Mass General Brigham
Mass General Research Institute

A Resource Guide:
The Universe of Digital Health Research Support Groups at Mass General Brigham

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Written by Conor S. O'Brien, Remona Kanyat and Dawei Jiang

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How to Use this Guide

This guide is meant to be used in conjunction with a larger three-part curriculum designed to help Mass General Hospital (MGH) researchers and staff in navigating digital health research at Mass General Brigham (MGB). This guide is a detailed overview and not meant to be fully comprehensive. Information has been compiled from a number of information sources and thus it is possible some material may be outdated. Please refer directly to each individual group's online materials for the most up-to-date content.

Digital Health Research Curriculum is divided into three categories to be covered in three educational courses:

Course 1 – Research Support Groups at MGB (mission, contacts, URLs, documents and FAQs)
Course 2 - Research Information Resources, Tools and Training
Course 3 - Digital Health Research Process

What is Digital Health?

Digital health methods include collection, transmission and/or dissemination of private or non-private, actively or passively collected data using software or technology on mobile or wirelessly communicating devices such as smartphones, sensors and wearable devices that collect health information, including:

- Mobile applications (apps), either under development or commercially available
- Homegrown smartphone apps or wearables
- Marketed apps or other software in the clinical research context
- Touchable or wearable technologies that gather physiologic and/or health data (sensors)
- Technologies that transmit data via Bluetooth or other wireless technology
- Electronic Health Record (EHR) analysis

Why is a Digital Health Review Required?

The rise of malware (including its risk to biomedical devices), ransomware, etc., puts digital health technologies at increased risk. Several MGB technical teams stay up to date on how vulnerabilities are being exploited and provide guidance and recommendations for reducing risk, as well as insight on how technology should be best used to ensure a safe and successful research study.

Who Reviews Digital Health Technologies?

There are many groups and stakeholders involved in the review of Digital Health Technologies for implementation in clinical research. The following provides an overview of those Centers, Groups, Cores, Divisions and Committees that support research. This document details each group's purpose, mission and focus and includes frequently used forms, documents, checklists and URL's.

The research support groups below are categorized alphabetically:

Biomedical Engineering (MGB)

Each hospital's biomedical / clinical engineering department provides safety reviews and implementation guidance for investigators to ensure a safe clinical care environment. Clinical engineers across the system are committed to ensuring that bedside technology is used appropriately and safely, performs properly, and is managed cost-effectively. Each hospitals biomedical engineering group strives to improve and develop devices and instrumentation for safe health care delivery, research, and innovation:

- Repairing, maintaining, and inspecting equipment
- Evaluating technology, installation, modification of existing systems, training, fabricating and development of custom devices, and managing regulatory requirements
- Applying strategic thinking to technology acquisition and development
- Providing technical administrative services, including parts and purchasing
- Conducting supplemental reviews of devices as required by the IRB

Website: http://biomed.partners.org/*
*Use MGB's VPN to access.

Center for COVID Innovation (MGB)

The Center for COVID Innovation facilitates the development of new innovations that flatten the COVID-19 curve and protect front line clinical staff across the MGB community and beyond. It is a joint research, engineering and development effort between MGH and BWH led by Dr. Guillermo Tearney and Dr. David Walt.

- Educates on what clinicians need to know for new innovations to be safely deployed and used
- Helps identify internal and external resources necessary to operationalize these ideas
- Identifies and empowers internal and external experts that can move ideas towards practice

Website: https://covidinnovation.partners.org
Email: covid_innovation_data@partners.org

Center for Innovation in Digital HealthCare (MGH CIDH)

Guides, supports, advocates and promotes digital health innovation. CIDH provides a core team to leverage and coordinate the multiple innovation and digital programs at MGH to achieve this mission. By augmenting the depth and breadth of those already engaged in this endeavor, CIDH positions Mass General Hospital to be the global leader in revolutionizing the healthcare industry into a digitally-based and human-centered continuous learning system:

- Coordinates and guides the development and integration of digital health innovation at Mass General Hospital, MGB and industry
- Facilitates and supports the necessary infrastructure for digital health care
- Promotes growth of digital health care initiatives at MGH
- Directly supports innovators in navigating the hospital support structure
- Leverages real-world, data-driven experience to guide digital health business models

Website: https://cidh.massgeneral.org/
Contact: cobrien@mgh.harvard.edu

Clinical Trials Office (MGB CTO)

