Clinical Research Resources and Environment

The Massachusetts General Hospital (MGH) is consistently ranked as one of the top hospitals in the nation. MGH is known for revolutionizing care and has a long, rich, and diverse tradition of excellence in clinical research that continues today. There are extensive resources for training clinical investigators and for performing high quality translational research. These resources include:

- An integrated full service primary, secondary, and tertiary care hospital network with access to large numbers of patients with common and rare conditions
- Approximately 1,360,000 square feet of research space
- A diverse population of thousands of basic and clinical scientists
- Multiple departments that provide structural support for clinical investigators

Resources and Environment @ Massachusetts General Hospital

MGH Research Institute

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.

MGH Division of Clinical Research

The MGH Division of Clinical Research (DCR), a division of the Research Institute, focuses exclusively on meeting the needs of the MGH clinical research community through education and faculty-support.

The DCR occupies the second floor of the Richard B. Simches Research Building located adjacent to MGH main campus. Common equipment resources available to investigators include PC workstations connected to a local area network, printers, document scanner, photocopy and fax machines, and conference space.

The DCR is organized into broad service categories with resources to facilitate the performance of high quality clinical research. Each Center and Unit has a faculty-director(s) providing one-on-one support to investigators. DCR Centers and Units include the following:

Bioinformatics Consortium
Biostatistics Center
Center for Clinical Research Education
Community Access, Recruitment and Engagement
Partners Biobank at MGH
Pediatric Translational Research Center
Center for Quantitative Health
Translational Research Center and Clinical Research Center
Comparative Effectiveness Unit
Drug Discovery Rounds Unit
Electronic Health Records (EHR) Research Unit
Global Health Research Unit
Imaging Biomarkers Unit
Information Technology Unit

Mentoring Corner
Omics Unit
Patient-Centered Outcomes Research (PCOR) Unit
Philanthropy Education Unit
Qualitative Research Unit
Research Ethics Consultation Unit
Study Hypothesis and Design Unit
Survey Research Unit
Trial Innovation Unit

MGH Translational and Clinical Research Center (TCRC)

The goal of the TCRC (a 14-bed unit), which is on White 12 on the main campus of the MGH, is to provide research infrastructure for clinical investigators who conduct patient-oriented research. The clinical research support provided by the TCRC includes outpatient and inpatient facilities, and the necessary support personnel, such as research nurses, nurse practitioners, research nutritionists, and administrative personnel.

Metabolism and Nutrition Research support includes metabolic weight assessment, indirect calorimetry, computerized nutritional and activity (past and present) assessment, DXA scans for assessment of bone density and body composition, bioimpedance analysis, anthropometry and exercise testing. Specialized nursing services include sampling of biologic fluids, frequent sampling protocols with maintenance of intravenous and intra-arterial lines, pharmacokinetic and pharmacodynamic studies, physiologic measurements, sleep studies, administration of research questionnaires, administration of research drugs, and assistance in the collection of a variety of other research data. The nursing staff also ensures subject safety, including routine and specialized surveillance during all research protocols. Research studies that are conducted in locations outside of the TCRC, so called “off-site”, can also be supported with TCRC resources and staffing. The investigations carried out by the TCRC can include studies of normal and abnormal human physiology and studies of the cause, prevention, progression, treatment and cure of diseases that afflict individuals from all backgrounds. Resources are provided to translate basic scientific discoveries into novel diagnostic and therapeutic methods that improve health care. Collaborations between basic and clinical scientists are encouraged.
Protocol applications to the TCRC adhere to NIH guidelines regarding inclusion of children, women and minority populations. The TCRC provides a unique environment for mentored training of health professionals in clinical research. The TCRC is funded by a grant from the National Center for Advancing Translational Science (NCATS).

The TCRC laboratory is dedicated to the on-site and timely preparation of laboratory samples acquired during clinical research on the TCRC. Samples are prepared for immediate assay in other research laboratories or hospitals, for shipment, or for storage for later study. All biological samples (blood, urine, stool, biopsy samples) can be handled, and the laboratory is geared to prepare, aliquot and ship/store numerous samples from studies performed on the TCRC on a given day. Attention is paid to the correct timing and labeling of samples as many studies incorporate pharmacokinetic/pharmacodynamic features as part of the study and frequent timed sampling is not uncommon. The TCRC laboratory specializes in handling high volume, efficient sampling, and monitoring of samples.

