

Title:	Human Research Protection Program (HRPP)
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:	August 1, 2008
Original Effective Date:	August 1, 2008
Revision Approval Date(s):	N/A
Current Revision Effective Date:	October 1, 2021
Next Review Date:	October 1, 2022
Contact Person:	Director, Human Research Office

1.0 THE HRPP

The Mass General Brigham HRPP is an integrated program with overall responsibility for the protection of the rights and welfare of human subjects in research for Mass General Brigham. The entities covered under the Mass General Brigham HRPP (HRPP Covered Entities) include:

- The Brigham and Women’s Hospital, Inc. (BWH)
- Brigham and Women’s Faulkner Hospital, Inc. (BWH/F)
- The General Hospital Corporation doing business as Massachusetts General Hospital (MGH)
- The MGH Institute of Health Professions, Inc. (MGH IHP)
- The McLean Hospital Corporation (McLean)
- Newton-Wellesley Hospital (NWH)
- North Shore Medical Center, Inc. (NSMC)
- Massachusetts Eye and Ear Infirmary (MEE)
- Partners Private Care, LLC (PPC)
- Partners Home Care, Inc. (PHC)
- The Schepens Eye Research Institute, Inc. (SERI)
- The Spaulding Rehabilitation Hospital Corporation (SRH)

- Spaulding Hospital - Cambridge, Inc. doing business as Spaulding Hospital for Continuing Medical Care Cambridge (Spaulding Cambridge)
- Spaulding Hospital of the Cape and Islands Corporation (Spaulding Cape Cod)
- Cooley Dickinson Hospital (CDH)

The HRPP includes specific review and oversight of research activities involving human subjects as conducted by the Mass General Brigham Institutional Review Boards; management of funding negotiations with government and private sponsors as conducted by the Mass General Brigham Research Management Office, the Mass General Brigham Clinical Research Office, and Mass General Brigham Innovations; provision and development of training and policies for researchers; coordination of interactions with potential as well as enrolled human subjects; conduct of quality improvement and assurance activities; and support of the compliance responsibilities of the covered institutions and investigators.

2.0 MISSION

A core mission of the Mass General Brigham HRPP and Mass General Brigham in general, is to advance care through excellence in biomedical research. Consistent with this core mission, the HRPP's mission is to help ensure that Mass General Brigham and its hospitals protect human subjects participating in research in accordance with legal requirements and ethical guidelines. This includes research that is conducted or sponsored by the HRPP Covered Entities or in which the entities are otherwise engaged.

The HRPP fosters a culture of compliance with the highest legal and ethical standards for human subject protection among the institutions, their investigators and all members of the broad research community. The Mass General Brigham HRPP is also committed to education of and outreach to persons interested in research.

3.0 ETHICAL PRINCIPLES

The Mass General Brigham HRPP is guided by the *Ethical Principles and Guidelines for the Protection of Human Subjects of Research*, generally known as the "Belmont Report."

The organizational officials, institutional officials, department heads/chairs/chiefs, professional staff, researchers and research staff (including students), Human Research Office (HRO) staff and all other employees of Mass General Brigham and the HRPP Covered Entities have the ethical obligation to protect human

subjects participating in research in accordance with legal requirements and ethical guidelines.

4.0 APPLICABLE LAWS

Laws, regulations, and other rules relevant to the Mass General Brigham HRPP include rules pertaining explicitly to research and human subject protections and rules that are not specific to research but that may affect its conduct or oversight. In research conducted or supported by governmental entities, entity regulations and requirements are followed as applicable (e.g., U.S. Department of Defense, U.S. Department of Justice). Key sources of requirements include the following:

Federal Statutes and Regulations:

- 20 U.S.C. 1232h (Consent in School-Based Surveys/Evaluations)
- 42 U.S.C. 241(d) (Certificates of Confidentiality)
- 42 U.S.C. 290dd-2 (Confidentiality of Substance Abuse Records)
- Pub. L. No. 104-191, 110 Stat. 1936 (HIPAA)
- Pub. L. No. 111-5, 123 Stat. 226 (HITECH)
- Pub. L. No. 113-240, 128 Stat. 2851, § 12 (Informed Consent for Newborn Screening Research)
- 21 CFR Part 11 (Electronic Records; Electronic Signatures)
- 21 CFR Part 50 (Protection of Human Subjects)
- 21 CFR Part 54 (Financial Disclosure by Clinical Investigators)
- 21 CFR Part 56 (Institutional Review Boards)
- 21 CFR Part 210 (Current Good Manufacturing Practice in Manufacturing, Processing, Packing or Holding of Drugs: General)
- 21 CFR Part 211 (Current Good Manufacturing Practice for Finished Pharmaceuticals)
- 21 CFR Part 312 (Investigational New Drug Application)
- 21 CFR Part 314 (Applications for FDA Approval to Market a New Drug)
- 21 CFR Part 320 (Bioavailability and Bioequivalence Requirements)
- 21 CFR Part 330 (Over-The-Counter (OTC) Human Drugs which are Generally Recognized as Safety and Effective and Not Misbranded)
- 21 CFR Part 361 (Radioactive Drugs)
- 21 CFR Part 601 (Biologics Licensing)
- 21 CFR Part 610 (Biological Products)
- 21 CFR Part 803 (Medical Device Reporting)
- 21 CFR Part 812 (Investigational Device Exemptions)
- 21 CFR Part 814 (Premarket Approval of Medical Devices)
- 21 CFR Part 820 (Quality System Regulation)
- 21 CFR Part 860 (Medical Device Classification Procedures)
- 34 CFR Part 98 (Consent in School-Based Examination/Treatment)
- 42 CFR Part 2 (Confidentiality of Alcohol/Drug Abuse Records)

