**CLINICAL RESEARCH @ MGH, PHS, and HMS**

**RESOURCES AND ENVIRONMENT**

The Massachusetts General Hospital has a long, rich, and diverse tradition of excellence in clinical research that continues to expand today. The extensive resources for training clinical investigators and performing high quality translational investigation include:

* An integrated full service primary, secondary, and tertiary care hospital network with access to large numbers of both local patients with common diseases and national and international patients referred for evaluation of rare disorders,
* Over 1,359,312 square feet of research space,
* A diverse population of thousands of basic and clinical scientists studying topics ranging from very basic molecular biology to direct patient management.

In addition, this document describes the structural support for clinical investigators including

1. [MGH Division of Clinical Research, a system-wide support for clinical investigators](http://www.massgeneral.org/research/dcr/)
2. [MGH Research Patient Data Registry (RPDR)](http://rc.partners.org/rpdr)
3. [MGH Clinical Research Center (CRC)](http://www2.massgeneral.org/crc/)
4. [Partners Human Research Committee](http://www.partners.org/Services/General/Research/Resources-For-Researchers/Partners-Human-Research-Committee.aspx)
5. [MGH Richard B. Simches Research Center](http://simches.mgh.harvard.edu/)
6. [MGH Multicultural Affairs Office](http://www.massgeneral.org/mao/default.aspx)
7. [MGH Center for Faculty Development](http://www2.massgeneral.org/facultydevelopment/)

VIII**.** [Partners HealthCare Department of Biomedical Engineering](http://biomed.partners.org/main/)

1. [Partners HealthCare Center for Integration of Medicine & Innovative Technology](http://www.cimit.org/) (CIMIT)
2. [Partners HealthCare Center for Personalized Genetic Medicine (PCPGM)](http://pcpgm.partners.org/)
3. [Partners HealthCare Research Computing](http://rc.partners.org/)
4. [Partners Biobank](https://biobank.partners.org/)
5. [Harvard Catalyst: The Harvard Clinical & Translational Science Center](http://catalyst.harvard.edu/)
6. [Harvard Medical School Master's Degree Programs for Clinical Investigation](http://catalyst.harvard.edu/services/scholars/)

**I. MGH Division of Clinical Research**

As an institution, the Massachusetts General Hospital (MGH) has become much more cognizant of the complexities of clinical research. A clearer **institutional vision** of future opportunities and a growing awareness of the crucial role clinical investigation must play in our institution’s future has emerged. As an institution, the MGH has become much more cognizant of the complexities of clinical research. In 2013, MGH launched the **Research Institute** whose mission is to unify all hospital programs that serve the clinical research community .Its mandate is to enhance translational (bench to bedside) research, train clinical investigators, increase clinical trial activity, support outcomes and disease management initiatives and coordinate the MGH’s efforts with those of Partners Healthcare entities, and the Harvard Medical School.

The Research Institute is catalyzing large-scale collaborations and disease-based research programs across MGH, engaging our patients so they can participate in research, enabling more formal and thoughtful planning of shared resources, and directing a continuous research operations improvement program. The **MGH Division of Clinical Research**, a key division of the Research Institute, focuses exclusively on meeting the needs of the MGH clinical research community.

MGH established the **Clinical Research Program** (DCR) (now the MGH Division of Clinical Research) in 1996 to improve the environment for clinical investigation at the MGH. Its mandate is to enhance translational (bench to bedside) research, train clinical investigators, increase clinical trial activity, support outcomes and disease management initiatives and coordinate the MGH’s efforts with those of the Brigham and Women’s Hospital, the Harvard-Dana Farber Cancer Institute Joint Venture, and the Harvard Medical School. Through academic enrichment programs and direct support services, it is contributing to a culture in which all forms of clinical research can flourish.

The hospital’s allocation of resources to fund the Division of Clinical Research (16 FTEs) demonstrates the deep institutional commitment to developing clinical investigators and clinical research. The leadership believes that the revolution in genetic information, combined with a need for intensive study of medical decision-making to optimize efficient medical care, both require a **substantial investment** in investigators.

Clinical investigators at the MGH, who have often worked at the margins of both departmental practices and basic research efforts, are increasingly visible in the mainstream of the research community. The **Clinical Research Council,** a subcommittee of the Executive Committee on Research, meets monthly and involves over 70 representatives from the major clinical research groups at the MGH. This **Council represents an institution-wide clinical research group which communicates across departments, addressing issues and generating policy.**

The Division of Clinical Research regularly communicates directly with clinical investigators through a differentiated e-mail distribution list of researchers who have IRB approved protocols. **Frequent e-mail correspondence** from the DCR has disseminates information regarding funding opportunities, educational offerings, policy issues, and changes to NIH and other federal policy and regulations.

The Division of Clinical Research occupies the second floor of the Richard B. Simches Research Building located adjacent to the Massachusetts General Hospital. **Common equipment resources** available to investigators include PC workstations connected to a local area network, document scanner, slide maker, photocopy and fax machines, and ink jet and color laser jet printers.

To support clinical investigation, the Division is organized in broad service categories with resources to facilitate the performance of high quality clinical research:

1. **Clinical Research Support Office (CRSO)**
2. **Clinical Effectiveness Research Unit (CERU)**
3. **Imaging Biomarker Consultation Unit (IBCU)**
4. **Patient Centered Outcomes Research (PCOR)**
5. **Electronic Health Record Research(EHR)**
6. **Information Management Unit**
7. **Omics Unit**
8. **Clinical Research Education Unit (CREU)**

**1A**. The **Clinical Research Support Office (CRSO),** headed by Andrew Nierenberg, MD, **serves** as the “front door” to the DCR for investigators seeking to develop a clinical research career. It serves to

1. Offer advice and support to beginning investigators to help them design a study, locate a mentor, obtain funding, and proceed through the MGH regulatory approval process;
2. Provide direct support services for investigators (biostatistical and database consultation, links to sponsors, study start-up and subject recruitment services, access to a pool of experienced study coordinators who can manage day-to-day protocol activities, and access to project management services for large or multicenter studies.)
3. Advocate for clinical investigators within the MGH system, serving on committees and managing special projects.

The Director of the CRSO serves as a **one-on-one advisor** for potential, junior, and established investigators. The office assists MGH clinical investigators in obtaining research funding by reviewing grants and recommending funding sources, and by guiding individuals through the MGH regulatory review process required for initiation of a clinical study, and by designing protocol-specific subject recruitment strategies to expedite study performance. In addition, the office supports a K23-K24 peer support and discussion group for recipients of these NIH career development awards. The group meets quarterly at a meeting which combines discussion of topics of mutual interests, conversations with senior clinical research faculty on career development and areas where MGH can develop additional support resources.

The CRSO supports a **Biostatistics Center** which provides PhD or masters-level statistical support to all clinical investigators. It provides free consultation prior to grant submission on study design, and statistical analyses for inclusion in grant submissions and protocols, statistical modeling, statistical analyses of preliminary data, sample size calculations, and other biostatistical issues. The service can assist in data analysis as time allows. Investigators planning large studies are encouraged to provide for statistical support for data analysis in grant application budget proposals.

The CRSO provides **study start-up services** for investigators initiating clinical studies in their departments, thereby helping reduce hurdles to the conduct of clinical research. CRSO staff offers assistance in preparing IRB submissions, preparing budgets, identifying study coordinators, collaborating with sponsors in securing support of investigator-initiated studies of scientific merit, and managing study initiation. CRSO staff is available to consult with investigators to design effective recruitment strategies tailored to the protocol’s target population, budget and timelines. The CSRO maintains of local and national recruitment resources, web sites, bulk and non-profit mailing rates, statistics on advertising returns by media, consultation to determine the best way to reach target populations, access local minority outreach programs, collaborative relationships with local community minority outreach programs. The CRSO also manages the **Research Study Volunteer Program (RSVP for Health), a steadily increasing database currently over 25,000 persons,** who have registered to be informed about clinical trials in their areas of interests. Database registrants are informed about studies either by email or U.S. mail as they elect. The database which is available free of charge to clinical investigators is particularly effective for studies where PIs would recruit subjects by newspaper advertisements, posters or flyers. In addition, the DCR has developed tools for investigators preparing grant and protocol submissions, templates for IND/IDE submissions, guidelines for preparing data safety monitoring plans (DSMP) and suggested wording for plans. The **study coordinator** **service** provides free needs assessments to investigators and offers experienced study coordinators on a fee-for-service basis.