Responsible for developing, negotiating and executing agreements and budgets for industry-sponsored clinical research conducted at MGB hospitals. CTO supports MGB investigators and their industry sponsors conducting Phase I-IV clinical trials. This includes contracting, budgeting and Clinical Trials Management Systems (CTMS) services:

- Industry Sponsored Clinical trial agreements (CTAs)
- Subawards for the performance of clinical research Small Business Innovation Research and Small Business Technology Transfer (SBIR/STTR)
- Confidentiality (CDA), Data Use Agreements (DUA) and clinical research support agreements (CRSA) with industry in support of clinical trials
- Drug/device donations from industry supporting federally sponsored research agreements (CTAs)
- Support **OnCore,** an enterprise-level clinical trial management system (CTMS) and **Advarra (Forte) Payments**, a system to streamline participant payments.

CTO has three functional area teams: Agreements, Finance and CTMS which allow for close collaborations between investigators, sponsors and the Clinical Trials Office.

CTO Agreements Team drafts, negotiates and executes a variety of clinical trial agreement types:

- Company Initiated and PI Initiated Clinical Trial Agreements and Amendments
- Support Agreements: core lab, steering committee, equipment and software loans
- Confidentiality Agreements
- Data Usage Agreements (DUAs)

CTO Finance Team assists investigators with:

- Budget preparation and negotiation, Payment Schedules, Fund Setup
- Medicare Coverage Analysis (MCA)
- Consultation
- Potential subject population analyses utilizing the Research Patient Data Registry (RPDR) database

CTO System team manages OnCore and Advarra (Forte) Payments to assist research teams:

- Protocol and Subject Lifecycle Management and Reporting
- Financial Management, including Sponsor Invoicing and Payment Reconciliation
- Research participant payments

Website: https://cto.partners.org/
Contact: Maureen Lawton mlawton@partners.org
General questions: CTOmailbox@partners.org

Note: Contact the Center for Innovation in Digital Healthcare (CIDH) to determine which group should process your contract.
Contact: cobrien@mgh.harvard.edu

Data & Tissue Sharing Committee (MGB DTSC)

DTSC oversees the implementation of the Policy on Specimen and Data Transfers and Access, including review and approval of requests to ensure that the transfer is part of an activity that furthers the institutional charitable missions of Mass General Brigham.

- Acts as a steward and facilitates consistent and responsible sharing of MGB clinical and research data and tissue assets to promote research and improve patient care
- Reviews and approves data and tissue sharing requests and recommends a path forward for any issues that arise related to the request
- Refines and updates Data and Tissue Sharing Guidelines as appropriate (see link below)
- Provides a forum for further policy development through use case evaluation and recommendations

Email: phspdtsc@partners.org

https://partnershealthcare.sharepoint.com/sites/phrmResources/c/Pages/Partners-Data-and-Tissue-Sharing-Committee-(PDTSC).aspx

Not all data and/or tissue sharing requests need to be reviewed by the DTSC. The DTSC has established a Triage Team to help contracting offices review access requests. Please contact an associate at one of the MGB contracting offices with further questions.

Data Science Office (MGB DSO)

Is the bridge between academic research and product development. Comprised of clinicians, data scientists, product managers, technical project managers and software engineers, the DSO leverages the expertise of MGB's world-renowned clinical investigators and data scientists to address complex problems in health care delivery, operations, and care coordination.

- Artificial Intelligence for Clinicians (AI4C) is a monthly lecture series program focused on digital innovations
- The Data Science Pathway (DSP) is an exclusive program for Mass General Brigham Radiology Residents to learn the fundamentals of Artificial Intelligence (AI) and Machine Learning (ML) in healthcare.
- The Foundational Training Curriculum in Machine Learning (FTC-ML) is a self-guided online training program will introduce you to the fundamentals of Machine Learning (ML) in healthcare, with an emphasis on practical concepts and knowledge. MGB clinicians, faculty, and staff with little or no background in computer science or mathematics are welcome to participate.
- The Medical Imaging Data Access Services (MIDAS) enables MGB investigators to obtain radiologic imaging studies for research purposes. The first product available under MIDAS is the Defined Exam Retrieval Service. Using this service, researchers can specify a list of imaging studies, up to 1,000 per request, from the clinical imaging archives and stored in a temporary location that has security and access control based on IRB permissions.