42 CFR Part 50 (Research Integrity: Objectivity in Research – Financial
Conflicts of Interest)
45 CFR Part 46 (Protection of Human Subjects)
45 CFR Parts 160 and 164 (Security and Privacy; Breach Reporting)

State Statutes and Codes:

M.G.L. c. 19A, § 15 (Elder Abuse Reporting)
M.G.L. c. 93H (Security Breaches)
M.G.L. c. 94C § 8 (Controlled Substances in Research)
M.G.L. c. 111, § 70E (Patients Rights/Informed Consent/Confidentiality)
M.G.L. c. 111 § 70F (Consent to HIV/AIDS Testing / Disclosure of Results)
M.G.L. c. 111 § 70G (Genetic Testing and Privacy)
M.G.L. c. 111 § 119 (Venereal Disease Records)
M.G.L. c. 111, § 202 (Disposition of Fetal Remains)
M.G.L. c. 111B, § 11 (Alcohol Abuse Treatment Records)
M.G.L. c. 111E, § 18 (Drug Dependency Treatment Records)
M.G.L. c. 111L (Human Embryonic Stem Cell Research)
M.G.L. c. 112, § 12E (Consent by Drug Dependent Minors)
M.G.L. c. 112, § 12F (Consent by Minors)
M.G.L. c. 112, § 12J (Experimentation on Fetuses)
M.G.L. c. 112, § 129A (Psychologist – Patient Communications)
M.G.L. c. 112, § 135A (Social Worker – Client Communications)
M.G.L. c. 119, § 51A (Child Abuse/Neglect Reporting)
M.G.L. c. 190B, Art. V. (Guardianships)
M.G.L. c.201D (Health Care Proxies)
M.G.L. c. 233, § 20B (Psychotherapist – Patient Communications)
M.G.L. c. 233, § 20K (Communications with Domestic Violence
Victims’ Counselor)
103 C.M.R. 180.07 (Research with Prisoners)
104 C.M.R. 31.00 (Department of Mental Health Research)
105 C.M.R. 130.381-87 (Consent for Autopsy Tissue)
105 C.M.R. 130.395 (Disposition of Fetal Remains)
105 C.M.R. 700.009 (Controlled Substances in Research)
105 C.M.R. 960.000 (Human Embryonic Stem Cell Research)
115 C.M.R. 10.00 (Department of Developmental Services Research)
201 C.M.R. 17.00 (Protection of Personal Information)
603 C.M.R. 23.00 (Access to Student Records/Information)

The Mass General Brigham HRPP applies the 2018 Common Rule to Common Rule agency-supported research approved on or after January 21, 2019. Additionally, research approved prior to January 21, 2019 may be eligible to transition to the 2018 Common Rule.

For clinical trials, the Mass General Brigham HRPP applies the International Council on Harmonisation – Good Clinical Practice E6-R2 (ICH-GCP E6) to the extent it is consistent with FDA and DHHS regulations.

The Mass General Brigham IRB does not review classified research.

5.0 SCOPE

The Mass General Brigham HRPP has jurisdiction over all human subject research conducted by the HRPP Covered Entities' investigators in connection with their institutional roles or responsibilities or under the auspices of the hospitals, or in which the hospitals are otherwise engaged, regardless of the location of the research or source of funding.

The HRPP Covered Entities are engaged in human subject research whenever its employees or agents for the purposes of the research (1) intervenes or interacts with living individuals to obtain data; (2) obtains or uses individually identifiable private information or biospecimens about living individuals (3) obtains the informed consent of human subjects., or (4) or receives an award to conduct human research even when all activities involving human participants are carried out by a subcontractor or employees or agents of another institution.

Mass General Brigham HRPP policies, procedures and guidance documents are made available to the research community via Research Navigator. Revisions to policies, procedures and/or guidance documents are posted on Research Navigator and may also be communicated to the research community via email or other mechanisms.