MGH Richard B. Simches Research Center
The Richard B. Simches Research Center contains an impressive 25% of the hospital’s total research space spanning eight stories on 267,000 square feet, the building is home to four thematic centers. The DCR 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.

MGH Thematic Centers

Massachusetts General Hospital is home to five thematic research centers where clinicians and scientists chart new terrain in biomedical research to treat and prevent human disease and bring the latest advances to patient care. Each Center works to develop creative approaches to treat a broad spectrum of diseases. Centers include:

- Center for Computational and Integrative Biology (CCIB)
- Center for Genomic Medicine (CGM)
- Center for Regenerative Medicine (CRM)
- Center for Systems Biology (CSB)
- Wellman Center for photomedicine

MGH Center of Diversity and Inclusion

1. MISSION

The Center for Diversity and Inclusion (CDI) promotes the recruitment and advancement of physicians and scientists underrepresented in medicine (URM); and seeks to develop a culturally competent and engaged workforce at Mass General where all can experience a true sense of belonging. CDI is one of the first academic hospital-based centers in the country dedicated to helping build a diverse and inclusive community of physicians and scientists.

2. FOCUS

CDI accomplishes its mission through three focus areas:

- Professional leadership development and workforce recruitment at all stages of a URM physician's and scientist's career: student, trainee, and faculty
- Cross-cultural education of staff and physicians to enhance the quality of care of patients and employee engagement
- Advancing the science of diversity and inclusion by measuring outcomes of our programs and interventions

3. STRATEGIC PRIORITES

CDI accomplishes its mission working with hospital and department leadership, as well as many local and national strategic partners, focusing on four strategic priority areas:

- Expose students underrepresented in medicine (URM) to academic research and clinical careers;
- Advance URM trainees and faculty through recruitment, career development, networking, mentorship and funding;
- Champion health equity, community outreach and social justice through advocacy and education;
- Drive organizational change by helping embed diversity and inclusion into the fabric of Mass General.

4. NOTABLE ACHIEVEMENTS FOR THE 2018 YEAR

4.1 Creation and development of CDI's first Annual Report

4.2. Recognition for mentorship in the Summer Research Trainee Program (SRTP).

For 26 years, SRTP has brought together talented college and medical students from across the country to engage in a novel research project with an MGH investigator. We expanded this program to 20 students in 2016, and the program was honored with a 2017 HMS Award for Program Excellence in Mentorship.

4.3. Expansion of the CDI Faculty Development Award Program.

We received commitment from the MGPO and Executive Committee on Research to double the number of Physician/Scientist and Clinician-Teacher Development Awards. We now fund four awards; two in each category.

4.4. Leadership involvement in hospital-wide strategic planning for diversity and inclusion, and community health.

CDI staff members were an integral part of developing the hospital-wide strategic plan for diversity and inclusion, which included a new hospital-wide diversity statement, a rapid response team, and the development of a culture survey and diversity metrics. In addition, CDI staff helped lead efforts in community health, developing the first social determinants of health education symposium for the hospital.

4.5 Champions in race discussions.

Both in our community and across the hospital, CDI and the RFC led important and difficult discussions about race. The CDI was a signature sponsor for the annual Stand Against Racism event at the MGH in 2018, featuring two members of the Boston Globe Spotlight team which published articles about race and racism in Boston. Our ultimate goal is to help build a diverse and inclusive community at Mass General.

5. Overall

In 2017-18, CDI met individually with Chairs and MGH affiliated residency program directors to help implement diversity and inclusion efforts in all MGH departments. During this past year, CDI served over 450 URM students, trainees and faculty, and provided cross-cultural education and unconscious bias training to approximately 2,500 physicians, scientists and interdisciplinary teams.

5.1 Hospital-wide Diversity and Inclusion Committee and Executive Committee on Community Health

CDI has been a key contributor to the hospital-wide MGH/MGPO Diversity and Inclusion Committee and the Executive Committee on Community Health (ECOCH), both of whom report into the General Executive Committee. In addition, CDI has been a leader in developing the hospital-wide strategic plan and implementation for diversity and inclusion, which identifies priorities for diversifying the clinical and research workforce and increasing representation of the community research and clinical trials, among many other priorities. CDI also led part of ECOCH's strategic planning process. Charged with improving the health across populations and throughout the lifecourse, ECOCH focuses on social and economic determinants of health, access to high quality care for low-income patients and collaborates with the MGH Diversity and Inclusion Committee around issues of race and racism.