The office also serves as an **interface between clinical investigators and sponsors**. The office is often the first point of contact for an investigator seeking a commercial sponsor or source of support to investigate a novel therapy. In addition, it is responsible for developing links with industrial sponsors, both small and large, and improving accessibility for industrial sponsors. Staff assists investigators in preparing profiles of their clinical research expertise and interests which are very useful in discussions with potential industry sponsors.

**1B.** **Clinical Effectiveness Research Unit (CERU),** co**-**directed by James Meigs MD, MPH and Eric Campbell, PhD provides consultation in design of epidemiology, comparative effectiveness, outcomes, and health services delivery research. Faculty expertise includes study design for **observational and interventional studies**. The program offers consultations on survey **development**, qualitative **and mixed methods study design including** data collection modalities, sampling, instrument development, analysis, and data interpretation.

The CERU program offers **consultations to investigators preparing grant submissions** and **seminars and workshops for junior faculty developing clinical effectiveness research projects.** The faculty of the CERU is particularly enthusiastic about supporting young investigators preparing K23 and K08 proposals.

A key resource developed by the CERU is the capacity - gained by extensive prior experience and supported by CERU data analysts – to **create research-grade analytic databases from the MGH and Partners Clinical Data Repository (CDR).** The CDR contains terabytes of electronic clinical care data that can be queried for research purposes using the Partners Research Patient Data Repository (RPDR) query tool. Based on the needs of investigators seeking consultation, the staff of CERU has developed validated algorithms and procedures for converting this “raw” clinical data into either study-specific research cohorts for direct analysis or into enriched source populations for efficient study recruitment.

**1C. Imaging Biomarker Consultation Unit**, headed by Bradford Dickerson, PhD provide consultations for investigators who are considering studies making use of the wealth of imaging technologies and expertise at MGH and beyond. Assistance is available for study design, IRB review, feedback on draft research proposals, and identification of potential co-investigators and collaborators. Requests from clinical investigators are triaged and assigned to specific consultants depending on expertise and availability. Imaging Biomarker Consultation helps investigators identify questions in their research that can be answered using imaging technologies and then access personnel and technologic resources within MGH and the Partners HealthCare System.

**1D. Patient Centered Outcomes Research (PCOR).** Under the leadership of Joshua P. Metlay, MD, PhD, Chief, Division of General Internal Medicine, the DCR’s Patient Centered Outcomes Research (PCOR) support services include: PCOR-focused educational programming offered through the Clinical Research Program Education Unit; PCOR consultations that **provide support with navigating the waters of PCORI**, assistance with PCOR **proposal preparation** and interpreting and incorporating **PCOR methodology**, and identification of potential co-investigators and collaborators; Identification and incorporation of patient reported outcomes measures into clinical research settings and linkage with other clinical datasets; **stakeholder engagement support** that helps create sustainable and meaningful relationships with those who have a stake and ought to have a voice in PCOR research, including patient and family groups, community health organizations, and policy stakeholders.

**1E. Electronic Health Record Research Unit.** Under the leadership of Roy H. Perlis, MD, MSc, Director, Center for Experimental Drugs and Diagnostics, the DCR’s s electronic health records (EHR) support services include educational programming aimed at **introducing investigators to the strengths and limitations of research using large clinical databases**, offered through the Clinical Research Program Education Unit, and consultations to help investigators **design and conduct studies making use of large electronic health record data sets.** These resources include framing questions which can be answered using these data sets; understanding tools required for generating and analyzing these databases; recognition of common pitfalls in using these data, and identifying potential co-investigators or collaborators. Clinical investigators can request consultations to assist in development of research proposals and generation of preliminary data to support such proposals, integration with other DCR units, such as PCOR, biostatistics, and information technology, and support to encourage development and deployment of new technologies to facilitate research using electronic health records.

**1F**. **The Information Management Unit,** headed by Henry Chueh MD, acquires, develops and supports the information technology needed to promote clinical research at MGH. Cognizant of the critical role communication plays within the clinical research community, the Unit is actively developing an interrelated set of communication and clinical research tools including:

1. **Clinical Research On Call** -- a **service-oriented website** dedicated to clinical research at MGH by offering “a one stop shop” of MGH resources which support clinical investigators. This intranet site contains critical policy and resource information to assist investigators in planning a clinical study, locating funding sources, preparing grant submissions, and managing day-to-day protocol activities. This site contains information and links to Partners HealthCare System, MGH and federal websites. The Clinical Research Program’s services to investigators and educational offerings and faculty leadership are also presented with email links to key contacts.
2. **Clinical Trials at Partners**: This site is available to the Partners HealthCare System community, the general public and the Boston area professional community. This provides on-line listings of active clinical trials and the MGH Research Subject Volunteer Program, **RSVP for Health**, a registry where individuals register to be notified about clinical studies in their designated areas of interest (e.g. healthy volunteer, or in therapeutic areas.). About 13,000 persons are currently enrolled in the database. RSVP for Health is available to investigators conducting IRB-approved protocols and is a resource to expedite subject recruitment to clinical studies.
3. Development of **web-based query tools** and patient data registries based on pooled data from institutional medical record systems such as COSTAR and the Electronic Medical Record to enable rapid exploration of the clinical information needed to characterize patient populations and assess clinical trial feasibility. The Partners HealthCare Systems’ Research Patient Data Registry (RPDR – see II, below), now available for investigator use, grew from this seminal work.
4. Development and support of **software and databases** for disease management studies.

The Information Management Unit staff is based at the Laboratory of Computer Science, an academic unit of the MGH Department of Medicine. . It is affiliated academically with Harvard Medical School, and serves as one of the sites for the National Library of Medicine’s national **Medical Informatics Training Fellowship** (as part of the Boston Informatics Fellowship Program). It was one of the first medical informatics laboratories to be established in the country.

**Key initiatives** based at the Laboratory of Computer Science include Web-COSTAR, the latest interface to a COSTAR database that has been in continuous operation for twenty years, eChart (a general purpose web-based medical record application), and active continuing support of the Obstetrics workstation and the HealthCare for the Homeless medical record system, two specialty medical records systems. Finally, the lab has developed a Research Patient Data Registry for Partners Healthcare that accesses data on all patients seen at affiliated institutions, including clinical laboratory and radiology data, as well as discharge summaries and diagnosis codes. (See Section II: Research Patient Data Registry, below)

**1G.** **1D.** The **Omics Unit** is led by Jordan W. Smoller, MD, ScD and Robert E. Gerszten, MD. The Unit provides education, consultation and services to facilitate and accelerate incorporation of genetics and functional genomics into the conduct of clinical research at MGH within the Partners framework.

Dr. Smoller offers expertise in genetic epidemiology and complex disease genetics, including the design, implementation and statistical analysis of genetic studies. Dr. Gerszten’s work focuses on emerging technologies for metabolomic and proteomic profiling of human biofluids, with expertise in optimizing sample throughput, cost, and breadth of analytical coverage. The combined expertise of these faculty leaders offers significant resources to investigators who are designing new studies or who are incorporating genetic, proteomics and metabolomic analyses into existing clinical studies.

The **education** services of the Omics Unit offer a range of educational opportunities to increase visibility of genetics and genomics research and assist individual PIs and study personnel in understanding opportunities and techniques. The Unit provides intellectual leadership, content and speakers for courses produced in conjunction with DCR’s Education Unit.

The Omics Unit works closely with the **MGH Center for Human Genetic Research (CHGR)** to meet the needs of clinical investigators who are developing and conducting genetics and genomics research studies. The Unit’s **consultation** arm advises individual clinical investigators on study design and choice of technology. It assembles and disseminates information on Core Services offered by the **Partners HealthCare Center for Personalized Genetic Medicine** and serves as the institutional expert on matters of institutional and governmental policy related to genetics and functional genomics techniques. The Unit provides consultation to PIs regarding the creation of local databases and use of system-wide, national, and other informatics tools. Lastly, the faculty leaders of the Unit provide advice to those investigators seeking to further their careers in genetics, proteomics and metabolomics research.

