

**PARTNERS HEALTHCARE SYSTEM, INC.  
BRIGHAM AND WOMEN'S HOSPITAL  
FAULKNER HOSPITAL  
MASSACHUSETTS GENERAL HOSPITAL  
MCLEAN HOSPITAL  
NORTH SHORE MEDICAL CENTER**

**Partners Human Research Protection Program (HRPP) Plan**

**1.0 THE HRPP**

The HRPP of Partners HealthCare System, Inc. (Partners) is the integrated program with overall responsibility for the protection of the rights and welfare of human subjects in research for The Brigham and Women's Hospital, Inc. (BWH), Faulkner Hospital, Inc. (FH), The General Hospital Corporation (also known as Massachusetts General Hospital) (MGH), The McLean Hospital Corporation (McLean), and North Shore Medical Center, Inc. (NSMC). In aggregate these are the Partners HRPP-covered entities. The HRPP includes specific review and oversight of research activities involving human subjects as conducted by these institutions' institutional review boards (collectively, the Partners IRB(s) or the IRB); management of funding negotiations with government and private sponsors as conducted by the Partners Research Management Office and the Partners Clinical Research Office; 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 Partners HRPP and Partners 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 Partners 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 Partners 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 Partners HRPP is also committed to education of and outreach to persons interested in research.

**3.0 ETHICAL PRINCIPLES**

The Partners 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), IRB staff and all other employees of Partners and the Partners HRPP-covered entities have the ethical obligation to protect human subjects participating in research at the Partners-HRPP covered entities in accordance with legal requirements and ethical guidelines.

#### 4.0 APPLICABLE LAWS

Laws, regulations, and other rules relevant to the Partners 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. 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)

Requirements of Specific Funding Authorities:

In research conducted or supported by governmental entities, entity regulations and requirements as applicable (e.g., U.S. Department of Defense, U.S. Department of Justice).

## 5.0 SCOPE

The Partners HRPP has jurisdiction over all human-subjects research conducted by the Partners 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 Partners HRPP-covered entities are engaged in human-subjects research whenever its employees or agents (e.g., professional staff) for the purposes of the research obtain: (1) data about the subjects of the research through intervention or interaction with them; (2) identifiable private information about the subjects of the research; or (3) the informed consent of human subjects for the research. They are also engaged in human-subjects research whenever a direct HHS award to support human-subjects research is received, even where all activities involving human subjects are carried out by employees or agents of another institution.

## 6.0 DEFINITIONS

*Human-subjects research* means activities that meet the DHHS definition of *research* and involve a *human subject* as defined by DHHS or meet the FDA definition of *clinical investigation* and involve a *human subject* or *subject* as defined by FDA. The DHHS definition for *research* and *human subject* and the FDA definition for *clinical investigation*, *human subject*, and *subject* are provided below:

*Research* as defined by DHHS means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. [45 CFR 46.102(d)]

*Human subject* as defined by DHHS means a living individual about whom an investigator (whether professional or student) conducting research obtains (1) Data through intervention or interaction with the individual, or (2) Identifiable private information. *Intervention* includes both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes. *Interaction* includes communication or interpersonal contact between investigator and subject. *Private information* includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and

information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record). Private information must be individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects. [45 CFR 46.102(f)(1)(2)]

*Clinical investigation* as defined by FDA means any experiment that involves a test article and one or more human subjects and that either is subject to requirements for prior submission to the Food and Drug Administration under section 505(i) or 520(g) of the act, or is not subject to requirements for prior submission to the Food and Drug Administration under these sections of the act, but the results of which are intended to be submitted later to, or held for inspection by, the Food and Drug Administration as part of an application for a research or marketing permit. The term does not include experiments that are subject to the provisions of part 58 of this chapter, regarding nonclinical studies. The terms *research*, *clinical research*, *clinical study*, *study*, and *clinical investigation* are deemed to be synonymous... [21 CFR 50.3(c) and 21 CFR 56.102(c)]

*Human subject* as defined by FDA means an individual who is or becomes a participant in research, either as a recipient of the *test article* or as a control. A subject may be either a healthy human or a patient. [21 CFR 50.3(g) and 21 CFR 56.102(g)]

*Test article* as defined by FDA means any drug (including a biological product for human use), medical device for human use, human food additive, color additive, electronic product or any other article subject to regulation under the act or under sections 351 and 354-360F of the Public Health Service Act (42 U.S.C. 262 and 263b-263n). [21 CFR 50.3(j) and 21 CFR 56.102(l)]

*Subject* as defined by FDA means a human who participates in an investigation, either as an individual on whom or on whose specimen an investigational device is used or as a control. A subject may be in normal health or have a medical condition or disease [21 CFR 812.3(p)].