Website: https://datascience.massgeneralbrigham.org/
Website intake form: https://datascience.massgeneralbrigham.org/contact/
Contact: Educational Activities: Dr. Katherine Andriole kandriole@bwh.harvard.edu

Department of Intelligent Automation (MGB DIA)

Aims to expedite delivery of Intelligent Automation capabilities while simultaneously managing risk and implementing a "best practices" approach, to develop automations to help improve workflow by removing the repetitive, high-volume tasks, and freeing up our employees to focus on more value add, interesting, and creative aspects of their work. DIA works to integrate a scalable Intelligent Automation solution(s) to achieve improved efficiency, accuracy and cost savings by training employees to become developers in these new technologies throughout MGB.

Contact: Pietro Schena – pschena@partners.org

Digital (MGB)

Digital is a newly formed group designed to develop a modern, well-functioning technology ecosystem that delivers the optimal experience and value to our patients, providers, researchers and employees and will integrate the system's data and analytics, digital health and information systems teams into one unified organization. This strategic change will allow the Digital team to efficiently deliver connected, seamless, brand-defining experiences that delight the people we serve — all powered by a unified platform ecosystem and future-thinking talent. The formation of this group has led to the restructuring of a number of departments at the hospital and enterprise level. Additional information is expected to be shared by leadership in mid 2022.

Contact: Chief Information and Digital Office, Jane Moran, MBA –
MGH CIO: Keith Jennings – kjennings@partners.org

Digital EPIC Team (MGB eCare)*

In July 2012, Mass General Brigham announced it would partner with Epic, the industry-leading provider of health information technology, to implement an integrated, electronic health record (EHR) in order to be a more agile, integrated and efficient system. eCare is also supporting MGB innovation and leadership in redesigning patient care models, advancing population health management, improving patient affordability, enhancing the patient experience, etc. eCare areas of focus include:

- Digital Health (DH) eCare (also known as Digital Health Steering Committee or Partners eCare Steering Committee): DH eCare handles requests for enhancements and integrations of EPIC.
    - Contact: Julie White; jwhite39@partners.org
- eCare ACE: "Agile Configuration and Execution" is a program/methodology used in eCare to build out enhancements (small system optimization changes) as part of the overall clinical enhancement portfolio of work. eCare ACE has several scrum teams using Agile methods to advance enhancement work.
- eCare HOV: Allows individuals a way to get EPIC requests prioritized and jump the queue in the normal development process by paying to accelerate development (pay-to-play service).
    - For HOV requests, submit a ServiceNow ticket. Contact: Brian Blackman bkblackman@partners.org
- Partners eCare Research Core (PeRC): Leverages Epic EHR to assist researchers in identifying and recruiting patients for research. Services include: gathering Epic-related patient data for research (in the form of reports and/or data extracts), recruitment related services (data reports and patient gateway) and developing patient questionnaires.

    - Additional resources: https://partnersecare.partners.org/
    - Questions or comments: partnersecare@partners.org

*This group may be reorganized within the structure of MGB Digital, to be determined at a later date.

Digital Governance (MGH)

Digital Governance is an oversight and decision-making body that manages many different requests that enter the MGH system through channels such as eCare and ServiceNow. Researchers and staff don't need to directly interface with this group.

Digital Health Innovation (MGB DHI)

An Enterprise program, DHI accelerates innovative efforts that address high priorities, system-wide challenges and reduces time to value realization by supporting execution of digital innovation projects, increasing capacity to innovate and sharing successes and learnings across the health system and externally:

- Collaborate with, enable and facilitate communication between site-based innovation teams to provide governance and leadership across the enterprise to reduce costs, increase awareness and increase efficiency
- Provide innovation tools and resources to encourage, enable and streamline innovation efforts across MGB
- Increase capacity locally and enterprise-wide to quickly implement and evaluate digital innovation pilot programs and identify those with lasting value to scale

- Partner with internal and external stakeholders to support commercialization of and investment in promising homegrown and vendor products and companies

Contact: Executive Director, Esther Kim -- ekim5@partners.org
https://pulse.massgeneralbrigham.org/hub/initiatives/eddh

Division of Clinical Research (MGH DCR)

The Centers and Units within the DCR provide a support structure for clinical, translational and nursing research, and provide study support via biostatistics consultations and access to the Partners Biobank. Individual units in the DCR provide assistance with omics, patient-centered outcomes research, electronic health records research, qualitative research and more.

