review Date:	January 15, 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 non-exempt human subject research conducted by Mass General Brigham employees or agents (e.g., professional staff) at sites other than those owned or controlled by Mass General Brigham (off-site research).

DEFINITIONS:
See Definitions in Human Subject Research

POLICY STATEMENT:
Off-site human subject research will be conducted in compliance with applicable international, federal, state, and local laws and regulations as well as any requirements of the performance site's institution or entity.

Research conducted by Mass General Brigham employees or agents wholly or partly in space or a site leased by them from another entity (the landlord) will be considered in the same way as research conducted in/at Mass General Brigham owned space/sites. However, the investigator is responsible for confirming with the landlord, the responsible Mass General Brigham office, or others as necessary that the specific proposed research activities are consistent with the activities permitted to be conducted in the space or at the site under the terms of the lease.

PROCEDURES:

Investigators must specify in the Insight application the places where Mass General Brigham employees or agents will conduct the research, including any off-site locations. These sites may be institutions, facilities, or entities such as Mass General Brigham and non-Mass General Brigham healthcare institutions; private physician or group practices; rehabilitation, nursing, or assisted living facilities; private or public primary schools, colleges or universities; and community or other activity-based centers. They may be located in Massachusetts, other U.S. states, or foreign countries.

1. REVIEW OF PERFORMANCE SITE

When reviewing human subject research that takes place off-site, the IRB will obtain and consider information about the performance site and study population appropriate to the procedures involved in the research and the degree of risk to subjects. The review may include some or all of the following information:

- The anticipated scope of the research activities that will take place at the site;
- The size and complexity of the institution/facility/entity;
- Standards of professional conduct and practice;
- Policies and procedures of site at which off-site research will occur;
- Applicable laws and regulations;
- The types of subject populations likely to be involved;
- Language(s) understood by prospective subjects;
- Method for equitable selection of subjects;
- Method for minimizing the possibility of coercion or undue influence in seeking consent;
- Method for protection of privacy of subjects;
- Method for maintenance of confidentiality of data; and
- Safeguards to protect the rights and welfare of vulnerable subjects;

Domestic Performance Sites Outside Massachusetts

When the performance site is in a state other than Massachusetts, institutional representatives of the performance site will be asked to provide information about the performance site and confirm that local applicable laws and requirements will be met. In addition, the IRB may consult with the Mass General Brigham Office of the General Counsel (OGC) about applicable state law.

When research is conducted in a state other than Massachusetts, the IRB will ensure that the participants are afforded protections that are at least equivalent to those provided by Mass General Brigham IRB policies and the ethical standards outlined in the Belmont Report.

International Performance Sites

When the performance site is outside the United States or its territories, consultants at the international site or within the United States will be asked to provide information about the researchers, performance site and applicable laws. Consultants in this context are individuals with personal knowledge of the local research context, such knowledge having been obtained through extended, direct experience with the research institution, its subject populations and its surrounding communities. The IRB must confirm the qualifications of the researchers and research staff conducting research in that country and consider the cultural, economic and political conditions in the country where the research will take place when reviewing the study population and recruitment and consent procedures and when assessing the risks and potential benefits to participants.

Research conducted outside the United States or its territories will generally be subject to approval of a local IRB or Ethics Committee (EC) and/or governmental officials, such as the Ministry of Health. When reviewing the research, the IRB will take into consideration the local IRB or EC review of the qualifications of the local researchers and research staff, the recruitment and consent procedures and language issues, as well as other culturally-based issues. When the research is federally-funded, IRB or ethics committee approval must be obtained from an entity in that country that has a current approved FWA and a registered IRB or ethics committee. The IRB will require documentation of the site's IRB approval, FWA and IRB registration status or verify existence on the OHRP website. A database of registered international IRBs searchable by country can be found on the OHRP website at http://ohrp.cit.nih.gov/search/. In addition, OHRP has compiled a listing of the laws, regulations and guidelines that govern human-subjects research in many countries around the world (see The International Compilation of Human Subject Research Protections).

When research is conducted outside the United States or its territories, the IRB will ensure that the participants are afforded protections that are at least equivalent to those provided by Mass General Brigham IRB policies and the ethical standards outlined in the Belmont Report. This includes: (1) initial and continuing review; (2) review of changes in approved research; (3) reporting and handling of complaints, unanticipated problems involving risks to subjects or others and noncompliance; and (4) post-approval monitoring. When the research is also subject to review of the local IRB or EC, the IRB requires documentation of review and approval throughout the project. When unanticipated problems or noncompliance are reported the IRB will require documentation of local IRB or ethics committee review and, when appropriate, will communicate directly with the local IRB or ethics committee. Post-approval monitoring will be coordinated with the local IRB or ethics committee when required and as needed.

2. ENGAGEMENT OF INSTITUTIONS IN HUMAN SUBJECT RESEARCH

As part of its review, the IRB will consider whether the performance sites listed in the application are engaged in human subject research and what, if any, additional IRB approvals are needed. The OHRP guidance document *Guidance on Engagement of Institutions in Human Subjects Research* will be used as the basis for determining engagement in human subject research. Such determinations will be made in collaboration and consultation with authorized representatives of the performance site.

Performance Sites **NOT** Engaged in Human Subject Research
When the research will be conducted off-site at a performance site that is **not** engaged in human subject research, the IRB may require written documentation of permission to use the facilities for research signed by the entity's legally authorized representative. For example, research conducted in the Boston Public Schools must be coordinated through the Boston Public Schools Office of Research, Assessment and Evaluation (RAE). See Policy and Guidelines for Conducting Educational Research in the Boston Public Schools http://www.bostonpublicschools.com/files/RAE-1.1%20Guidelines%20for%20Conducting%20Research.pdf. The IRB has a template agreement that may be used for this purpose (Performance Sites Not Engaged in Research).

Performance Sites Engaged in Human Subject Research
When the performance site is engaged in human subject research, refer to policy on Single IRB Review..

OTHER APPLICABLE MASS GENERAL BRIGHAM POLICIES:

Single IRB Review

REFERENCES:

OHRP *Guidance on Engagement of Institutions in Human Subjects Research*
Policy and Guidelines for Conducting Education Research in the Boston Public Schools

DEVELOPMENT AND CONSULTATION:

Human Research Office
Office of the General Counsel