## 7.0 GOVERNANCE

Governance of the Partners HRPP is coordinated among Partners Corporate and the Partners HRPP-covered entities.

Partners HealthCare System, Inc. is the overall corporate parent of the Partners HRPP-covered entities as well as a number of other health care provider entities. Partners has a Board of Directors, which generally manages and directs the overall health care system. However, the Partners 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 of Trustees, which carry out core responsibilities with respect to the hospitals. The Partners HRPP-covered entities are each distinct recipients of all types 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 at the Partners HRPP-covered entities provide assurance that the IRBs designated in the FWAs are knowledgeable about the local research context and will comply with the terms of the FWAs.

Partners provides some centralized services (e.g., research management, legal, information systems, compliance and human resources). The Partners 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 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.

In 1996, BWH and MGH combined the operation and management of their respective IRBs into a single integrated IRB system, known as the Partners IRB(s) or the IRB (also known as the Partners Human Research Committee(s) or the PHRC). Cooperative Amendments were filed with the Office for Human Research Protections (OHRP) to codify this agreement, and the current FWAs reflect this arrangement. Subsequently, FH (2005), NSMC (2013) and McLean (2014) decided to rely on the Partners IRBs registered to BWH and MGH for IRB review of its human-subjects research. These reliances are reflected in the Partners HRPP-covered entities' FWAs and in agreements executed by the parties.

The integrated IRB operation is managed by staff of Partners Human Research Affairs, which is a centralized department responsible for supporting human-subjects research services for the Partners HRPP-covered entities' investigators. In addition to the centralized Human Research Affairs Office, other key centralized functions for the HRPP include: Research Management; General Counsel; Information Systems; and Research Compliance.

Although the ultimate responsibility for the protection of human subjects of research resides with the individual institutions, the Partners HRPP coordinates and carries out review and oversight activities on behalf of the Partners HRPP-

covered entities and reports directly to the designated Institutional Official of each institution.

## 8.0 KEY ROLES AND RESPONSIBILITIES

### 8.1 Partners Chief Academic Officer

Anne Klibanski, M.D., the Chief Academic Officer (CAO), reports to the President and Chief Executive Officer of Partners. The CAO is responsible for providing the necessary resources for those components of the HRPP that are under her authority.

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

- ❑ Human Research Affairs, which includes the Partners IRBs and Quality Improvement Program
- ❑ Research Compliance
- ❑ Partners Innovation that supports interactions with commercial partners via the following distinct Departments:
  - Research and Licensing
  - Business Development
  - Innovation Fund

### 8.2 Partners Chief Financial Officer

Peter Markell, the Chief Financial Officer (CFO), reports to the President and Chief Executive Officer of Partners. Partners Research Management, a corporate component of the HRPP, reports to the CFO. Partners Research Management includes the following distinct departments:

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

### 8.3 Institutional Officials

The Partners 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 IRB is the sole entity that can grant approval for non-exempt research activities involving human subjects, i.e., no one within the institution may approve such human-subjects research that has not been approved by the IRB. The FWAs have been approved by OHRP and are updated as necessary when information changes.

The IO for each 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 IRB with the necessary local resources through the Partners annual budgeting process, which allocates IRB operating costs to the relevant Partners entities, and
- Supporting the authority and decisions of the Partners IRB(s).

The Institutional Official for Brigham and Women’s Hospital and Faulkner Hospital is Paul J. Anderson, M.D., Ph.D., Chief Academic Officer and Senior Vice President of Research.

The Institutional Official for Massachusetts General Hospital is Harry W. Orf, Ph.D., Senior Vice President for Research.

The Institutional Official for McLean Hospital is Scott L. Rauch, M.D., President and Psychiatrist-in-Chief.

The Institutional Official for North Shore Medical Center is Mitchell S. Rein, M.D., Chief Medical Officer and Senior Vice President for Medical Affairs.

#### 8.4 Partners Institutional Review Boards

The Partners Institutional Review Boards (Partners IRB(s)) are registered with DHHS/OHRP and FDA. The IRB registrations are updated and submitted to OHRP/FDA as needed when there are any changes to the membership of the IRBs. Within Partners HRA, it is the Partners IRB(s) specifically that are responsible for review and oversight of human-subjects research under its scope of authority.

