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| Title: | Review of Multi Site Human-Subjects Research: Investigator-Initiated Collaborative 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 HealthCare <input type="checkbox"/> Partners HealthCare Departmental <input type="checkbox"/> Institution |
| Applies to: | Employees, Professional Staff or Other Agents of Brigham and Women's Hospital (BWH), Brigham and Women's Faulkner Hospital (BWFH), Massachusetts General Hospital (MGH), McLean Hospital (McLean), North Shore Medical Center (NSMC), Spaulding Rehabilitation Hospital (SRH), and MGH Institute of Health Professions (MGH IHP) |
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| 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 multi site collaborative non-exempt human-subjects research initiated by investigators who are employees or agents (e.g., professional staff) of the applicable Partners-affiliated entities.

DEFINITIONS:

See Definition of Human-Subjects Research

Employees or agents means members of the applicable Partners-affiliated entities' workforce who: (1) act on behalf of the institution; (2) exercise institutional authority or responsibility; or (3) perform institutionally designated activities. Employees and agents include professional staff, students/interns, contractors, and volunteers, among others, regardless of whether the individual is being paid by the hospital.

Collaborating individual investigator means an investigator who is: (a) not otherwise an employee or agent of the applicable Partners-affiliated entities; (b) conducting collaborative research activities whether on or off-site from applicable Partners-affiliated entities; and (c) not acting as an employee of any institution with respect to his/her involvement in the research being conducted by the applicable Partners-affiliated entities (*independent investigator*) OR acting as an employee or agent of an institution that does not hold an OHRP-approved FWA and does not routinely conduct human-subjects research (*institutional investigator*).

POLICY STATEMENT:

When employees or agents of the applicable Partners-affiliated entities conduct investigator-initiated non-exempt human-subjects research in collaboration with other institutions or with collaborating individual investigators as defined herein, each collaborating institution and/or collaborating individual investigator engaged in human-subjects research must obtain IRB approval for the research they are conducting. The OHRP guidance document *Guidance on Engagement of Institutions in Human Subjects Research* will be used as the basis for determining engagement in human-subjects research. Such determinations will be made in collaboration and consultation with authorized representatives of the collaborating institution and/or the collaborating individual investigators, as applicable.

Investigators must specify in the Partners Human Research Insight/eIRB Application the outside institutions and/or individuals involved in the research. When outside parties involved in the research are institutions, the applicable Partners-affiliated entities' investigator must provide the PHRC with: 1) contact information for the collaborating institution's IRB, if any, and if the institution has no IRB, with contact information for the institution's Institutional Official or other authorized representative for research; and 2) if applicable, the collaborating institution's Federalwide Assurance (FWA)#.

PROCEDURES:

Collaborating Institutions

Per relevant guidance from OHRP, when multiple institutions are engaged in the same non-exempt human-subjects research, the collaborating institutions may enter into joint review arrangements, rely upon the review of another qualified IRB, or make similar arrangements to avoid duplication of effort. When an institution is engaged in only part of the non-exempt human-subjects research, the institution must ensure that the part of the research project in which the institution is engaged is reviewed and approved by the institution's IRB or, on behalf of the institution, by another appropriately qualified IRB or Ethics Committee (EC) listed on the institution's FWA. Alternatively, each institution may decide to review the entire research project, even if the information about the entire project is not necessary to approve the part(s) of the research in which the institution is engaged.

1. Reliance of Collaborating Institutions on the PHRC (Partners IRB)

Collaborating institutions engaged in non-exempt human-subjects research may request to rely on the PHRC for review of the research. In such cases, the PHRC will consider the request and, if it is granted, an IRB Authorization Agreement (IAA) also referred to as a Reliance Agreement must be executed by both institutions. The relying institution must have an active/approved FWA.

In the absence of such a reliance arrangement, each institution will independently review the research project.

2. Reliance of the applicable Partners-affiliated entities on Collaborating Institution's IRB

The applicable Partners-affiliated entities may rely on the IRB of a collaborating institution when all or the majority of the non-exempt human-subjects research is being conducted at the collaborating institution or when the collaborating institution's IRB has more relevant or

specialized expertise and/or knowledge of the site where the research will be conducted. In such cases, an IAA must be executed by both institutions. The institution relied upon for IRB review must have an active/approved FWA.

In the absence of such a reliance arrangement, each institution will independently review the research project.

3. Joint Review Arrangements

When the applicable Partners-affiliated entities and the collaborating institution are each engaged in only part of a non-exempt human-subjects research project, each may decide to review only the part(s) of the project in which they are engaged. In such cases, the applicable Partners-affiliated entities' Principal Investigator is responsible for providing the PHRC with information about any changes to the research required by the collaborating institution's IRB that are material to the part(s) of the research in which the applicable Partners-affiliated entity is engaged. If either institution wishes to rely on the other for review of the part(s) of the project in which it is engaged, an appropriate IAA must be executed to document the reliance. For example, when the research is being conducted largely or entirely off-site, the PHRC may rely on the collaborating institution's IRB for review of the local research context or other aspects of the part of the project in which the applicable Partners-affiliated entity is engaged for which the collaborating institution's IRB has more relevant or specialized expertise and/or knowledge. The PHRC will make decisions about appropriate joint review arrangements depending on the circumstances of the particular project.

In all cases where the collaborating institution is conducting its own review of non-exempt human-subjects research (not relying on the PHRC for review), documentation of the collaborating institution's IRB approval of the research and, if federally-funded, the institution's FWA# will be required and maintained by the PHRC as part of its review. When the research is not federally-funded, in its discretion, the PHRC may find it acceptable that the research has been reviewed and approved on the collaborating institution's behalf by an appropriately qualified IRB or other internationally recognized Ethics Committees; for example, those that adhere to the World Health Organization (WHO), Declaration of Helsinki, Council for International Organizations or Medical Sciences (CIOMS) or other similar guidelines, or to the International Council on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use Good Clinical Practice guidelines (ICH-GCP).

Collaborating Individual Investigators

When a collaborating individual investigator, whether an independent investigator or an institutional investigator, is engaged in non-exempt human-subjects research, the applicable Partners-affiliated entity may choose to extend its FWA to cover the collaborating individual investigator. In such cases, an Individual Investigator Agreement outlining the terms and conditions of this arrangement must be executed by both parties. See Individual Investigator Agreement.

REFERENCE:

OHRP Guidance on Extension of an FWA to Cover Collaborating Individual Investigators and Introduction to the Individual Investigator Agreement

OHRP Guidance on Engagement of Institutions in Human Subjects Research

DEVELOPMENT AND CONSULTATION

Human Research Office

Office of the General Counsel