6.0 GOVERNANCE

Governance of the Mass General Brigham HRPP is coordinated between Mass General Brigham and the HRPP Covered Entities. Mass General Brigham is the overall corporate parent of the HRPP Covered Entities as well as several other health care provider entities. Mass General Brigham has a Board of Directors, which generally manages and directs the overall health care system. However, the HRPP Covered Entities are each legally separate corporate entities (of note, BWH and FH share the same intermediate corporate parent). As such, they each have their own Boards which carry out core responsibilities with respect to the hospitals. The HRPP Covered Entities are each distinct recipients of external funding and have their own Federalwide Assurances (FWAs) signed by their own Institutional Officials (IOs), who are legally authorized to represent each institution. The IOs of the HRPP Covered Entities provide assurance that the IRBs designated in their FWAs are knowledgeable about the local research context and will comply with the terms of the FWAs.

Mass General Brigham provides some centralized services (e.g., research management, legal, information systems, compliance and human resources). The Mass General Brigham HRPP evaluates the adequacy of resources during the annual budget process. Each component of the HRPP is responsible for assessing

whether it has the resources necessary to carry out its responsibilities for the protection of human research subjects as described in the HRPP plan, and for requesting additional resources, as needed. The individual entities carry out most other operations and follow the same annual budget process.

Although the ultimate responsibility for the protection of human subjects of research resides with the individual institutions, the Mass General Brigham HRPP coordinates and carries out review and oversight activities on behalf of the HRPP Covered Entities.

8.0 KEY ROLES AND RESPONSIBILITIES

8.1 Mass General Brigham Chief Academic Officer

The Chief Academic Officer (CAO), reports to the President and Chief Executive Officer of Mass General Brigham. The CAO is responsible for providing the necessary resources for components of the HRPP under his/her authority.

Corporate components of the HRPP that report to the CAO include:

- Human Research Affairs (HRA)
- Clinical Trials Office (CTO)
- Research Information
- Innovation that supports interactions with commercial partners via the following distinct Departments:
 - Research and Licensing
 - Business Development
 - Innovation Fund

8.2 Vice President, Human Research Affairs

The Vice President of Human Research Affairs (VP HRA) reports to the CAO and provides leadership and oversight for the HRPP. The VP is responsible for:

- Compliance & Education Office
- Human Research Office (HRO)
- Mass General Brigham Institutional Review Boards (Mass General Brigham IRB)
- Embryonic Stem Cell Research Oversight Committee (ESCRO)
- Research Navigator Office (RNO)

8.3 Mass General Brigham Chief Financial Officer

The Chief Financial Officer (CFO), reports to the President and Chief Executive Officer of Mass General Brigham. Mass General Brigham

Research Management (RM), a corporate component of the HRPP, reports to the CFO. Mass General Brigham Research Management includes the following distinct departments:

- Pre-Award
- Post-Award/Contracts (Grants)
- Research Finance
- Clinical Research Office

8.4 Institutional Officials

The HRPP Covered Entities each have an approved FWA on file with OHRP. The FWAs are executed by a senior official of the institution, referred to as the Institutional Official (IO).

The IO understands the institution's responsibilities under the FWA, assures the protection of human subjects of research, and assures that the designated IRBs are knowledgeable about the local research context and will comply with the terms of the FWA. The IO ensures that the designated IRB is the sole entity that can grant approval for research activities involving human subjects, i.e., no one within the institution may approve such research that has not been approved by the IRB. The IO may, however, disapprove research that has been approved by the IRB. The FWAs have been approved by OHRP and are updated as necessary when information changes.

The IO for each Mass General Brigham institution is responsible for:

- Setting the “tone” for an institutional culture of respect for human subjects;
- Ensuring effective institution-wide communication and guidance on human-subjects research issues;
- Ensuring that investigators fulfill their responsibilities;
- Facilitating participation in human subject protection education activities;
- Serving as a knowledgeable point of contact for OHRP, FDA, the Office of Research Integrity (ORI) and other relevant federal and state agencies;
- Ensuring required reporting to OHRP, FDA, ORI and other relevant federal and state agencies; and
- Serving as or delegating the role of institutional Research Integrity Officer.

Administratively, the IO is responsible for:

- Providing the Mass General Brigham IRB with the necessary local resources through the Mass General Brigham annual budgeting process, which allocates Mass General Brigham IRB

- operating costs to the relevant Mass General Brigham entities,
and
- Supporting the authority and decisions of HRA and its components.

8.5 Mass General Brigham IRB

The Mass General Brigham IRB is registered with DHHS/OHRP and the FDA. The HRO updates the IRB registrations and submits them to OHRP/FDA as needed. Within HRA, it is the Mass General Brigham IRB specifically that is responsible for review and oversight of human subject research under its scope of authority.

The Mass General Brigham IRB provides a centralized service to support operational efficiency, minimize redundancy of review and foster collaboration among the institutions' investigators. The Mass General Brigham IRB exercises its responsibility for protection of human research subjects with independence of decision-making. Only the Mass General Brigham IRB or those on which Mass General Brigham relies through an executed reliance group (designated reviewing IRB) are allowed to grant approval for human subject research. Human subject research approved by an IRB may be subject to further institutional review and approval; however, no one within the institution may approve human subject research that has not been approved by the Mass General Brigham IRB or a designated reviewing IRB.