As noted above, the activities of the Partners HRPP-covered entities' IRBs have been integrated to improve operational efficiency, minimize redundancy of review and foster collaboration among the institutions' investigators. The IRBs exercise their responsibilities for protection of human research subjects with independence of decision-making. Only the IRBs are allowed to grant approval for any non-exempt research activity involving human subjects. Human-subjects research approved by the IRBs may be subject to further institutional review and approval; however, no one within the institution may approve non-exempt human-subjects research that has not been approved by the IRB.

When further institutional review and approval is required, the Human Research/IRB Office is responsible for coordinating review and verifying approval of the research by the applicable ancillary committees, departments, groups or individuals. When the research has received all required institutional approvals, the IRB notifies the Principal Investigator and study contacts of approval and publishes the IRB-approval/activation letter and the IRB-approved consent form(s), as well as applicable recruitment materials in eIRB/Insight. The eIRB/Insight application contains a complete record of protocol submissions and documentation of IRB and ancillary committee reviews and approvals.

#### 8.5 Partners Human Research Quality Improvement Program

The Partners Human Research Quality Improvement Program (QI Program) is responsible for assisting the institutions and investigators in fulfilling their human-subjects research responsibilities through compliance with federal and state regulations governing human research and for promoting an environment in which human-subjects research will be conducted according to the highest legal and ethical standards. The QI Program accomplishes these goals through on-site assessments and educational activities conducted both prior to, and during active conduct of the study.

The QI program is responsible for and has the authority to:

- Conduct routine (not for-cause) audits that focus on compliance with all relevant regulations. These audits may be conducted on any study that has been approved by the Partners IRB;
- Conduct directed (for-cause) audits at the request of the Partners IRB or the Institutional Officials;
- Assist investigators in study start up activities including study management documents and data collection tools;
- Assist Sponsor-Investigators in meeting their IND or IDE holder responsibilities including education, on-site assessments, and review of IND or IDE application submissions;
- Provide practical and specific educational in-services for investigators and research teams; and

- Assist investigators in understanding and complying with clinical trials registration and reporting requirements.

#### 8.6 Partners Research Management

The Partners Research Management Office is responsible for the programmatic, administrative and financial monitoring of all awards made to BWH, MGH, and beginning in June of 2015 for McLean Hospital, 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, the Research Management Office is responsible for certifying to federal and non-federal sponsors that the grant application or funding proposal has been reviewed and approved by the Partners IRB(s). The Partners IRBs are responsible for reviewing the description of the human research in the application or proposal for funding for consistency with the human research protocol(s) submitted to the Partners IRBs. The Partners IRBs are responsible for ensuring that the Partners IRB protocol record is linked to the grant/contract/agreement proposal funding or otherwise supporting the research within the integrated research management database and for providing additional information about IRB approvals as needed.

#### 8.7 Partners Clinical Research Office

The Partners Clinical Research Office (PCRO) is responsible for developing, negotiating and executing agreements and associated budgets for industry-sponsored clinical research on behalf of BWH, FH, MGH, McLean, NSMC and certain other entities within the Partners system (Newton-Wellesley Hospital, Spaulding Rehabilitation Hospital Corporation, and Partners Community Physician Organization). In negotiating these agreements, PCRO agreement associates pay particular attention to issues related to freedom to publish, rights to use and control data including confidentiality of study data, patient confidentiality, compliance with the Common Rule and HIPAA Privacy Rule, and subject injury and indemnification. Of note, PCRO, in collaboration with the senior research leadership at the Partners HRPP-covered entities, the Partners Office of the General Counsel, and Human Research Affairs, has developed standard terms and policies for acceptable provisions in clinical trial agreements. Executed agreements are made available to the PHRC for review for consistency with the informed consent documents.

When the research is industry-sponsored, the clinical trial agreement must be executed between the sponsor and Partners PCRO and the research activity must be approved by the IRB before the research may begin.

8.8 Department Chairs/Chiefs

Department chairs/chiefs are responsible for ensuring that investigators conducting human-subjects 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.

The BWH, FH, and MGH department chairs/chiefs are also responsible for compliance with the requirements of Massachusetts General Laws (M.G.L.) 94C Controlled Substances Act Section 8 governing research projects and studies. Department chairs/chiefs must fulfill annual registration and reporting requirements with the Commonwealth of Massachusetts Department of Public Health. The Department of Public Health registers all applicable chairs/chiefs of departments and obtains annual reports on clinical investigations involving schedule II and IND drugs that are being conducted at the institution by members of the registered department.