The **services** function assists clinical investigators with the start-up of genetics and genomic studies, helps create Informed Consent documents for genetic studies, and identifies resources to educate study participants about genetics and genomics. Again, working closely with CHGR, the Unit advises study personnel on the handling and storage of samples, and refers to genetics, proteomics and metabolomics study coordination resources and genetic counseling services as needed.

The Omics Unit also serves as a bridge to BWH & PHS initiatives in genetics and genomics. In the spirit of Translational Research, the Unit links MGH clinical investigators with each other and with basic scientists, and establishes **collaborations** within the Partners framework and beyond.

**1H**. The **Clinical Research Education Unit** **(CREU)** co-directed by Andrew Nierenberg, MD , offers clinical investigators a well developed curriculum to supplement their clinical research education during their tenure at MGH. Courses range from survey to in-depth seminars and provide investigators with invaluable educational opportunities and tools to support the continued development of their clinical research careers. CREU courses are taught by MGH and Harvard faculty who are experts in their fields and focus on: Biostatistics; The Design and Conduct of Clinical Trials; Genetics/Genomics; The Protection of Human Subjects; Research Tools; Data Management; Grant Writing; Research Management; and Scientific Communication. Educational opportunities are offered at times that make them easily accessible to busy clinical investigators. In 2009, 2,856 people attended the CREU’s investigator courses.

The CREU provides a broad variety of educational opportunities that investigators may choose from to support the further development of their careers. The CREU curriculum may be viewed at: [http://hub.partners.org/DCR/](http://hub.partners.org/crp/) . Investigators may review all courses offered by the CREU by viewing the “Course Compendium” on the website above and design a curricular pathway that best fits their needs. One of the major functions of the faculty of the DCR is to mentor those investigators who may need additional support in developing a tailor-made career development plan.

If investigators are seeking to fill additional gaps in their education, CREU courses may be supplemented by those offered through the Harvard Clinical and Translational Science Center (The Harvard Catalyst): <http://catalyst.harvard.edu/education.html> . These courses further expand upon those offered by the CREU and support the following core competencies in clinical/translational research: Biostatistics; Bioethics; Clinical Trials Design and Assessment: Drugs, Devices, Biologics; Human Subjects Research Protection; Health Data Standards: Federal Human Research Policies; Management (Data, Research Resources); Informatics; Genetics; Team Leadership; and Communication Arts: Verbal, Written (Presentations, Papers, Grants). A sample list of courses offered to investigators and study staff appears in Appendix 1.

**II.** [**MGH Research Patient Data Registry (RPDR)**](http://rc.partners.org/rpdr)

The Research Patient Data Registry (RPDR) serves as a central clinical data registry consisting of 450 million records on approximately 2 million MGH and BWH patients and 350 million diagnoses, medications, and procedures including demographic and visit information. Investigators access the RPDR using an online query tool. In the past year, the RPDR has been used by over 400 faculty users, and has supported over 3000 queries, with over 130,000 patients identified for IRB-approved protocols. The RPDR is a key resource for investigators who may query the database to obtain aggregate information to assess the feasibility of conducting specific clinical studies and, with IRB approval, obtain medical record data about specific patients in the target population. The RPDR brings clinical information to the researcher's fingertips and ensures the security of patient information by controlling and auditing the distribution of patient data within the guidelines of the IRB. Specific patient information includes primary care provider, visits, diagnoses, medications, procedures, laboratory results, pathology and radiology reports, operative notes, and discharge notes.  A major new feature now allows investigators to import medical record numbers into the RPDR database to retrieve clinical data on these patients for use in querying research patient data sets.

Characteristics of the RPDR are as follows

**· Population**   
The database contains information on inpatients and outpatients from BWH and MGH billed through the TSI billing system and inpatients and outpatients billed through the MGH MGPOs and through the seven BWH billing foundations. The RPDR population includes 90-98% of the total patient population at BWH and MGH from 1993 to present.

**· Patient Demographic Data**   
The RPDR extracts patient demographic data from the Enterprise Master Patient Index (EMPI). The RPDR database imports and maintains the following demographic information that the user may query: Gender, Age, Language, Race, Marital Status, Religion, Veteran Status, State, Zip, Country, and vital status as determined by matching against a social security deceased file. RPDR also imports identifiable demographic data from the EMPI, which is available to RPDR users with the appropriate IRB approval. This data includes patient name, address, city, social security number, home phone number, work phone number, date of birth, and primary care provider.

**· Diagnosis Data**   
Through the RPDR a user may query diagnoses data to obtain aggregate totals of various diagnoses and groups of diagnoses. The RPDR contains BWH inpatient and outpatient diagnosis information from 10/96, MGH inpatient data from 10/92 and MGH outpatient information from 10/93. RPDR identifies diagnosis by ICD-9-CM standards. A user has the ability to query diagnoses through the use of a hierarchical tree structure, thus eliminating the need for the user to know the exact ICD-9-CM terms used by the RPDR.

**· Procedure Data**   
Inpatient procedure data is also available to RPDR users. Users may obtain aggregate information about inpatient and some hospital-based outpatient procedures performed at MGH and BWH. Inpatient procedure information is available from October 1992 for MGH patients and from October 1996 for BWH patients. Outpatient procedure information for the MGH and BWH is limited to "observation" patients, surgical day patients and ER patients. RPDR identifies procedures by ICD-9-CM standards.

**· Medication Data**  
Inpatient medication data is available from October 1992 for MGH patients and from October 1996 for BWH patients. Outpatient medication information for the MGH and BWH is limited to "observation" patients, surgical day patients and ER patients. Medication data is obtained through cost codes generated by the TSI billing systems.

**· Provider Information**   
The RPDR database stores provider information. Individual provider information is rolled up into specialty categories to permit users to query for aggregate information by institution and department. Users cannot query against an individual provider without IRB approval. The RPDR database stores the provider's name, specialty, ID number and the site where the provider practices.

**· Encounter information**  
Encounter (or visit) information is maintained so patients can be chosen only from one hospital, or from specific clinics, or by inpatient/outpatient status.

**Institutional Review Board and HIPAA Compliance**  
**IRB Approval**: The RPDR is a clinical patient data registry. The Institutional Review Board (IRB) defines a clinical patient data registry as a database that contains a limited set of data that may be derived from an electronic medical record, laboratory database, and other databases. A registry does not contain the vast amount of information that is typically part of a complete patient medical record, paper or electronic. The purpose of the registry is to provide clinical investigators with the ability to perform a variety of queries for pre-study, pre-trial patient cohort identification. The queries provide aggregate information and are designed to deny access to information about individual patients or physicians. Under federal regulations, electronic searches of clinical patient data registries fall into a category of research that may be classified as exempt from IRB approval if the IRB so chooses. Effective 1997, the Partners IRB designated such searches as exempt from review and approved classes of users for access to the registries

**HIPAA Compliance**: In compliance with the requirements for patient confidentiality by Partners HealthCare System and the HIPAA privacy rule, the RPDR instituted a data obfuscation algorithm that results in a slight randomization in the aggregate numbers it returns.

# III. [MGH Clinical Research Center (CRC)](http://www2.massgeneral.org/crc/)

**Environment – Massachusetts General Hospital Clinical Research Center**

The MGH Clinical Research Center at Massachusetts General Hospital (MGH), funded primarily by the NIH and MGH, provide the infrastructure to carry out human research in a wide variety of clinical disciplines. The CRC includes an inpatient and outpatient unit located on the 12th and 13th floors of the White Building on the main MGH campus and an outpatient unit on the 2nd floor of Building 149 at the Charlestown Navy Yard (CNY). The CRC provides the personnel, research environment and specialized equipment necessary to carry out patient-centered research on the causes, treatments and cures of human diseases. The CRC enables clinical investigators to plan and conduct their research, using state-of-the-art study designs, research methods, biosample collection and preparation, and data acquisition and analysis, all while maintaining the highest patient care and safety standards.