8.6 Mass General Brigham HRO

The HRO provides administrative and operational support to the Mass General Brigham IRB and acts as a liaison to other parts of the HRPP. When further institutional review and approval is required, the HRO is responsible for coordinating review and verifying approval of the research by the applicable ancillary committees, departments, groups or individuals. The HRO collaborates with the Compliance & Education Office and Mass General Brigham Covered Entities to provide education in human subject protections and the ethical conduct of research.

When the research has received all required institutional approvals, the IRB notifies the Principal Investigator and study contacts of approval and provides the IRB approval documentation, approved consent form(s), and any approved recruitment materials in the Mass General Brigham institutional research management system, Insight. The Insight application contains a complete record of protocol submissions and documentation of

Mass General Brigham IRB and ancillary committee reviews and approvals.

8.7 Mass General Brigham Human Research Affairs Compliance and Education Office

The Mass General Brigham Human Research Affairs Compliance and Education Office is responsible for providing education and support to investigators and study staff conducting clinical research studies at Mass General Brigham institutions. In addition, the Compliance and Education Office is required and has the authority to conduct audits (routine , targeted, and for cause) of human subject research studies at Mass General Brigham institutions to ensure compliance with applicable federal and state research regulations and institutional policies.

Education:

The Compliance and Education Office provides education to institutions, departments, or to study teams on a variety of human subject research topics including but not limited to the following: Essential Documents/Regulatory Binders, Informed Consent process, Clinical Trials registration and reporting requirements, Sponsor-Investigator responsibilities, Clinical Research Boot Camp, Writing a Clinical Research Protocol, and Inspections and Audits of Clinical Research.

Support:

The Compliance and Education Office is available to provide support to the research community at Mass General Brigham institutions by consultation and by making available to investigators and research staff a variety of study management tools and document templates Consultations can be requested for a variety of human research related matters including but not limited to: General Study Requirements, Study Start Up, FDA Inspection Prep, IND/IDE application submission to the FDA, and Clinical Trials.gov registration and reporting, The Compliance and Education Office director serves as the Institutional Liaison for FDA inspections.

Audits:

The Compliance and Education Office conducts onsite and remote routine, targeted (spot checks), and for-cause/directed audits of human subject research at Mass General institutions. Typically, audits are preceded by a consultation to explain the scope of the audit and audit process as well as address any questions or concerns of the PI and study team. Various tools, checklists, and policies will be provided in advance of the audit, including a Self-Assessment Checklist. Following an audit there is a close out meeting and the Audit Report and Audit Observations are sent to the investigator.

8.8 Mass General Brigham RM

The Mass General Brigham RM is responsible for the programmatic, administrative and financial monitoring of all awards made to HRPP Covered Entities under federally and non-federally sponsored projects. This office, in partnership with the Principal Investigator and his/her department administrator has the obligation, throughout the life of an award, to monitor the activities of awardee institutions and sub-recipients to make certain that project objectives are completed and all funds are used for authorized purposes in compliance with applicable, laws, regulations, and provisions of the prime contracts or grant agreements.

When the research proposal involves human subjects, RM is responsible for certifying to federal and non-federal sponsors that the grant application or funding proposal has been reviewed and approved by the Mass General Brigham IRB. The Mass General Brigham IRB is responsible for ensuring that the protocol record is linked to the grant/contract/agreement proposal funding or otherwise supporting the research within the Insight system.

8.9 Mass General Brigham CTO

The Mass General Brigham CTO is responsible for developing, negotiating and executing agreements and associated budgets for industry-sponsored clinical research on behalf of entities within the Mass General Brigham system. In negotiating these agreements, CTO agreement associates attend to issues related to freedom to publish, rights to use and control data including confidentiality of study data, patient confidentiality, compliance with applicable federal regulatory requirements, and subject injury and indemnification. Of note, CTO, in collaboration with the senior research leadership at the HRPP Covered Entities, the Mass General Brigham Office of the General Counsel, and HRA, has developed standard terms and policies for acceptable provisions in clinical trial agreements. The CTO notifies the IRB when terms outside the standard terms or policies are being proposed for input from the IRB on whether the proposed terms are acceptable and when accepted, ensure that the consent reflects any revised terms. When the research is industry-sponsored, the clinical trial agreement must be executed between the sponsor and CTO and the research activity must be approved by the Mass General Brigham IRB or its designated reviewing IRB before the research may begin.

8.10 Department Chairs/Chiefs

Department chairs/chiefs are responsible for ensuring that investigators conducting human subject research are qualified by training and experience to conduct the proposed research. In addition, department chairs/chiefs are responsible for ensuring that investigators have sufficient resources (time, research personnel, and access to appropriate populations) and facilities to conduct the proposed research. For each research activity involving an intervention or interaction with human subjects submitted to the IRB for approval, the department chair/chief or designee must certify that s/he accepts responsibility for assuring adherence to federal and state research regulations and institutional policies governing the protection of human subjects, including applicable institutional credentialing requirements.