8.9 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-subjects 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 Partners IRB for approval, the PI must certify that s/he accepts responsibility for assuring adherence to applicable federal and state research regulations and hospital 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 Partners Policy on Interactions with Industry and Outside Entities (hereafter the “Partners Conflicts of Interest Policy”) (all

Partners investigators). 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 Partners IRB(s). 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 Partners IRB(s) 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. However, co-investigators and research staff must be qualified by training and experience to perform these responsibilities. Additionally, co-investigators and research staff must be in compliance with the Partners Conflicts of Interest Policy, and, if applicable, the HMS 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 Partners 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: (1) are familiar with the FederalWide Assurance governing the research; (2) have completed the Partners human-subject protection training requirements; (3) have completed the applicable institutional credentialing processes, if any, required to conduct the research; (4) understand the Harvard Faculty of Medicine and Partners conflicts of interest rules and will at all times during the course of the research be in compliance with those rules; and (5) accept the obligation to comply with all applicable federal regulations and state laws, institutional policies and procedures, and the requirements and determinations of the Partners Human Research Committee with respect to the research.

#### 8.10 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 Partners 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 Partners IRB staff, is available on the Partners IRB public web pages.

The Partners Research Consent Form template provides the Partners 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.

#### 8.11 Partners Office of the General Counsel

The Partners Office of the General Counsel (OGC) has overall responsibility for all legal work arising from the activities of Partners and its affiliated hospitals and entities.

Within the OGC, a Research and Technology Section focuses on research and related work. Four lawyers in this Section counsel the Partners system on human-subjects 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 institutional review board (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 Partners Human Research Affairs and the Partners IRBs. Frequent conversations, meetings, and e-mail exchanges take place on a wide range of research issues. In addition, the OGC closely advises several other research clients within the HRPP, including the Partners Clinical Research Office, Partners Innovation, and research leadership across the Partners system.

#### 8.12 Partners Office of Research Compliance

The Partners Office of Research Compliance (ORC) was established in 2007 to support the research mission of Partners and its affiliated hospitals 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 Partners Vice President for Compliance, Audit and Business Integrity, with a dotted line reporting relationship to the Partners Chief Academic Officer. The ORC serves as a resource to the individual hospital research compliance programs, as well

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. Of note, ORC coordinates Responsible Conduct of Research (RCR) training. The Partners IRB collaborates with the Partners ORC on matters related to non-compliance in human-subjects research.

8.13 Partners 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 Committee on Outside Activities (COA) (formerly named the Committee on Conflicts of Interest (CCOI)) (See Section 8.15). The Partners IRB collaborates with the OII frequently on matters relating to conflicts of interest in human-subjects research.

8.14 Professional and Institutional Conduct Committee

For over fifteen years Partners has had a committee called the Professional and Institutional Conduct Committee (PICC). PICC is a committee of the Partners 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 ERB decide should go to PICC.

8.15 Committee on Conflicts of Interest/Committee on Outside Activities

In 2009, as the result of the two-year-long Commission on Interactions with Industry and its subsequent recommendations, Partners created a new Committee on Conflicts of Interest (CCOI). CCOI was created as a management committee, and was intended to provide a committee that could meet more frequently than a Director's committee like PICC can, and to handle a larger volume of specific cases.

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

The specific functions and authority of CCOI are to review and resolve matters that present potential conflicts of interest, relating to either institutional interests or the interests of Partners individuals, by applying,

interpreting and articulating conflicts-related policy, except for those matters that are the responsibility of the Partners Education Review Board (ERB) or PICC. In performing its functions, the Committee has the authority to:

- i. Develop, adopt and oversee implementation of details of policy within existing policy framework;
- ii. Consider and address issues of academic and institutional integrity (e.g., dissemination of research results; grants of IP rights) that arise in matters involving conflicts of individuals;
- iii. Develop, adopt and oversee implementation of appropriate resolution of such matters, including approval of plans to manage actual or potential conflicts of interest and, where it deems it appropriate, prohibiting certain activities or actions;
- iv. Receive information and comments from relevant individuals;
- v. Develop, adopt, and oversee implementation of such policies as are necessary for compliance with applicable federal, state and local laws pertaining to individual and institutional conflicts of interest; and
- vi. Determine which matters within its areas of responsibility to refer on to the Partners Professional and Institutional Conduct Committee.