The MGH CRC provides services to investigators performing a wide variety of physiological and treatment studies in both adult and pediatric populations, including healthy volunteers and individuals with a large variety of conditions and diseases. The CRC provides routine and specialized nursing and nutrition services, and medical oversight. The Nursing and Metabolism & Nutrition Research (MNR) staff are specially trained and experienced in the conduct of human research to ensure the highest quality data. The Medical Research Officer (MRO) can provide guidance for protocol development and implementation, and medical oversight. The comprehensive resources of the CRC allow an investigator to implement complex studies effectively and efficiently.

The leadership of the CRC provides guidance to new as well as experienced investigators regarding the conduct of research on the CRC.

**Resources – Massachusetts General Hospital Translational and Clinical Research Centers**

**Facilities/Space:**  The CRC is located on White12/13 on the main campus of Massachusetts General Hospital with approximately 11,000 sq. ft., organized to support the management of adult and pediatric populations participating in clinical and translational research. The White 12 facility consists of 4 infusion chairs and 18 beds, a metabolic kitchen, medication room and a laboratory for preparation and processing of samples. Metabolism & Nutrition Research staff, space and equipment are located on White 13. Administrative offices are located at 125 Nashua Street. There is an additional 800 square feet of outpatient space in Building 149 at CNY, consisting of 4 outpatient chairs, a shielded exam room and a standard exam room for studies of investigators located at CNY and for any study visit that must be coordinated with special imaging located at CNY. Additional laboratory space and freezers are available on Bulfinch 4.

**Nursing:** Nurses are experienced clinical and research RNs who are proficient with specialized medication administration, monitoring, IV insertion and maintenance, as well as timed sample collections. In addition to RNs, the CRC has Adult and Family Nurse Practitioners who collaborate with the PIs to carry out necessary research activities including consenting, medical procedures and examinations, and are part of the MRO team.

**Metabolism & Nutrition Research (MNR):** The MNR department of the MGH CRC is located on White 13 and is staffed by expert Registered Dietitians and diet technicians. The specialized MNR unit includes a research metabolic kitchen, DXA instrument and metabolic cart. Research dietitians perform anthropometric and metabolic assessments, bone mineral density and body composition measurements, physical activity assessment, and nutrition counseling. Nutrient analysis of food intake can be completed using a research nutrient database. Specialized weighed and controlled meals and single nutrient doses can be prepared and administered.

**Medical Research Officer (MRO):** The MROassists new and established clinical researchers in navigating the process of finding research collaborators, in protocol, grant and budget development, IRB submissions, and conducting cross-institutional research. The MRO can also provide medical oversight for certain tests and procedures that require a credentialed provider.

**Laboratory:** The MGH CRC has processing laboratories located on White 12, Bulfinch 4, and at CNY. All laboratories have the requisite equipment for sample preparation and temporary storage. These include -20 and -80 degree freezers, refrigerators, and refrigerated and room temperature centrifuges.

IV **Partners Human Research Committee**

The Electronic Regulatory Binder is a project within REDCap that was developed by [Partners Human Research Quality Improvement (QI) Program](http://researchlist.partners.org/t/109778/1554401/18495/10/) and [Enterprise Research Infrastructure & Services (ERIS)](http://researchlist.partners.org/t/109778/1554401/16104/11/). The Electronic Regulatory Binder can assist sites with the electronic storage and maintenance of regulatory documents for Partners IRB approved protocols. This project is unique in that it contains:

* Data collection instruments that capture required regulatory information similar to what is generally captured in the [QI Regulatory Binder](http://researchlist.partners.org/t/109778/1554401/18496/12/) for all studies.
* Branching logic that identifies and collects study specific regulatory information, such as laboratory certifications, and FDA forms.
* Report builder for developing site specific reports including delegation of responsibility log, protocol amendment tracking log, and consent version tracking log.
* Calendar for keeping track of due-dates for regulatory documents.
* User rights application for the PI to grant different levels of viewing/editing rights for study staff.

To request a copy of the project for an IRB approved protocol: log into [REDCap](http://researchlist.partners.org/t/109778/1554401/15830/13/) with your Partners username and password, click the tab titled "Request New Project" and complete the fields for requesting the Electronic Regulatory Binder template.  General instructions for using the project to enter and store regulatory information can be found on the project's homepage.  For additional questions and comments related to this project, contact QA/QI Analyst, [Michele Gomez](mailto:%20mgomez6@partners.org?subject=Electronic%20Regulatory%20Binder%20Tool%20in%20REDCap).

**V.** [**MGH Richard B. Simches Research Center**](http://simches.mgh.harvard.edu/)

The new Richard B. Simches Research Center was opened in 2005. The building contains an impressive 25% of the hospital’s total research space. Spanning eight stories on 267,000 square feet, the new building is home to four thematic centers. The **Center for Human Genetics Research** investigates the genetic roots of disease. The **Center for Regenerative Medicine and Technology** concentrates on the use of stem cells to repair or replace damaged tissues and organs. The **Center for Computational and Integrative Biology** utilizes discoveries in biomedical and computational research to develop new drug therapies. And the **Center for Systems Biology and Physiologic Genomics** analyzes the ways in which the human body's biological and physiological functions work together to affect health and disease.

Instead of the traditional departmental method, the hospital took this novel thematic center approach to assigning space in order to foster and facilitate collaborations amongst research programs and across disciplines. The Simches Center also provides supplementary space for the Cancer Center, Psychiatry Clinical Research, the Cardiovascular Research Center, Renal Medicine, Pediatric Surgery. The Clinical Research Program is situated in this facility adjacent to core space consisting of examination rooms, phlebotomy and support facilities where subjects enrolled in clinical studies are seen.

**VI.** [**MGH Multicultural Affairs Office**](http://www.massgeneral.org/mao/default.aspx)**: Increasing Diversity at MGH:**

In 1992, the Multicultural Affairs Office ("MAO") was founded to address the issue of increasing the number of under represented minority physicians at MGH, principally in the Department of Medicine. In 2000, with MGH support MAO evolved into a Hospital and community wide resource, and now works with virtually all departments at MGH. Currently MAO has 2 full-time administrators, a part-time physician manager of trainee affairs, and 3 part-time physicians of color who are intricately involved in MAO's initiatives and serve as an advisory board.

**Mission**:

MAO's mission is to facilitate and promote the advancement of URM physicians, as well as to develop culturally competent physicians, at MGH. We believe this mission is crucial to enhancing the quality of patient care and research at MGH. In light of this mission, MAO has three broad based objectives: professional leadership and workforce diversity; education and research, and community outreach

**Accomplishments**:

Professional Leadership and Workforce Diversity:

MAO sponsors national and local outreach programs that target underrepresented minorities at different levels of their education and expose them to the many resources for training in the sciences at MGH.

* The Summer Research Trainee Program ("SRTP"). In its 12th year at MGH, SRTP selects 10-15 minority junior and senior college, as well as 1st and 2nd year medical students, through a vigorous national competition to partake in an eight (8) week research session at MGH. These students are paired with MGH preceptors in a basic science laboratory, clinical or health policy research sites. Over 98% of the undergraduates who have completed SRTP have gone onto medical school or graduate school in the sciences.
* The Hispanic Medical Students Mentorship Program. Founded in 2000 by Dr. Ernesto Gonzalez, one of MAO's Associate Directors, this Mentorship Program is one of two pilot programs in the nation. It is designed to pair Latino medical students from medical schools in Massachusetts (i.e., Boston University, Harvard, Tufts and University of Massachusetts) with physician/researcher mentors. The Mentorship Program currently has over 34 active student mentees and 50 mentors, and is starting its second year.
* The office began to actively provide outreach, mentorship and guidance to minority Harvard Medical Students in 2000. It currently has bi-annual receptions for minority students to network with MGH residents, faculty and residency training program directors and Chiefs of Service. In late 2001, we began a Minority Housestaff Organization (see below) mentorship program for HMS minority students, in which HMS students are paired with minority residents at MGH.