8.11 Principal Investigators, Co-Investigators, and Research Staff

Primary responsibility for protecting the rights and welfare of human subjects participating in research rests with the principal investigator (PI). PIs may not commence human subject research prior to obtaining IRB approval and, as appropriate, other institutional approval of their research activities. The PI must have a staff appointment and may not be a resident or research fellow or other trainee. For each research activity submitted to the Mass General Brigham IRB for approval, the PI must certify that s/he accepts responsibility for assuring adherence to applicable federal and state research regulations and Mass General Brigham policies relative to the protection of the rights and welfare of subjects enrolled in the research.

PIs must be qualified by training and experience to conduct the research and must be in compliance with the *Harvard Faculty of Medicine Conflicts of Interest Policy* (if they have a Harvard Medical School faculty appointment) and the *Mass General Brigham Policy on Interactions with Industry and Outside Entities* (Mass General Brigham COI policy). The PI's department chair or chief or his/her designee must review and sign new applications for any research that involves an intervention or interaction with human subjects prior to submission to the Mass General Brigham IRB. When the research involves the administration of a drug or use of a device for research purposes, the PI must be a licensed physician. Exceptions to this requirement are made by the Mass General Brigham IRB on a case-by-case basis. Exceptions require a licensed physician co-investigator and approval of the department chair/chief.

PIs may delegate responsibilities to appropriately qualified co-investigators and research staff that are qualified by training and experience to perform these responsibilities. Additionally, co-investigators and research staff

must be in compliance with the Mass General Brigham COI policy, and, if applicable, the *Harvard Faculty of Medicine Conflicts of Interest Policy*. The PI remains responsible for the conduct of all persons to whom s/he delegates tasks.

All investigators and research staff must complete the Collaborative IRB Training Initiative (CITI) program or an equivalent program accepted by Mass General Brigham in order to participate in the conduct of human research and must complete the continuing education requirements every three years.

Investigators and research staff must be listed on any protocol in which they are involved as study personnel. For each protocol to which they are added as study staff, investigators and research staff must certify that they:

- are familiar with the Federalwide Assurance governing the research;
- have completed the Mass General Brigham human subject protection training requirements;
- have completed the applicable institutional credentialing processes, if any, required to conduct the research;
- understand the Harvard Faculty of Medicine and Mass General Brigham conflict of interest rules and will at all times during the course of the research be in compliance with those rules; and
- accept the obligation to comply with all applicable federal regulations and state laws, institutional policies and procedures, and the requirements and determinations of the Mass General Brigham IRB with respect to the research.

8.12 Research Participants

Massachusetts has a patients' rights law, which provides that a person has the right to refuse to serve as a research subject and to refuse care or examination when the primary purpose is educational or informational rather than therapeutic [M.G.L. ch.111 70E(i)]. This law is generally consistent with federal requirements for informed consent or assent to research. Information about Patient Rights and Responsibilities is available through the Mass General Brigham HRPP-Covered Entities' Admitting and Registration Services Department and on the individual Hospital websites.

Information about being a participant in a research study and the rights of every individual asked to participate in a research study, along with contact information for Mass General Brigham IRB staff, is available on the Mass General Brigham IRB public web pages.

The Mass General Brigham Informed Consent template provides the Mass General Brigham IRB telephone number for individuals to call if they wish to speak to someone other than the investigator about their rights as a research subject, their concerns about the research, or a complaint about the research.

Participants are encouraged to call if they feel they are being pressured to enroll in the research or, once enrolled, to continue with the research.

8.13 Mass General Brigham Office of the General Counsel

The Mass General Brigham Office of the General Counsel (OGC) has overall responsibility for all legal work arising from the activities of Mass General Brigham Covered Entities.

Within the OGC, a Research and Technology Section focuses on research and related work. Attorneys in this Section counsel the Mass General Brigham system on human subject research issues, policies, and legal requirements; research compliance matters; research integrity and related misconduct investigations; conflicts of interest; intellectual property; technology transfer and licensing; clinical trial agreements; HIPAA-related concerns and general research affairs. Their work relating to human subject protection includes, for example, drafting and reviewing IRB and other institutional policies, reviewing consent form language and other templates, advising on project-specific issues (e.g., informed consent, confidentiality), counseling on privacy requirements, assisting in investigations of alleged noncompliance, advising on liability issues, and generally interpreting and advising on new and existing legal requirements and conflicts between applicable laws.

The OGC has a close working relationship with Mass General Brigham HRA and the Mass General Brigham IRB. In addition, the OGC advises several other research clients within the HRPP, including the Mass General Brigham CTO, Mass General Brigham Innovation, and research leadership across the Mass General Brigham system.