Free Services

- Hands-on research support
- Consultations with DCR faculty (6-8 hours)
- Investigational Drugs and Devices (IND/IDE) submissions
- Assistance with subject recruitment
- Identification of funding sources and budgeting for clinical studies
- Help with National Institutes of Health (NIH) and Patient-Centered Outcomes Research Institute (PCORI) applications
- Digital Healthcare Advisory Services through CIDH

Paid Services include Project Management, and assistance with IRB new application submissions.

Websites: https://dcr.massgeneral.org/
Contact: tkoretskaia@partners.org

Similar research support group to DCR at BWH called the Center for Clinical Investigation:
https://www.brighamresearchcci.org/

Enterprise Research Infrastructure and Services (MGB ERIS)

Composed of service-oriented teams that directly support and collaborate with MGB researchers, EIRS provides the interface between researchers and MGB Information Systems (IS) and advocacy and guidance on behalf of research to the many Enterprise projects.

- Research Computing Core is a team of Engineers, Developers and Systems Administrators providing fee-for-service consulting, discounted software licenses and storage services
- ERISOne Linux Cluster platform team provides assistance to researchers who want to develop their projects in the supported platforms
- Develops and delivers enterprise-wide IT services for the research community that includes Linux, Windows and Storage support, along with Discovery Informatics Platform for Research (DIPR) and database hosting for research
- Steers mobile and Apple endpoint strategy, as well as architect the platforms used to leverage the technologies at MGB
- Consults on collaboration and file-sharing tools used on an enterprise level at Mass General Brigham

ERIS established Advisory Boards composed of senior Principal Investigators (PI)s and subject matter experts involved in computing and computing technology to guide and develop the Research Information Service & Technology (IS&T) strategy for the research community.

Website: https://rc.partners.org/about/who-we-are-risc/enterprise-research-infrastructure-services
Educational Discounts on software: https://rc.partners.org/kb/article/1345
ERIS Contact: Brent Richter brichter@partners.org (857) 282-3777

Executive Committee on Research (MGH ECOR)

ECOR is the central planning and policy-making body of MGH. It is a standing committee of the MGH General Executive Committee (GEC) with specific responsibilities, including:

- Provide guidance on awards and grants
- Formulate research policies
- Develop a research plan congruent with the clinical mission of the Enterprise
- Represent the needs of the MGH scientists to the GEC
- Develop recommendations for the GEC and the MGH President on resource allocation issues
- Evaluate and monitor the quality of the science; and optimizing communication

Interim Support Funding (Bridge Funding): is open to Principal Investigators during a lapse or delay in their research funding from the National Institutes of Health (NIH) or another Federal agency (e.g., DOD). Must have applied for long-term support (R01, R21, U01 and P01).

Website: https://ecor.mgh.harvard.edu
ECOR Interim Support Funding: https://ecor.mgh.harvard.edu/Default.aspx?node_id=427
ECOR Resources: https://ecor.mgh.harvard.edu/resources
Contact: (617) 643-7420; ecor@mgh.harvard.edu

Harvard Catalyst

Also known as Harvard University's Clinical and Translational Science Center, Harvard Catalyst supports training of the next generation of researchers, providing:

- Courses and educational programs
- Research consulting, including tools for study design and guidance on regulatory issues
- Policy Atlas, a comprehensive database used to more easily identify data sources that can be used for policy-relevant research or to discover new sources for health data. Users can search through various health topics, policy-relevant data, case studies etc.
- Pilot funding for novel, high-impact projects

  Learning in person https://catalyst.harvard.edu/in-person_learning_matrix.html
  Learning online: https://catalyst.harvard.edu/online_learning_matrix.html
  Contact: https://catalyst.harvard.edu/

Human Research Affairs Compliance and Education Office (MGB)

Formerly the Partners Quality Improvement (QI) Program, the Human Research Affairs Compliance and Education Office provides education and support to investigators and study staff conducting clinical research studies at MGB institutions. This office has the authority to conduct audits (routine and for

cause) of human subject research studies at MGB institutions to ensure compliance with relevant federal and state regulations and institutional policies.