**Underrepresented Minority (URM) Physicians and Residents**

MAO is also integrally involved in the recruitment of URM physicians to the 21 residency programs at MGH (including joint programs). As part of this effort, MAO staff meet individually with minority applicants to share not only information about what it is like to train and work at the MGH, but about what it is like to do as a physician of color. The MAO staff met with more than 70 minority candidates during this recruitment season, and hosted recruitment dinners which gave current minority residents and senior faculty an opportunity to participate in and give further insight to the candidates.

MAO also plays a crucial role in the retention and development of URM residents and faculty at MGH. Following are a number of accomplishments relating to this initiative. In 2001, MAO established the first Minority Housestaff Organization at MGH. The purpose of this organization is to provide an interdisciplinary forum for URM residents, which addresses issues of career guidance, mentorship, networking, and community outreach; and assists with recruitment of incoming residents.

Seminars in career development, mentorship, etc.

* Seminars and forums on health outcomes disparities research
* MAO staff provide career counseling and advice to URM residents and faculty at MGH, and work as advocates to help URM faculty rise through the HMS faculty appointment promotions process
* Receptions welcoming URM incoming residents and acknowledging accomplishments of graduating residents
* Receptions acknowledging URM physician achievements

**Education and Research**

* Minority Faculty Development Award**,** established in 2002, was created to help promote the research careers of URM scientists at MGH. The award is $30,000 per year for two years of financial support, as well as a $60,000 loan forgiveness over the course of 3 years (with a maximum of $20,000 per year).
* MAO, through Dr. Joseph Betancourt, Program Director for Multicultural Education, developed the first cross-cultural education curriculum at MGH. This curriculum was implemented for residents in the Department of Internal Medicine in the Spring 2002, and will eventually be rolled out to medical students, residents and faculty in other disciplines at MGH.
* Recent research shows that minorities suffer poorer health outcomes when compared to the majority of Americans. Several physicians affiliated with MAO conduct research on the topic of race and ethnic health disparities as various entities in both the private and public sectors are providing funding for this area of research. In an ongoing effort to educate the MGH community, these researchers provide/will be providing seminars and presentations relating to this topic.

**Community Outreach**

As the programs at MAO continue to evolve, we find ourselves more involved in programs affecting the community affiliated with MGH. For example:

* The Minority Housestaff Organization is collaborating with high schools in the Boston area, providing mentorship and guidance to students of color.
* MAO works closely with the Office of Community Outreach at Harvard Medical School to partner in projects such as the first annual Latino Heritage Forum.
* MAO works closely with Human Resources and Patient Care services to sponsor numerous events for employees concerning issues of diversity, including the first annual Latino Heritage Celebration at MGH in November 2001.

VII. [MGH Center for Faculty Development](http://www2.massgeneral.org/facultydevelopment/)

The MGH Center for Faculty Development was established in 2005. The primary focus of this center is to offer a comprehensive and innovative program to maximize professional success for faculty. The mission of the Center for Faculty Development is to work in conjunction with the Department Chairs to facilitate and monitor the career advancement and job satisfaction of all faculty at the MGH, given the expanding complexity of their roles. In order to accomplish this mission, the Center provides support and education to the faculty regarding the promotion process, counseling, advice, and support, sponsors programs that promote academic and career development The Center includes the two branches of the **Office of Women's Careers (OWC)**, as well as the **Office of Research Career Development (ORCD).**

The **Office for Women’s Careers (OWC)** at MGH was created to foster a gender equitable environment to assure that talented women will be given the same opportunity as men to succeed in research and clinical careers at MGH. Results of the office’s work can be seen in both the significant increase in women faculty at MGH and HMS as well as the increased utilization of the Office over the past several years. Through many programs and collaborations, OWC provides career development resources for women. The office focuses on reducing barriers to career advancement, regularly meeting with department chiefs to review career progress of women faculty and meets with women faculty to mentor and advise them. They also provide programs on topics such as leadership skills, negotiation, promotion, mentoring, presentation skills, finance, and grant writing.

**The Office for Research Career Development (ORCD)** serves to enhance and advocate for the careers of individuals within our research community in order to attract, retain and advance talented biomedical research scientists. Many new programs and initiatives will emanate from the ORCD to address the unique needs and concerns of the research community. All of these endeavors will seek to enhance the careers of basic scientists and researchers at MGH so that they may flourish in their activities and aspire to greater success.

**VIII.** [**Partners HealthCare Department of Biomedical Engineering**](http://biomed.partners.org/main/)

PHS department of Biomedical Engineering offers two highly specialized Prototyping and Fabrication Facilities that provide custom designs and tooling to meet the needs of researchers and clinicians within Partners Healthcare. The staff of professional machinists offers experience in the manufacturing of custom tools and fixturing for researchers and clinicians. The department has two completely tooled shops to provide the services our customers need. One is located at Massachusetts General Hospital; the other shop is located on at Brigham and Women's Hospital. Services include the manufacturing of one-of-a-kind products, design and development of models, product customization, CAD services, equipment repairs, and 3D printing/rapid prototyping.

**X.** [**Partners HealthCare Center for Integration of Medicine & Innovative Technology**](http://www.cimit.org/) **(CIMIT®)**

CIMIT's mission is to improve patient care by bringing together scientists, engineers, and clinicians to catalyze development of innovative technology, emphasizing minimally invasive diagnosis and therapy.

CIMIT® is a non-profit consortium of world-leading academic and research institutions founded by Partners HealthCare System, Massachusetts General Hospital, Brigham & Women's Hospital, Massachusetts Institute of Technology, and Draper Laboratory. Started in 1994 with seed funding from philanthropy and Massachusetts General Hospital, CIMIT received major federal funding through the Department of Defense in 1998.

Under the leadership of John Parrish, MD, Director, CIMIT has assembled a superb team of clinicians, scientists and researchers to lead its scientific programs and a solid management team with expertise in operations, technology development and program management. CIMIT is a crucible in which teams of clinicians, scientists and engineers identify difficult problems, generate new ideas and develop innovative solutions. CIMIT encourages results-oriented collaborations that are monitored, measured, and analyzed for their ultimate application in a clinical setting.

## CIMIT Forum

The CIMIT Forum is a weekly meeting (Tuesdays at 4 PM), which is open to the whole scientific community and is regularly attended by people in the technology business, students, researchers engineers and clinicians. Each week, presentations are made regarding either new technological developments or stubborn clinical problems. Speakers are invited from around the world and from the rich research milieu of our local institutions, chosen for their pioneering work on new procedures, new applications, or new technologies. The format is designed to stimulate discussion and the interchange of ideas. The talks are short (20 - 30 minutes) with adequate time for questions. Discussants who are expert in the speakers’ field are invited to probe and help the audience draw out the speakers and help stimulate understanding and new ideas.

# CIMIT awards

CIMIT supports projects that meet peer review metrics for uniqueness, quality and contribution. The projects with a path to improve clinical care are multi-disciplinary and preferably multi-institutional, outside of the normal academic patterns of collaboration. The major determinants of funding for any CIMIT® Research project are aspects of *project quality* (clinical need, scientific merit, and novelty) and *project design* (fit within CIMIT focus, degree of collaboration, clarity of milestones and defined exit strategy).

**Research program awards** allow a project to progress from **New Concept**, through **Proof-of-Principle**, to **Applications Development**. A CIMIT Associate Director supports each project. **Major Program awards** provide more substantial and longer-term support that fosters CIMIT’s presence in selected areas of strategic importance. **Fast forward awards** are designed to quickly and efficiently identify and capture important core clinical or technical tools that have been developed to a higher degree at another institution, and bring them back to Partners and the CIMIT Consortium. **Individual career development awards** are designed to promote the career development of talented and creative investigators from diverse technical and clinical disciplines, to do multi-disciplinary work in applying technology to problems in healthcare.

## CIMIT core programs

CIMIT also supplies a mechanism to facilitate the transfer and ultimate application to patient care. Successful ideas must be legally protected in order to guide their journey to the market place. Regulatory and reimbursement issues must be understood. Marketing plans must be developed. Devices must be matched with the most appropriate manufacturers. Programs in **Technology Assessment, Technology Development, Industry Liaison, Regulatory Affairs**, and **Education** facilitate this work.