8.14 Mass General Brigham Office of Research Compliance

The Mass General Brigham Office of Research Compliance (ORC) supports the research mission of Mass General Brigham by providing independent oversight of research compliance programs, activities, and processes to ensure quality and integrity in research. The Corporate Director of the ORC reports to the Mass General Brigham Vice President for Compliance, Audit and Business Integrity, with a dotted line reporting relationship to the Mass General Brigham Chief Academic Officer. The ORC serves as a resource to the individual hospital research compliance

programs and acts as a corporate-level resource. The ORC provides education and training to principal investigators, hospital research administrators, and corporate research management staff, facilitates the development of system-wide research policies and procedures, and coordinates and monitors research management activities for compliance with federal, state and local laws and regulations. ORC coordinates the Responsible Conduct of Research (RCR) training. The Mass General Brigham IRB collaborates with the Mass General Brigham ORC on matters related to non-compliance in human subject research.

8.15 Mass General Brigham Office for Interactions with Industry

The Office for Interactions with Industry (OII) implements and oversees all policies relating to interactions with industry and outside activities, including oversight and integration of all conflict of interest disclosure processes. OII staffs and manages the COA. The Mass General Brigham IRB collaborates with the OII frequently on matters relating to conflicts of interest in human subject research.

8.16 Professional and Institutional Conduct Committee

The Mass General Brigham Professional and Institutional Conduct Committee (PICC) is a committee of the Mass General Brigham Board of Directors and has been charged with the oversight of institutional policies relating to scientific and professional conduct and institutional research activities, including conflicts of interest.

PICC is responsible for:

- High-level policy issues;
- Resolution of limited categories of specific cases; and
- Other matters which the CCOI or the Mass General Brigham Education Review Board (ERB) decide should go to PICC.

8.17 Committee on Outside Activities

The purpose of COA is to handle matters that present potential conflicts of interest with respect to institutional interests and with respect to all Mass General Brigham individuals other than members of governing Boards.

The specific functions and authority of COA are to review and resolve matters that present potential conflicts of interest, relating to either institutional interests or the interests of Mass General Brigham individuals, by applying, interpreting and articulating conflicts-related

policy, except for those matters that are the responsibility of the Mass General Brigham ERB or PICC.

9.0 RESEARCH COMMITTEES

Mass General Brigham and the Mass General Brigham HRPP Covered Entities have several research committees that provide guidance to the institutions on research issues and serve as a forum for investigator feedback and input into institutional research-related policies and procedures.

9.1 Mass General Brigham Academic Executive Committee

The Mass General Brigham Academic Executive Committee (AEC) brings together IOs and physician and scientific leaders from across Mass General Brigham to consider research policies and initiatives with system-wide implications. The group also serves as a forum for consideration of topics stemming from federal funders and relations with industry. The Mass General Brigham AEC meets monthly and is chaired by the Mass General Brigham CAO.

9.2 Mass General Brigham Research Compliance Committee

The Mass General Brigham Research Compliance Committee (RCC) brings together research operational and compliance leadership from the Mass General Brigham Covered Entities to review compliance policies and monitoring activities, in addition to providing research leadership with education on new regulatory requirements. The Mass General Brigham RCC serves as a mechanism for ensuring consistency across Mass General Brigham in interpreting and implementing research regulations and policies. The committee is chaired by the Mass General Brigham Chief Research Compliance Officer.

9.3 BWH Biomedical Research Institute

The BWH Biomedical Research Institute (BRI) provides a virtual foundation for interdepartmental and individual research at BWH. By encouraging scientific collaborations and sharing of resources, the BRI sets a new standard of research excellence. The BRI's overarching mission is to accelerate discoveries that improve human health; supporting strategies include fostering groundbreaking, interdepartmental and interdisciplinary research, ranging from basic fundamental studies to clinical innovations. It strives to provide a clear voice (both internally and externally) for the entire BWH research community, raise the profile of research at BWH,

develop mission-centric collaborations with external entities and engage the scientific community in fundraising.

The BRI is led by an Executive Committee (EC) which includes three directors and the Senior Vice President of Research (IO). The BRI is governed by the BRI Research Oversight Committee (ROC) made up of department representatives, BRI Center and Program Co-Chairs, elected representatives and the BRI EC. The ROC, which is responsible for directing the BRI, was established to foster transparency and accountability in the decision-making process for the BWH research enterprise and to plan new strategic initiatives.

The BRI includes ten thematic research centers that develop and support collaborative research initiatives. The centers are supported by four resource- and technology-based programs, which provide tools applicable across the scientific disciplines. Together, this infrastructure allows our diverse community of clinicians and scientists to communicate more effectively, providing numerous opportunities for them to collaborate on research aimed at curing, treating and preventing a host of human diseases and conditions.