5.2 Professional Workforce Diversity

SRTP was recognized as a program leader for mentorship of the student pipeline: The Summer Research Trainee Program (SRTP) was founded in 1992 to inspire students who are underrepresented in medicine (URM) to consider careers in academic medicine and biomedical research. 2018 marked the third year 20 (up from 15 in prior years) college and medical school students were selected through vigorous national competition to conduct novel research with MGH faculty preceptors in basic science labs, clinical research sites, health policy and health services settings. Students were assigned to investigators in 13 different departments for a nine-week period, and were exposed to

group mentorship, career workshops, research seminars, as well as networking and social events with the CDI community. This experience culminated with student research project presentations to the MGH research community, and students received feedback from an evaluation panel of research faculty. 350 students have participated in SRTP since its founding. Several participating students stayed on in labs and have published their work; 4 presented posters in MGH's Clinical Research Day (one received the Departmental award); and two returned as medical students to work with their assigned PIs. Previous SRTP participants state that the program added tangible value to their subsequent training and career decision making, and had a marked impact on their decision to pursue careers in an academic setting. SRTP was recognized this past year for its commitment to mentorship, as the recipient of the **2017 HMS Award for Program Excellence in Mentoring**.

CDI helped recruit record numbers of URMs in residency spots: In 2018, 13% (n=31) of the residents who matched in 20 MGH/integrated residency programs were URM, with several programs exceeding 25%. This is above the percentage of URM national medical graduates. CDI worked closely with all MGH affiliated residency programs in their recruiting efforts. CDI hosted 10 applicant receptions during the interview season to provide an opportunity for applicants to meet the CDI community of URM residents, fellows and faculty in a more relaxed setting and receive a perspective on training at MGH and living in the Boston area. CDI also participated in, and sponsored trainees to attend, national recruitment fairs to meet students and potential applicants throughout the year (e.g., SNMA, LMSA, HMS residency showcase).

CDI continued to promote clinical and research faculty through the CDI Faculty Development Award Program (FDA): With funding from ECOR and the MGPO, CDI sponsored four faculty development awards in 2017. Since 2004, CDI has awarded 50 faculty development awards totaling $6 million in funding. The purpose of this program is to increase opportunities for URM faculty, and who are committed to diversity, inclusion and equity, to advance to senior positions in academic medicine and leadership at MGH. The two award categories include: The Clinician/Teacher Development Award (CTDA) and the Physician/Scientist Development Award (PSDA). Each award provides $120,000 over four years and is designed for MGH-appointed faculty pursuing different career goals. In a recent study, CDI found recipients bring in eight times the Award investment to Mass General in the form of external grants. Recipients are also more likely to stay at MGH (88%) than those individuals who do not receive funding (60%).

5.3 Critical Race and Equity Initiatives

Throughout the 2017-18 year, CDI hosted a series of cross-cultural education sessions focused on developing strategies for teaching effective cross-cultural dialogue at MGH. Session participants explored challenges in facilitating cross-cultural dialogues and learned how to apply the training to a team-based learning environment. CDI also co-sponsored several focus group and hospital-wide discussions on race, equity and racism, including a Stand Against Racism, featuring two members of the Boston Globe Spotlight team which published articles about race and racism in Boston.

CDI also worked closely with the Mongan Institute for Health Policy and the MGH Diversity Committee to develop metrics of diversity and inclusion for the institution, including a hospital-wide diversity culture survey. Survey results were shared with leadership and the hospital community in town hall formats.

MGH Center for Faculty Development

The primary focus of the MGH Center for Faculty Development (CFD) is to offer a comprehensive and innovative program to maximize professional success for faculty. The mission of the CFD 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 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 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. These endeavors will seek to enhance the careers of researchers at MGH so that they may flourish in their activities and aspire to greater success.