* The **Office of Technology Development** provides support and resources to investigators preparing to move their innovative ideas through the technology transfer process and into the private sector. The OTD assists CIMIT investigators with the creation and management of intellectual assets, valuation of technologies and exit strategies. This office serves as a design laboratory for developing business systems for translational research programs.
* The **Technology Assessment** and Outcomes Analysis Program works with investigators in CIMIT’s programs to develop economic and outcome models with which to evaluate the use of technologies under development.
* The **Regulatory Affairs** monthly newsletter, regular forums with government agencies, including FDA and HCFA and white papers on important current topics are made available to all CIMIT collaborators.
* The **Industry Liaison** program provides a link between CIMIT investigators and partners from industry who are best equipped to affect patient care by commercializing CIMIT’s innovations.

### IX. [Partners HealthCare Center for Personalized Genetic Medicine (PCPGM)](http://pcpgm.partners.org/):

The Partners HealthCare Center for Personalized Genetic Medicine (PCPGM) (formerly Harvard Medical School-Partners HealthCare Center for Genetics and Genomics) PCPGM began operations in 2001. From the time of its founding up to the present, PCPGM has maintained a focus towards meeting its mission to utilize genetics and genomics to improve the care of patients through the promotion and implementation of personalized medicine in caring for patients throughout the Partners HealthCare System and in healthcare nationally and globally. In late 2008 the name of the Center was changed to its current one to reflect a heightened focus on translational issues related to moving genetics and genomics into clinical practice. Previous direct discovery components were moved out of the Center and into affiliated academic medical centers. The name change also affirms Partners HealthCare's emphasis on personalized medicine. PCPGM’s scientific director is Scott Weiss, M.D.

## Biosample Services Facility (BSF):

PCPGM offers a core service biological sample management option. The service intended to offer resources to Partners investigators with current open IRB-approved protocols that need assistance in blood samples obtained from subjects recruited into these studies. The BSF provides a standardized workflow for receiving whole blood from appropriately consented patients and then processing those samples to yield DNA, EBV transformed lymphoblast cell lines, and or plasma/serum. The BSF can provide short term cryogenic storage of these purified products but due to limitations of space for freezers we ask investigators to please make arrangements for long term storage within their own resources. All samples are stored in bar coded vials and we track sample histories in our BSF LIMS system. In addition, we are able to offer services for transfer of DNA from tubes into 96 well format plates.

## DNA Sequencing - High Throughput:

The PCPGM Sequencing Group employs high throughput sequencing technologies to enable a wide range of project capabilities: We are able to provide services to the Partners community using our recently added Illumina GA II sequence analyzers with paired end read capability. Services for the Illumina platform include consultation on experiment design, library construction, SAGE analysis, miRNA screening, sequence analysis of RNAi pools, ChiP sequencing, resequencing portions of human genes, and whole genome sequencing or resequencing of bacterial genomes. For sequencing projects requiring di-deoxynucleotide sequencing methods we also will discuss sequencing strategies and approaches applicable to operations on our ABI 3730xl Analyzers.

## Genotyping:

The genotyping facility is able to support genotyping analysis with several different SNP detection formats. Platform selection is made depending on the desired numbers of SNPs to be analyzed and numbers of samples available for analysis to allow for the most robust and cost effective project application. Platforms available are a Sequenom Compact mass spectrometry system, an Illumina BeadStation 500, and ABI 7900 Taqman machine. The Center provides flexible, high quality, high throughput SNP genotyping to the Harvard Partners research community, including Harvard Medical School, hospitals in the Partners Healthcare network, investigators in the Dana Farber / Harvard Cancer Center, and the Harvard School of Public Health. We also offer mouse genotyping with a whole genome 768 SNP Illumina custom Mouse panel. All services include assistance with SNPs selection and choice of platform for any particular project. Each project must be priced independently and a quote can be generated quickly for any investigator. Genotype results are provided to the user in electronic format via the PCPGM web portal.

## Microarray:

The PCPGM Microarray Facility offers RNA expression analysis services for the Partners community using two major platforms. We offer services based on use of Affymetrix arrays and Illumina arrays. Our services include an initial consultation to assist in selection of arrays and experimental design. We then move forward with lab services that include starting with total RNA which is QC’d by Agilent Bioanalyzer before we begin any chip related work. Clients may also elect as an alternative to send us material ready for hybridization and scanning. When starting with total RNA we undertake the bench processes for creation of labeled product ready for hybridization, hybridize the products to the appropriate arrays, and then scan for analysis. We are also able to offer RNA amplification support for projects where RNA is limiting. We maintain our entire project data sets on a LIMS system with files backed up nightly via the Partners IT services. Investigators may access their account via the web as needed and download this data for other uses. We also offer a standard basic comparative analysis report with each project.

## Other Technologies:

All of the PCPGM laboratory operations are supported by a full compliment of liquid handling robotics for high throughput processes, CO2 incubators, freezers for LN2, -80C, -20C, and 4C, in a fully monitored building with emergency power backup on critical equipment. To minimize cross contamination risk we maintain a specialized room separated from the main laboratory spaces and dedicated only for pre PCR activities.PCPGM Web Portal:

## The PCPGM's current IT infrastructure includes core applications developed by the center to support clinical and research uses of genetics and genomics. Security is taken very seriously with a focus on protecting patient privacy and safeguarding researcher confidentiality.

## Our integrated environment provides researchers the ability to:

* Place orders and receive results from multiple laboratories by signing on to a single system
* View order history with associated raw data files and analysis, which are archived in a secure and backed up repository
* Access to this information from any location
* Share information with collaborators quickly and securely
* Track financials including who placed orders
* View order status
* Access study specific sample catalogs in real time for samples stored within the BioSample Services Facility

Behind the scenes, the system supports laboratory workflows and integrates with instruments and other LIMS to increase data flow integrity.   
  
On the clinical side, the IT infrastructure provides our Laboratory for Molecular Medicine with:

* Tools that increase data flow integrity across the testing process, from start of work to case sign-out
* Case-centric views and tools for technicians and geneticists, as well as, batch centric views for laboratory workflow
* Knowledge management and reporting infrastructure geared toward supporting the genetic testing process

## Laboratory of Molecular Medicine:

The Laboratory for Molecular Medicine (LMM) is a CLIA-certified clinical diagnostic laboratory operating within the Partners HealthCare Center for Personalized Genetic Medicine. The LMM received its final regulatory approval and began offering testing services in November of 2003. The mission of the LMM is to bridge the gap between research and clinical medicine, translating novel discoveries into cutting-edge tests and accelerating the adoption of new molecular tests into clinical care. The laboratory is in a unique position to accomplish this by virtue of its two primary assets - access to the cutting edge technologies of the PCPGM, and access to prominent researchers and physicians within the Harvard Medical School and Partners Healthcare systems, who will provide the breakthroughs leading to next generation diagnostics.  
  
Techniques available within the Center that take advantage of high-throughput and cutting-edge technology are integrated into the various tests developed in the lab. For example, the Sequencing Facility provides high-throughput DNA sequencing for gene tests involving direct sequencing. The Microarray Facility allows for large-scale parallel approaches in multi-gene analyses, particularly for studies involving tumor classification. Also emerging as a key tool to facilitate research and clinical studies will be integration of our Genotyping service in such areas as pharmacogenomics and complex trait analysis where genetic variation may be used to understand variable responses to therapeutic treatments.   
  
In addition, the LMM has developed in training for clinical and research fellows providing them with a unique environment to gain skills in medicine, technology and basic research.

**X.** [**Partners HealthCare Research Computing**](http://rc.partners.org/)

Partners Information Services (IS), a division within Partner Healthcare Systems (PHS), manages all data and voice communication networks as well as other core infrastructure systems and applications across the Partners environment. The PHS data network provides 100Mb/s Ethernet connections to the desktop with 1Gb/s access layer connections to the core. The network core consists of redundant fiber optic backbones capable of 10Gb/s among 4 major Partners datacenter 1Gb/s connections are provided to instruments and systems for users with higher bandwidth requirements. Partners is connected to the Internet2 via a 1Gb/s link via its ISP, Harvard University. Redundancy is maintained from all areas of the network to the single ISP. Infrastructure services and key applications are accessible to authorized users from any Windows, Macintosh, or UNIX workstation with access to the PHS network.

