PARTNERS HEALTHCARE SYSTEM, INC.
BRIGHAM AND WOMEN'S HOSPITAL
FAULKNER HOSPITAL
MASSACHUSETTS GENERAL HOSPITAL

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) and The General Hospital Corporation (also known as Massachusetts General Hospital) (MGH). 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 Office of Grants and Contracts 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 the support of the compliance responsibilities of the covered institutions and investigators.

2.0 MISSION

A core mission of BWH, FH, MGH and Partners is to advance care through excellence in biomedical research. Consistent with that, the HRPP's mission is to help ensure that in being a leader in research, Partners and its hospitals protect human subjects participating in research conducted or sponsored by BWH, FH or MGH, or in which BWH, FH or MGH are otherwise engaged, in accordance with legal requirements and ethical guidelines. 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."

4.0 APPLICABLE LAWS

Federal Regulations:

- 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 601 (Biologics Licensing)
- 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)
- 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. 93H (Security Breaches)
- M.G.L. c. 94C §8 (Controlled Substances in Research)
- M.G.L. ch. 111L (Human Embryonic Stem Cell Research)
- M.G.L. ch. 111, §70E (Patients Rights/Informed Consent)
- M.G.L. c.111 § 70F (Consent to HIV/AIDS Testing)
- M.G.L. c.111 § 70G (Genetic Privacy)
- M.G.L. c.112, §12F (Consent by Minors)
- M.G.L. c.112, §12J (Experimentation on Fetuses)
- M.G.L. c.201, §§6A-6B (Guardianships)
- M.G.L. c.201D,6; 2-1-2 to 201-4 (Health Care Proxies)
- 104 C.M.R. 31.00 (Department of Mental Health Research)
- 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 Mental Retardation Research)
- 201 C.M.R. 17.00 (Protection of Personal 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 BWH, FH or MGH 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.

BWH, FH and/or MGH 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. BWH, FH and/or MGH are also engaged in human-subjects research whenever it receives a direct HHS award to support human-subjects research, 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 BWH, FH and MGH.

Partners HealthCare System, Inc. is the overall corporate parent of BWH, FH and MGH 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. Within Partners, BWH and FH share the same intermediate corporate parent. However, BWH, FH and MGH are each legally separate corporate entities. As such, they have their own Boards of Trustees, which carry out core responsibilities with respect to the hospitals. BWH, FH and MGH are each distinct recipients of all types of external funding. BWH, FH and MGH each have their own Federalwide Assurances (FWAs) signed by their own Institutional Officials (IOs), who are legally authorized to represent each institution. The individual who serves as the IO for BWH also serves as the IO for FH. The IOs at BWH, FH, and MGH 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 and human resources). The individual entities carry out most other operations.

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. In 2005, FH decided to rely on the Partners IRBs registered to BWH and MGH for IRB review of its human-subjects research. This reliance is reflected in the current FH FWA and in an agreement executed by the parties.

The integrated IRB operation is managed by staff of Partners Research Management, which is a centralized department responsible for supporting research services for BWH, FH and MGH investigators. These services include among others, administrative IRB support, grants and contracts, industry-sponsored research and research finance. In addition to centralized Research Management, other key centralized functions for the HRPP include: the Office of the 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 BWH, FH and MGH and reports directly to the designated Institutional Official of each institution.

8.0 KEY ROLES AND RESPONSIBILITIES

8.1 Partners Chief Scientific Officer

Dennis A. Ausiello, M.D., the Chief Scientific Officer (CSO), reports to the President and Chief Executive Officer of Partners. The CSO is responsible for providing the necessary resources for those components of the HRPP that are under his authority. Corporate components of the HRPP that report to the CSO include:

- Partners Research Management, which includes:
  - Clinical Research Office
  - Grants and Contracts
  - Research Finance
  - Human Research Affairs, consisting of the IRB and Quality Improvement Program
- Research Compliance
- Research Ventures & Licensing (RVL) that supports interactions with commercial partners via the following distinct Departments:
  - Research and Licensing
  - Business Development
  - Innovation Fund

8.2 Institutional Officials

BWH, FH and MGH 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.

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 the 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 the Brigham and Women's Hospital and the Faulkner Hospital is Barbara Bierer, M.D., Senior Vice President for Research.

The Institutional Official for the Massachusetts General Hospital is F. Richard Bringhurst, M.D., Senior Vice President for Research.

8.3 Partners Institutional Review Boards

The 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 BWH and MGH IRBs have been integrated to improve operational efficiency, minimize redundancy of review and foster collaboration among the institutions' investigators. The BWH and MGH 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.

8.4 Partners Human Research Quality Improvement Program

The Partners 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, review of self-assessments completed by investigators, 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;
- Review Sponsor-Investigator responsibilities of IND or IDE holders with investigators; and
- Provide practical and specific educational in-services for investigators and research teams.