The Post Doctoral Division (PDD) of the ORCD, addresses the specific needs and career advancement of the research fellows at MGH. Areas of emphasis for this office are to:

- Provide programming for career advancement, professional development, networking and work life balance.
- Enhance awareness of, and compliance with, the MGH Post-Doc Policy, including its exception policy.
- Act as central point of contact for post-doc fellows regarding information, resources, and issues.
- Ensure the Annual Career Planning discussion takes place (and that the form is completed).
- Facilitate orientation sessions for newly-arrived post-docs to familiarize them with the MGH. Provide individual counseling, advice and support.

MGH Executive Committee on Research (ECOR) is the central body for research governance, bringing together a broad representation of internal stakeholders to provide strategic guidance to the hospital's leadership regarding research priorities. ECOR has a major internal grants and awards program, virtually a mini-foundation, which annually reviews nearly 800 applications from MGH investigators and fellows, and awards approximately 150 internal grants. The grants program provides interim/bridge support to faculty whose NIH or other federal funding is delayed or otherwise interrupted. ECOR also awards the Martin Prize, the Howard Goodman Award, the Claflin Awards, the MGH Physician-Scientist Development Award through the Center for Diversity and Inclusion and the Tosteson Fund for Medical Discovery post-doc fellowship awards.

In January 2011, ECOR launched the MGH Research Scholars Program, a major initiative to award research support to outstanding faculty in the MGH research community in support of innovative, cutting-edge research. 36 Scholars have been appointed so far, each receiving research funding of $100,000 a year for 5 years.

Resources an Environment @ Partners Healthcare

Partners Research Information Science and Computing

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. Partners Research Information Science and Computing (RISC), a department of Partners IS, supports research by providing scientific services and technology, a centralized clinical data registry, genomics IT, specimen banking, and administrative systems. These specialized applications, processes and resources support basic, biomedical and clinical research missions. All grant/contract proposals have access to these facilities and services. Programs under RISC include the following:

Enterprise Research Infrastructure and Services (ERIS) provides information services and technologies to enable and drive innovation in research.

Phenotype Discovery Center (PDC) develops computational methods and platforms to help harness the power of big data in the field of medical research.

Research Patient Data Registry (RPDR) is the centralized clinical data registry/warehouse. The RPDR gathers data from hospital systems and stores it in one place, bringing clinical information to a researcher's fingertips and ensuring the security of patient information.

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.

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.

Partners HealthCare Personalized Medicine (PPM) translates and integrates the science of genetics and genomics into medical practice. Its focus is on constantly increasing the benefit genetics provides for patients facing life threatening and debilitating disease. This requires scalable information technology that spans research and clinical domains and connects laboratories to clinicians. Partners Personalized Medicine works closely with ERIS to design and maintain the infrastructure that supports the field's rapid evolution. Services and facilities include:

- Biosample Services Facility (BSF)
- DNA Sequencing
- Genotyping Facility
- Microarray Facility the products to the appropriate arrays, and then scan for analysis.
- RNA amplification

All PPM laboratory operations are supported by a full complement 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 a specialized room separated from the main laboratory spaces and dedicated only for pre-PCR activities.

Laboratory of Molecular Medicine is a CLIA-certified clinical diagnostic laboratory operating within the Partners HealthCare Center for Personalized Genetic Medicine. 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. In addition, the Lab has developed a training program for clinical and research fellows providing them with a unique environment to gain skills in medicine, technology and basic research.

https://rc.partners.org/about/who-we-are-risc/partners-personalized-medicine
https://personalizedmedicine.partners.org/About/Contact-Personalized-Medicine.aspx

Additional resources include the following:

Systems to Identify Subjects or Request Data

Enterprise-wide data services are available to help Partners investigators and research groups expedite the process of obtaining data for analysis or to gauge study feasibility. Repositories of clinical samples and data, as well as public data sets, are accessible to researchers through the tools and processes outlined below.

- Research Patient Data Registry (RPDR)
- Partners Biobank
- Mi2B2 Medical Image Access
- Shared Data Sets (IDEA)
- Partners eCare Workbench and Research Core

Data Collection

The electronic data capture (EDC) support service helps coordinate, lead and support faculty and research study staff in their EDC, web-based survey and application needs for research studies. EDC support will help identify the optimal study tool given the investigator's requirements and facilitate the training of personnel in its uses and functions.