The CCOI was created by the Partners CEO on October 1, 2009. It began operations in January 2010 and meets monthly.

In 2014, as the result of some membership and other changes, CCOI was renamed to the Committee on Outside Activities. Its functions remain the same.

## 9.0 RESEARCH COMMITTEES

Partners and the Partners 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 Academic Executive Committee

The Partners Academic Executive Committee (AEC) brings together physician and scientific leaders from across the Partners HealthCare System to consider research policies and initiatives with system-wide implications. The group also serves as a forum for consideration of topics stemming from NIH activities and relations with industry. The Partners AEC meets monthly and is chaired by the Partners Chief Academic Officer.

### 9.2 Partners Research Compliance Committee

The Partners Research Compliance Committee (RCC) brings together research operational and compliance leadership to review compliance policies and monitoring activities, in addition to providing research leadership with education on new regulatory requirements. The Partners RCC serves as a mechanism for ensuring consistency across the Partners HealthCare System in interpreting and implementing research regulations and policies. The committee is chaired by the Partners Corporate Director of Research Compliance.

### 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.

#### BRI Research Centers and Programs

The BRI includes ten thematic research centers that develop and support collaborative research initiatives not tenable by individuals and single departments alone. 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

#### BRI Leadership

The BRI is led by an Executive Committee (EC) which includes three directors and the Senior Vice President of Research and is governed by the 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 research enterprise and to plan new strategic initiatives.

#### 9.4 MGH Research Institute

The Massachusetts General Hospital 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 the Massachusetts General Hospital 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. Our researchers work side-by-side with clinicians to harness the latest advances in science and foster innovation at every stage. We partner with academia, industry, governments, philanthropists and our 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.

#### MGH Research Institute Steering Committee

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

#### 9.5 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 Partners Directors of Human Research Affairs, 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 Partners-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.

#### 9.6 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 Partners 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 Partners 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 the Partners HRPP-covered entities rely on another entity for IRB review or are relied upon by another entity for IRB review, the parties must execute a reliance agreement that describes how the responsibilities for human subject protection are divided between the Partners HRPP-covered entity and the non-Partners entity. Both parties must have current FWAs and, in most cases, employees or agents of Partners must be collaborating with employees or agents of the non-Partners entity on one or more research projects. When the Partners IRB cedes review to another entity, the Human Research Office creates a record in Insight/eIRB to track initial and continuing IRB review and approval.

Reliance agreements generally address the following:

- Scope of covered research
- FWA status of the parties

- Responsibility 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 Partners HRPP considers the following when deciding whether or not to rely upon another entity for IRB review:

- 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 Partners 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 the FWAs and in agreements executed by the parties.

#### 10.2 Harvard School of Public Health

The Partners 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 Spaulding Rehabilitation Hospital

BWH and MGH occasionally rely upon the Spaulding Rehabilitation Hospital IRB for review of collaborative research. These are considered on a case-by-case basis. This reliance is reflected in agreements executed by the parties.

#### 10.4 Harvard Catalyst (Clinical and Translational Science Award (CTSA) to Harvard Medical School)

MGH, BWH, and McLean will rely upon the IRB of another Harvard Catalyst institution for review of collaborative research on a case-by-case basis. This reliance is reflected in an agreement executed by the Harvard

Catalyst institutions, which include, among others, Beth Israel Deaconess Medical Center, Brigham and Women's Hospital, Children's Hospital Boston, Dana-Farber Cancer Institute, Harvard Medical School (includes the Harvard School of Dental Medicine), Harvard School of Public Health, Harvard University Faculty of Arts and Sciences, Joslin Diabetes Center, and Massachusetts General Hospital.

10.5 Other Institutions

The Partners HRPP-covered entities will rely upon the IRB of another institution for review of collaborative research on a case-by-case basis. When this occurs, a single project reliance agreement is executed by the parties.

10.6 Commercial/Independent IRBs

BWH, MGH, and McLean will rely upon certain commercial/independent IRBs for review of select phase III and IV industry-sponsored multi-site research on a case-by-case basis. Reliance upon commercial/independent IRBs is reflected in reliance agreements executed by the parties. When relying on commercial/independent IRBs, the Partners IRB receives notification of all proposed amendments and continuing reviews and copies of approval notification letters and approved protocols and consent forms.