8.5 Partners Office of Grants and Contracts and Research Finance

The Partners Offices of Grants and Contracts and Research Finance are responsible for the programmatic, administrative and financial monitoring of all awards made to BWH, FH and MGH, as well as to sub-recipients, 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 Office of Grants and Contracts 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 PHRC is 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 PHRC. The PHRC is responsible for linking the PHRC protocol record to the grant/contract/agreement record within the integrated research management database and for providing additional information about IRB approvals as needed.

8.6 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, and certain other entities within the Partners system (Newton-Wellesley Hospital, Spaulding Rehabilitation Hospital Corporation, and Partners Community HealthCare, Inc). 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 BWH, FH and MGH, the Partners Office of the General Counsel, and the Office of 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.

8.7 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 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 department chair/chief is 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 appropriate 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.

8.8 Investigators

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 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/or 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 the Harvard Faculty of Medicine Policy on Conflicts of Interest and Commitment, if applicable. 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.

8.9 Research Participants

Massachusetts has a patient 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 BWH, FH and MGH 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 PHRC staff, is available on the Partners Human Research Committee website.

The Partners Research Consent Form template provides the PHRC 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.

Partners Human Research Affairs will periodically evaluate the organization's outreach activities to research participants and make changes when appropriate. Such evaluations will be informed by the BWH Center for Clinical Investigation, MGH Clinical Research Program, BWH/MGH Offices of News and Public Affairs, and others as appropriate.

8.10 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. Five 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 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, Research Ventures & Licensing, and research leadership across the Partners system.

8.11 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 Director of the ORC reports to the Partners Chief Compliance Officer with a dotted line reporting relationship to the Partners Chief Scientific 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 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.

8.12 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 Conflicts of Interest (CCOI) (See Section 8.14). The PHRC collaborates with the OII frequently on matters relating to conflicts of interest in human-subjects research.

8.13 Professional and Institutional Conduct Committee

For over a decade 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.

The specific PICC functions have undergone some change with the creation of the OII and the implementation of the PHS CCOI as described in 8.14.

8.14 Committee on Conflicts of Interest

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). Relationships of senior Partners executives shall not be allowable unless also approved by the Partners Professional and Institutional

Conduct Committee. In performing its functions, the Committee shall have 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.

PICC will remain as a committee responsible for:

- High-level policy issues;
- Resolution of limited categories of specific cases;
- Cases involving outside members of Partners Boards of Directors/Boards of Trustees (which are specifically exempted from CCOI authority);
- Cases involving relationships of senior Partners executives that have been already approved by the CCOI; and
- Other matters which the CCOI or the ERB decide should to go PICC.

9.0 RESEARCH COMMITTEES

Partners, BWH and MGH 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 Partners Research Council

The Partners Research Council (PRC) 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 Research Council meets monthly and is chaired by the Partners Chief Scientific Officer.

9.2 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. Established in 2005, the mission of the BRI is to accelerate the pace of scientific discovery by fostering groundbreaking, interdepartmental and interdisciplinary research within the hospital's research community, as well as to provide a clear voice both within the hospital and outside its walls, for all researchers at Brigham and Women's Hospital.

BRI Research Centers and Programs

The BRI includes eight thematic research centers that develop and support collaborative research initiatives not tenable by individuals and single departments alone. The centers are supported by five 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 Research Center
- Cardiovascular, Diabetes and Metabolic Disorders Research Center
- Center for Human Genetics
- Connors-BRI Center for Research on Women's Health and Gender Biology
- Musculoskeletal Research Center
- Neuroscience Research Center (in connection with the BWH Institute for the Neurosciences
- Regenerative Therapeutics
- Regenerative Medicine and Tissue Engineering
- Women's Health

BRI Programs:

- Bioinformatics Program
- Biomedical Imaging Program
- Clinical Investigation Program (in connection with the BWH Center for Clinical Investigation)
- Pre-Clinical Models Program
- Technology Innovation Program (in connection with the multi-institutional Center for Integration of Medicine and Innovative Technology)

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.

9.3 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 and the MGPO President. The Partners Directors of Human Research Affairs, Research Finance, and Grants and Contracts 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.

10.0 RELIANCE AGREEMENTS WITH OTHER INSTITUTIONS

10.1 Dana-Farber Cancer Center

Partners routinely relies 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 BWH and MGH FWAs and in an agreement executed by the parties.

10.2 Harvard School of Public Health

Partners relies 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

Partners occasionally relies 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 an agreement executed by the parties.

10.4 McLean Hospital

Partners occasionally relies upon the McLean Hospital IRB for review of collaborative research. These are considered on a case-by-case basis. This reliance is reflected in an agreement executed by the parties.

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

Partners 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 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.

10.6 Other Institutions

Partners 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.

11.0 HRPP RESOURCES

Resources for the HRPP are allocated to the individual Partners entities engaged in human-subjects research overseen by the Partners HRPP. All PHS, BWH and MGH departments are required to submit annual budgets based on certain budget assumptions, such as increases in salary and wages, inflation, and cost saving measures. Departments requesting growth beyond the budget target must submit a request for new programs that includes a description of services and key metrics that support the new program request. HRPP key metrics include scope, services provided, volume of activity, turnaround time, staffing, supplies and equipment, and compliance.