- Redcap
- Studytrax
- Freezerworks
- Labarchies electronic laboratory notebook

Analyze Data

High-performance analysis servers, compute clusters and storage are available for data processing and analysis by research groups across the organization. Computational Resources:

- Bioinformatics Data Processing
- Medical Image Processing
- Statistics, Analysis and Visualization
- Big Data Analytics and Machine Learning

Access to Academic Software

- Endnote
- Graph Pad
- MATLAB
- Safari Books
- SAS
- SPSS
- STATA
- R- User Group

RISC Boilerplates and Templates

- IT Security
- IT Infrastructure

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,

Partners Biobank and Biobank Portal

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.

The Biobank 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.

Through its affiliation with the Crimson Core, 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 anonymized.

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.

RedCap Electronic Regulatory Binder

The Electronic Regulatory Binder is a project within REDCap. 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
- 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.

Recruiting Patients for Clinical Trials

Partners offers researchers access to many tools to assist with finding participants for research projects.

RALLY is a database of current research projects at Partners Healthcare institutions. Researchers may add their trials to the database by following the instructions posted here.

ResearchMatch is a national registry that can help 'match' researchers with participants who are interested in a specific therapeutic area. ResearchMatch registration .

The Research Patient Data Registry (RPDR) is the central link to the Partners clinical data registry. The RPDR's online query tool provides users with aggregate numbers of patients that meet user-defined characteristics and criteria such as diagnoses, procedures, medications and/or laboratory results. The Data Request Wizards allow the user to ask for more detailed medical record information on the identified patient population. This process requires an approved IRB protocol.

The Research Study Volunteer Program, RSVP for Health, is a registry of individuals interested in clinical research at MGH and Brigham and Women's Hospital. RSVP for Health users can search the database by disease area, age, race, gender, and ethnicity. Once participants are identified, RSVP for Health sends potential volunteers an email containing the IRB-approved study announcement and prepares letters for those who wish to be contacted through US mail. The identity of potential volunteers is maintained until they choose to contact you. Find more information and apply for an RSVP account.

The ACT Network through Harvard Catalysts is a real-time platform allowing researchers to explore and validate feasibility for clinical studies across the NCATS Clinical and Translational Science Award (CTSA) consortium, from their desktops. ACT helps researchers design and complete clinical studies, and is secure, HIPAA-compliant and IRB-approved.

Partners Research Cores

Research core facilities at Partners HealthCare bring state-of-the-art instrumentation, methodologies and expertise crucial to the promotion of research. There are over eighty cores, across the Partners Hospitals, established to share their expertise, facilities and equipment to efficiently use resources, promote collaboration, and further enhance the competitiveness of Partners investigators to secure research funding.

Partners HealthCare Department of Biomedical Engineering

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.

Partners HealthCare Center for Integration of Medicine & Innovative Technology (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® 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 application 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 supplies a mechanism to facilitate the transfer and ultimate application to patient care. Successful ideas must be legally protected 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.

Resources an Environment @ Harvard

Harvard Catalyst: The Harvard Clinical & Translational Science Center

Harvard Catalyst is a pan-Harvard University enterprise dedicated to improving human health. It leverages the intellectual force, technologies, and clinical expertise of Harvard. Its academic, health care, and community partners all share a common goal of improving human health. Catalyst offers collaboration between investigators, educational and training opportunities, and research tools and resources.
The KL2/Catalyst Medical Research Investigator Training (CMeRIT) program provides advanced training in clinical and translational research to senior fellows and junior faculty from all health professions represented by Harvard Catalyst, including medicine, dentistry, and nursing. Awardees will pursue a mentored research project in their area of expertise. It is expected that the research performed within the KL2/CMeRIT program will provide the basis for an independent NIH award (e.g., K23, K08, or R01).

The Grant Review and Support Program (GRASP) is a multi-year program that guides junior investigators who have already obtained a career development award to understand the rules of engagement and the grant writing process, gain new skills, and to ultimately write competitive grant applications to achieve research independence.

Masters Programs in Clinical Research at Harvard

Harvard Medical School Master's Degree Programs for Clinical Investigation

Harvard Medical School offers Masters Programs in Clinical Research which emerged from separate fellowship training programs to serve different clinical research constituencies.

The Harvard School of Public Health Program in Clinical Effectiveness 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.

Masters in Biomedical Informatics - Harvard/MIT Joint Program

The goal of the program is to provide research training in biomedical informatics for M.D.s and other health professionals whose clinical research builds on informatics. 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.