**Research IT General**

Partners Research Computing, a department of Partners IS, maintains dedicated hardware and facilities for scientific computing. All grant/contract proposals have access to these facilities and services including the Partners High Performance Computing Facility (pHPC), database hosting, very large storage and archive enterprise solutions, server hosting, datacenter space to house servers and rack equipment within the PHS datacenter built 2006, secure backup, and secure data transfers.

**High Performance Computing**

The HPC facility provides computational resources and expertise to researchers who are developing and analyzing computational and/or data intensive models in all aspects of research and informatics. These resources currently include more than 200 terabytes of storage for research analytics, with additional storage resources available for files and archiving and to secure data. The facility maintains two computing environments, clusters and large memory machines. The computational cluster currently contains more than 700 cores of processing power, with at least 2GB RAM per core, fiber-attached to 32 Terabytes of clustered high-performance storage for extreme I/O demand and database access. Empirical benchmarking has shown the cluster to have a total output of 3.9 Tflops. The large memory machine is currently configured with 128GB RAM and 32 cpu's connected to high performance storage.

Additionally, MySQL, PostgreSQL, and Oracle RDBMS's have been integrated and tuned for use with cluster algorithms. The cluster utilizes the LSF scheduler from Platform Computing and Hewlett Packard's XC cluster management software. Many scientific and academic applications and databases are hosted on the systems and kept current to the latest revisions. Commercial software is also hosted such as Matlab and Mathematica, SAS, Ingenuity, to name a few.

The facility staffs Ph.D.'s and Master's level personnel with extensive experience in computational science, programming and computational support including systems administration and architecture, database, bioinformatics, and application support. These personnel help ensure that faculty and researchers take full advantage of the available resources.

**Cloud Computing and Storage**

The Discovery Informatics Platform for Research (DIPR) provides to research grants a set of virtual services that are maintained using enterprise-class IT systems within the Partners secure data center and within the Partners network. These services consist of virtual servers for web or application hosting on either Windows or Linux systems, file storage and database hosting and management. DIPR consists of a 16-node VMWare ESX cluster. Each node is an HP BL460c with 32GB of RAM & 8 Intel Xeon 3GHz x64 cores. Guest operating systems achieve a level of High Availability via VMWare's VMotion technology, which seamlessly moves a guest from one physical server to another in the event of a machine failure. Structured data can be stored within MySQL, PostgreSQL or Oracle clustered database that each are maintained on dedicated hardware systems consisting of at least 64GB RAM and 16 CPU's. Finally unstructured data can be stored on a file server connected to the cloud for small storage requirements. For larger requirements, research computing maintains a storage system able to scale into petabytes for file storage. The latter is provided at a minimal cost to the research community.

The virtual services and databases are backed up nightly via the enterprise backup system, IBM Tivoli Storage Management, and maintained on enDCRyted storage tapes for tapes that are stored off site.

**Security**

All systems are secured behind the Partners firewall and follow Partners Healthcare Information Security policies for authenticated, minimum access. All systems are patched, monitored and scanned routinely for vulnerabilities and intrusions by the systems administrator and PHS Information Security. Data is encrypted, where applicable, in compliance with state and federal government standards, regulations, and in accordance with Partners Security and Privacy policies. All configuration changes that could affect accessibility or security are approved by management. All systems administrative personnel and support staff have completed the NIH training program in Computer Security and has additionally completed their certification in The Collaborative IRB Training Initiative (CITI) program. CITI was developed by experts at PHS, MGH, and BWH and with outside institutions in the "IRB community" and consists of courses in the Protection of Human Research Subjects for Biomedical Research.

XI **Partners Biobank and Biobank Portal**

The availability of high-quality, affordable human samples is core to the mission of Partners HealthCare personalized Medicine. The Partners HealthCare Biobank is a large research data and sample repository. It provides researchers access to high-quality, consented samples to help foster research, advance our understanding of the causes of common diseases and advance the practice of medicine. By using consented, annotated and high quality samples, investigators can generate high-quality data that advances personalized medicine.

The Biobank information technology team maintains a network that collects, tracks, queries and distributes samples to investigators across the Partners system. To date there are 30,000 consented subjects in the Partners Biobank whose data is available in the Biobank Portal. Data in the Biobank Portal includes electronic medical record data, patient health surveys, statistically-validated disease definitions and a utility for selecting healthy controls. In 2015, the Biobank announced enhanced graphing and reporting of query results; ability to create and download date-shifted sets of patient data for analysis and sample requests; ability to request de-identified and identified samples, and ability to request genomic data on 5000 subjects who have been genotyped by the Partners Biobank.

Consented blood samples:

The Bionank provides samples (plasma, serum and DNA) collected from consented patients. They are linked to clinical data from the Electronic Medical record as well as additional health information collected by the Biobank team. Over 30,000 patients have provided samples to the Burbank.

Crimson blood samples:

Through its affiliation with the Crimson Cores maintained in the BWH and MGH Pathology Departments, the Partners Biobank provides investigators with blood samples that were discarded after clinical testing. The samples may be collected based on cohorts of patients that are developed through the Partners Research Patient Data Registry (RPDR). They may be collected based on clinical test results. Both the samples and clinical data are anonomized

Biobank Portal:

The Biobank Portal is a web-based tool that researchers can use to query data

about consented Partners Biobank subjects and to make sample requests for

plasma, serum, and DNA.

**XII.** [**Harvard Catalyst: The Harvard Clinical & Translational Science Center**](http://catalyst.harvard.edu/)

The Harvard Catalystis a pan-Harvard University enterprise dedicated to improving human health. It is a shared enterprise of Harvard University, its ten schools and 18 affiliated academic healthcare centers (AHCs), the Boston College School of Nursing, MIT, the Cambridge Health Alliance, Harvard Pilgrim Health Care, and numerous community partners. Harvard Catalyst was founded in May 2008 with a five year, $117.5 million Clinical and Translational Science Award from the National Center for Research Resources at the National Institutes of Health, as well as $75 million from the Harvard University Science and Engineering Committee, Harvard Medical School, Harvard School of Public Health, Beth Israel Deaconess Medical Center, Brigham and Women’s Hospital, Children’s Hospital Boston, Dana-Farber Cancer Institute, and Massachusetts General Hospital.

The resources of Harvard Catalyst, several of which have particular value for junior investigators, are available to all faculties at Harvard regardless of their institutional affiliation or academic degree, including:

**Collaborative Resources**

* Harvard Catalyst Profiles - a research social networking application
* Grant Central - an online, collaborative grant development and project management tool
* Research Navigators - science faculty who are available to welcome and orient investigators to the research technologies and services of Harvard, as well as to each other

**Educational and training opportunities**

* Introduction to Clinical Investigation - a five-day course on the principles and methods of clinical investigation
* Intensive Training in Translational Medicine - a two-week course on the principles and practice of translational research
* Advanced fellowships like the KL2 Medical Research Investigator Training (MeRIT) program
* The Advanced Curriculum Compendium - An online, searchable database of advanced didactic courses developed and offered by Harvard’s affiliated AHCs

**Research tools and resources**

* Consultations in biostatistics, medical imaging, genetics, and other research fields
* Core facilities offering services for investigators
* Access to de-identified clinical data and information about archived pathology specimens
* Access to de-identified, aggregate counts of clinical interactions that meet certain clinical criteria
* Regulatory support
* The Laboratory for Innovative Translational Technologies - a laboratory offering access to cutting edge sample preparation and analysis technologies and equipment
* The Harvard Catalyst Clinical Research Center, which coordinates and makes available to all Harvard faculty the resources of the five former Harvard-affiliated General Clinical Research Centers (GCRCs; at Beth Israel Deaconess Medical Center, Brigham and Women’s Hospital, Children’s Hospital Boston, Massachusetts General Hospital, and MIT) and a CLIA-certified Harvard Catalyst Central Laboratory

**XIII.** [**Harvard Medical School Master's Degree Programs for Clinical Investigation**](http://catalyst.harvard.edu/services/scholars/)

Harvard Medical School has four individual Masters Programs in Clinical Research which emerged from separate fellowship training programs to serve different clinical research constituencies. The Program in Clinical Effectiveness (PCE), by far the largest program, solely provides course work. Trainees’ research is conducted outside PCE, in mentors’ labs. The three other Masters Programs have a primary responsibility for research mentoring as well as course work**.**

**1.** The **Program in Clinical Effectiveness** was established at the Harvard School of Public Health in 1987 and has been a glowing and growing success. The program is designed for the clinician seeking quantitative and analytic skills for clinical research or health care administration. The curriculum currently includes Clinical Epidemiology, Biostatistics, and elective courses in Decision Analysis, Current Issues in Health Policy, Health Care Ethics, Outcomes Measurement, and the Role of the Physician Manager in Health Care. The courses are taken over the summer and require full-time intensive participation. Individuals wishing to obtain a Master’s Degree continue courses in the second summer as well. The most common Masters degree path for Program graduates is an MPH with the Concentration in Clinical Effectiveness.