BRI Research Centers:

- Cancer
- Cardiovascular, Diabetes and Metabolic Disorders
- Infectious & Immunologic Diseases
- Human Genetics
- Connors-BRI Center for Research on Women's Health and Gender Biology
- Lung
- Musculoskeletal
- Neurosciences
- Patient-centered Comparative Effectiveness
- Regenerative Medicine

BRI Programs:

- Bioinformatics
- Biomedical Imaging
- Clinical Investigation (in connection with the BWH Center for Clinical Investigation)
- Pre-Clinical Models

9.4 MGH Executive Committee on Research

The MGH Executive Committee on Research (ECOR) is the central planning and policy-making body of the MGH research enterprise. ECOR

is a standing committee of the General Executive Committee (GEC) and its membership includes representatives elected from the Chiefs' Council and from the research community at-large as well as appointed faculty members and senior management, including the MGH President, the MGPO President, and the Senior Vice President for Research. The Mass General Brigham VP HRA, Research Finance, and Research Management are non-voting members of ECOR.

ECOR meets twice monthly and ECOR leadership meets twice monthly with the MGH President. ECOR's chair and vice-chair are faculty members and have three-year terms; the vice-chair usually succeeds to the chairmanship, thereby assuring continuity.

The specific responsibilities of ECOR include:

- Developing a research plan congruent with the clinical mission of the MGH and the Mass General Brigham-wide science enterprise;
- Representing the needs of the MGH scientists to the GEC;
- Formulating research policies within the framework established by the Trustees and the President;
- Developing recommendations for the GEC and the President on resource allocation issues;
- Evaluating and monitoring the quality of the science; and
- Optimizing communication between administration and investigators.

The Research Council, sponsored by ECOR, meets once a month as a town meeting of the investigator community and is open to the entire research community. The ECOR elected representatives serve as the Executive Committee and the Research Council chair and co-chair are the two full-professor elected representatives to ECOR. The goal of these meetings is to provide communication between ECOR and the investigator community and to bring important issues and resources to the attention of the research community.

9.5 MGH Research Institute

The MGH Research Institute is the largest hospital-based research enterprise in the United States with a community of over 6,000 people working across more than 30 institutes, centers and departments. Embedded within MGH and with a mission to support, promote and guide the hospital's existing research enterprise, the Research Institute is built on a culture of excellence, rooted in compassion, innovation, and groundbreaking scientific achievement. Researchers work side-by-side with clinicians to harness the latest advances in science and foster

innovation at every stage. The Research Institute partners with academia, industry, governments, philanthropists and the community to make medical advancements sustainable, and ultimately, to prevent disease and find cures to improve the lives of our patients and those across the globe.

The MGH Research Institute is directed by a Steering Committee whose members include the MGH President, Senior Vice President for Research, ECOR leadership, the Research Institute Scientific Director, the Director of the Division of Clinical Research, and the Chiefs of Medicine and Surgery.

9.6 McLean Research Committee

The McLean Research Committee is chaired by the Chief Scientific Officer and the President and Chief as *ex officio*. Senior faculty members (associate professor or above) are welcome to attend this meeting, which occurs monthly. The purpose of this meeting is to inform senior leadership and scientists of any research policy updates, including any issues with implications for the broader research community. The meeting agenda includes scientific and research updates from the research community, administrative and policy updates from research administration, and serves as a place where updates from Mass General Brigham IRB would be disseminated to the research community.

A sub-group of the Research Committee serves as voting members of the “SAM” (Subcommittee on Administrative Matters) for consideration of ad hoc capital requests and equipment moves, as well as other projects and requests for institutional funding.

9.7 McLean Research Steering Committee

The McLean Research Steering Committee is chaired by the Chief Scientific Officer. Laboratory directors and their designees are welcome to attend this meeting, which occurs monthly. The purpose of this meeting is to provide research updates and announcements to the research community and to discuss research operations at McLean, including implementation of new research policies and research updates. Members of the research community are able to attend to provide feedback to leadership and input into institutional research-related policies and procedures.

9.8 McLean Research Administration Advisory Committee

The McLean Research Administration Advisory Committee is chaired by the Senior Director of Research Administration. Representatives from

each research building on campus are invited to attend this meeting, which occurs quarterly. The purpose of this meeting is to discuss research policy issues, in particular how to implement new policies throughout the research community, e.g., how to integrate a new Mass General Brigham policy on the McLean campus. Members of the research community are able to attend to provide feedback to leadership and input into institutional research-related policies and procedures.

10.0 RELIANCE AGREEMENTS WITH OTHER INSTITUTIONS

When Mass General Brigham relies on an external IRB for oversight, or when an external entity relies on the Mass General Brigham IRB for oversight, Mass General Brigham will be responsible for executing a reliance agreement that describes how the responsibilities for human subject protection are divided between Mass General Brigham and the non-Mass General Brigham entity. When the research involves federally-funded research, an appropriate assurance must be held by the entities party to the agreement. In most cases employees or agents of Mass General Brigham must be collaborating with employees or agents of the non-Mass General Brigham entity on one or more research projects. When research is subject to the HHS Common Rule, Mass General Brigham complies with the requirement to rely on the review of a single IRB for that portion of cooperative research conducted in the United States. The HRO is responsible for maintaining reliance agreements and associated documentation.

The Common Rule requires that any institution located in the United States that is engaged in cooperative research must rely on the review of a single IRB for that portion of the research conducted in the United States. “Cooperative research projects” are projects covered by this policy which involve more than one organization in the United States. The IRB will enter into a written reliance agreement with other organizations to (i) take on oversight of some or all participating sites in a multi-site study or (ii) rely on the review of another qualified IRB for research activities taking place at the Covered Organization when engaged in cooperative research projects.

Reliance agreements generally address the following:

- Scope of covered research
- FWA status of the parties
- Responsibilities for HIPAA determinations in connection with the covered research
- IRB independence and authority
- IRB decisions
- Compliance responsibilities of relying entity

- Reporting of noncompliance, injuries and subject safety, unanticipated problems (including reporting to external oversight/funding authorities)
- Cooperation in investigations and corrective actions
- Recordkeeping and access to minutes
- Termination of the relationship and provision for continued oversight of ongoing research
- Communications

The HRO ensures the reliance agreement is approved and executed by the appropriate officials of the organizations involved.

- When the Mass General Brigham IRB has been designated the IRB of record, the IRB review process and oversight will be governed by Mass General Brigham IRB policy and the terms outlined in the executed reliance agreement.
- When Mass General Brigham cedes its oversight for research activities to another qualified IRB, the IRB review process and oversight requirements will be governed by the terms outlined in the executed reliance agreement.
- The Mass General Brigham HRPP Covered Entities and their researchers will comply with the reviewing requirements and determinations of the reviewing IRB.
- HRO provides the reviewing IRB with requested information about local requirements or local research context issues relevant to the reviewing IRB's determinations prior to review.
- HRO will notify the reviewing IRB when local requirements or research context impacting the reviewing IRB's oversight are updated.
- Mass General Brigham officials will not approve research that has not been approved by the reviewing IRB.
- Researchers must cooperate with the reviewing IRB with regard to their responsibility for initial and continuing review, record keeping, reporting, and must provide information in a timely manner to the reviewing IRB.
- Researchers and research staff must disclose conflicts of interest according to the reliance agreement and comply with any conflict of interest management plans.
- Researchers must report promptly to the reviewing IRB any proposed changes to the research and cannot implement changes without prior review and approval by the reviewing IRB, except where necessary to eliminate apparent immediate hazards to the participants.
- Researchers will not enroll participants in research prior to review and approval by the reviewing IRB as well as meeting all other applicable requirements and approvals for the study.
- When required by the reviewing IRB, researchers will obtain, document, and maintain records of consent for each participant or their legally authorized representative.
- Researchers will comply with all reporting requirements of the

reviewing IRB according to the reliance agreement and Mass General Brigham IRB reporting requirements when relying on an external IRB.

- Researchers will comply and cooperate with monitoring requirements of both the reviewing IRB and Mass General Brigham.
- HRO will provide contact information for researchers and staff to obtain answers to questions, express concerns, and convey suggestions regarding the use of the reviewing IRB.
- Mass General Brigham will ensure researchers and staff have appropriate qualifications and expertise to conduct the research, are knowledgeable about laws, regulations, codes and guidance governing their research, and are knowledgeable about the organization's policies and procedures

The Mass General Brigham HRPP considers the following when deciding whether or not to rely on an external entity for IRB review:

- Whether the research is subject to the Common Rule cooperative research single IRB review requirement
- Whether the research involves minimal risk or more than minimal risk
- Where the research interventions will be performed, and by whom
- Qualifications and experience of the researchers performing more than minimal risk interventions or procedures
- For more than minimal risk research, whether the entity has acceptable liability insurance coverage and other safety-related issues
- Whether the entity is AAHRPP-accredited

10.1 Dana-Farber Cancer Center

The Mass General Brigham HRPP-covered entities routinely rely on the Dana Farber Cancer Center IRB for review of oncology research conducted under the auspices of the Dana Farber/Harvard Cancer Center. This reliance is reflected in reliance agreements executed by the parties. An exception is Phase I research conducted at the Mass General Hospital Cancer Center that is an industry protocol and industry sponsored is reviewed by the Mass General Brigham IRB.

10.2 Harvard School of Public Health

The Mass General Brigham HRPP-covered entities rely upon the Harvard School of Public Health IRB for review of the occasional research proposal that involves prisoners. This reliance is reflected in an agreement executed by the parties.

10.3 Commercial/Independent IRBs

Mass General Brigham will rely upon designated commercial/independent IRBs for review of select phase II and IV multi-site research on a case-by-case basis and for Phase 0-I research by exception with approval from the VP HRA. Reliance upon commercial/independent IRBs is documented in reliance agreements executed by the parties. When relying on commercial/independent IRBs, the Mass General Brigham IRB has access to all proposed amendments and continuing reviews and copies of approval notification letters, approved protocols and consent forms.