**2. Scholars in Clinical Science Program:** To meet the needs of translational investigators, many of the course directors of the Program in Clinical Effectiveness have joined with the faculty of the MGH Clinical Research Program, the General Clinical Research Center, and senior clinical investigators at other Harvard teaching hospitals to develop the Scholars in Clinical Science Program (SCSP), a second Master’s level program for clinical investigators. Initially funded by a K 30 award, this program tends to place greater emphasis on hypothesis-driven, “small-n” clinical research projects and is designed to provide more highly trained individuals to perform clinical research in an academic and/or industrial setting; and provide sufficient training in leadership skills to be effective leaders of a complex research group, academic department, academic medical center, or industrial or managed care group.

The **program includes** an intensive summer didactic course, building on the summer curriculum for the Program in Clinical Effectiveness, with a longitudinal seminar program and a mentored GCRC based clinical research project. The summer course includes Epidemiology, Biostatistics, Business and Leadership Skills, Genetics, Clinical Trials, Pharmacology, including genetics and economics, and Tools of Clinical Investigation. The longitudinal seminar includes experimental design and critical thinking using the case method. Degree requirements include the completion of a core of Masters level courses, outlined below, as well as the completion of a K23 grant application, or two peer-reviewed publications, or a traditional thesis.

**3: Clinical Investigator Training Program (CITP) – HMS/HST**

***This masters program was begun*** in 1993 to train postdoctoral physician scientists in the techniques of human investigation with the goal of generating a cadre of successful clinical investigators. It is a joint program between the Beth Israel Deaconess Medical Center and the Health Sciences and Technology (HST) Program at HMS and the Massachusetts Institute of Technology. CITP provides more of a background in pharmaceutical and drug-discovery research.This program is funded with unrestricted grants from Pfizer and Merck. Emphasis is placed on translational research projects that utilize both bench and clinical research tools. The core research project is designed by the trainee in collaboration with his/her mentor(s). Most trainees have two mentors, one with primary responsibility for a laboratory component and one expert in the translational (patient-oriented) component. The trainees must commit 80% of their time to the research project and the didactic portion of the CITP program for two years.

The Masters of Science Degree from HMS requires that all candidates attend the didactic sessions on a regular basis; complete a of a formal written thesis equivalent either a grant application, a peer-reviewed first-authored research publication, or a written thesis that covers the background, rationale, and data derived to date on the research project; successful progress on the candidate’s primary research project; a formal oral presentation summarizing the research project; and 5) successful completion of a written qualifying examination.

**4:** **Masters in Biomedical Informatics - Harvard/MIT Joint Program**

The goal of the program is to provideresearch training in biomedical informatics for M.D.s and other health professionalswhose clinical research builds on informatics. The Master’s degree program in biomedical informatics (BMI) has been offered by Health Science Technology since 1996. Admission to the program requires that students hold an advanced degree or be concurrently enrolled in a health profes­sion­al degree program (e.g., M.D. or D.M.D.). There are a variety of career paths for degree recipients from this program, including academic research and teaching, institutional man­age­ment (e.g., chief infor­ma­tion officer), public policy, information systems development in hospi­tals or industry, research and development in the biotechnology industry, and clinical practice along with informatics support for departmental research and development.

Four graduate level subjects consist of: Biomedical Computing, Medical Artificial Intelligence, Biomedical Decision Support, genomics and computational biology, and an elective class, depending on the specific interests of the student, in computer science, engineering, decision science, epidemiology, health systems management, bioinformatics, etc.

11-12-15 kr

**Appendix 1: MGH Clinical Research Program - Courses offered annually for Investigators**

**Study Design and Analysis**

* Introduction to Survey Research & Design (4 sessions)
* Basic Biostatistics for Clinical Research (4 sessions)
* Applied Biostatistics for Clinical Trials (4 sessions)
* Problem-Based Biostatistics in Clinical Research (4 sessions)
* Design & Conduct of Clinical Trials (*see course outline below*)\*\*

**Genetics/Genomics**

* Genetic Code
* Genetic Literacy
* Epigenetics
* Biobank
* Sequencing

**Issues in the Protection of Human Subjects**

* Maintaining Research Subject Privacy and Information Security: What Clinical Researchers Must Know
* Ethics of Clinical Research Protocols
* Reporting of Clinical Research Results
* What Constitutes a Minimal Risk Study?

**Professional Development**

* Conquering the K: Applying for an NIH Career Development Award (7 sessions)
* Clinical Research Fellows Orientation: Starting Your Clinical Research Career at MGH
* How to Make a Poster
* Good Clinical Practice in an Academic Research Institution (4 sessions)
* How to Give a Presentation

**Grand Rounds**

* Neurology: Toward Novel Therapeutics for Neuropsychiatry: Targeting Neuroplasticity
* Medicine: Atrial Fibrillation: Can Genetics Inform Patient Care?
* Medicine: Human genetics, type 2 diabetes and target validation for drug discovery

**IRB/QI Roundtables**

* Session I: Part I: IRB: New Submissions Initial Full Board Review
* Session I: Part II: QI: Study Start-Up
* Session II: Part I: IRB: Continuing Review & Amendments
* Session II: Part II: QI: Source Documentation
* Session III: Part I: IRB: Amendments & Reporting to the IRB
* Session III: Part II: QI: Protocol Adherence & Reporting Requirements
* Session IV: Part I: IRB: Consent Form Writing
* Session IV: Part II: QI: Informed Consent Process

**Continuing Education**

* Bio-Specimen Processing Basics
* Budgeting for Industry Sponsored Clinical Trials
* Clinical Trials.gov
* Delegation of Responsibilities in a Clinical Research Study
* Managing and Reporting Unanticipated Problems and Including Adverse Events
* Pitching and Consenting Research Opportunities in Acutely Ill Subject Populations
* RedCap: Getting Started
* RedCap: Data Entry and Survey Admin
* RedCap: Making Changes to Projects
* Research Subject Advocacy Materials and Resources for Research Nurses and Research Coordinators
* Research Subject Remuneration and Reimbursement: Policy Review and Navigating the Process
* Subject Recruitment and Retention Series
* Study Electronic Data Capture: StudyTRAX & REDCap

\*\*\*Design & Conduct of Clinical Trials (16 sessions)

* Session 1: Introduction to Clinical Trials
* Session 2: Design and Analysis of Randomized Trials
* Session 3: Working with a Statistician
* Session 4: Selecting and Recruiting Study Subjects and Ethical Issues in Clinical Research
* Session 5: Data Management and Beyond Data Management
* Session 6: Protecting Patients: Why and How?
* Session 7: Phase I Trials and Phase II Trials
* Session 8: Alternative Study Designs and Phase III Trials
* Session 9: Important Issues in the Conduct of International Trials and Phase IV Trials
* Session 10: Working Session with Course Faculty
* Session 11: Clinical Trial Funding Strategies and Getting into the Game and Playing the Angles, Funding Ancillary Studies, and Academic Spin-offs
* Session 12: Negotiating with Industry: What They Want; What You Need
* Session 13: Topic TBD
* Session 14: Topic TBD
* Session 15: Topic TBD
* Session 16: Participant presentations