Three core functions:

- Education: study start up, regulatory binder/essential documents, informed consent process, ClinicalTrials.gov, Sponsor-Investigator responsibilities, Inspections and Audits
- Support: guidance via the study management tools and document templates to support research activities (i.e., new Principal Investigator (PI) seeking guidance, Investigational New Drug (IND) application to the FDA, ClinicalTrials.gov, etc.)
- Audits: conduct routine, targeted (spot checks), and for-cause/directed audits of human subject research to verify compliance with research regulations and institutional policies

Study management tools, guidance documents and document templates:

- https://partnershealthcare.sharepoint.com/sites/phrmResources/rsm/rsf/Pages/study-management-tools.aspx
- https://partnershealthcare.sharepoint.com/sites/phrmDepartments/poc/qi
- Email: humanresearchqi@partners.org

Information Services (MGB IS)*

The IS Service Hub can be used to browse knowledge, such as how-to instructions and troubleshooting information:

- Make a request for various computer issues (i.e., mapping to a printer or software integration)
- Fix a technical issue by getting support for something that isn't working properly or is broken
- Get help with EPIC
- Questions on technical workflows

Website: https://partnershealthcare.service-now.com/isservicehub/
Contact: 857-282-4357
*This group may be reorganized within the structure of MGB Digital, to be determined at a later date.

Innovation (MGB)

The Innovation group coordinates industry relationships and Intellectual Property (IP) management across MGB. Their goal is to take medical inventions and innovations discovered by MGB researchers and provide the appropriate support and infrastructure to allow technology development, commercialization and ultimately, the development of products to benefit patients.

- Negotiates funded non-clinical research agreements from for-profit entities
- Negotiates Material Transfer Agreements
- Negotiates Non-clinical research Confidentiality agreements (CDAs) and Non-disclosure agreements (NDAs) from for-profit entities
- Provides invention commercialization services
- Research translations strategy and funding
- New company creation, International consulting, Licensing and Venture investing

Website: https://innovation.massgeneralbrigham.org/
Innovator's Commercialization Guide:

https://innovation.massgeneralbrigham.org/wp-content/uploads/2021/02/Innovators-Commercialization-Guide-FINAL-circulation-2-1-21.pdf

The Innovation Transactional Affairs Group (TAG) is responsible for developing, negotiating and executing data sharing agreements with industry for research that has been determined to be de-identified by IRB:

- Industry-sponsored basic/non- clinical research agreements/sponsored research agreements (SRAs)
- SBIR/STTR Subawards for the performance of basic/non-clinical research
- Any outgoing agreements issued under SRAs
- Confidentiality (CDA) and Data Use Agreements (DUA) with industry (basic/non- clinical research)
- Invention licensing agreements
- Material Transfer Agreements (MTAs) and Tissue Transfer Agreements (nonprofit entities)

Contact: TAG Director - Chris Beares: cbeares@partners.org

The Licensing Group

- New inventions, Market technologies, Negotiate sponsored research agreements and option/license agreements
- Support IP portfolios and maintain relationships with licensees

Contact: Managing Director, Licensing - Rebecca Listfield, PhD -- rlistfield@partners.org

Note: Contact the Center for Innovation in Digital Healthcare (CIDH) to determine which group should process your contract.
Contact: cobrien@mgh.harvard.edu

Innovation Discovery Grants (MGB IDG) Program

The IDG program aims to enhance the commercial outcomes of the MGB community and to increase its innovative potential. It is designed to stimulate new inventive concepts, identify areas of commercially significant scientific strength, and accelerate commercialization of MGB intellectual assets. The IDG program will fund projects that can demonstrate tangible outcomes towards commercialization licensing opportunities, or a spinoff company, that improves patient health. Winners can earn up to $100,000.

Website: https://innovation.massgeneralbrigham.org/about/special-programs/partners-innovation-development-grants-program

Innovation Hub (BWH iHub)

The Brigham and Women's Hospital (BWH) iHub provides digital health innovation strategy to the hospital's community of clinicians, researchers and staff by guiding the evaluation, testing and implementation of their innovations into the hospital. Serving as a connection point between experts at BWH and the broader innovation ecosystem of start-ups, industry and venture capitalists, iHub helps enable and advance collaboration needed to achieve the promise of digital health innovation.

iHub aids innovators:

- Formulate ideas and concepts
- Refine products

- Connect with entrepreneurs and digital health leaders to support and nurture ideas
- Develop business plans, strategy and market analysis
- Execute digital health pilots and testing innovative solutions

Website: https://bwhihub.org/
Contact: Innovation Strategy Manager, Chen Cao -- ccao@bwh.harvard.edu
Email: ihub@partners.org

Institutional Review Board (MGB IRB)

MGB IRB: The administrative body established to protect the rights and welfare of human research subjects recruited to participate in research activities conducted under the auspices of the institution with which it is affiliated.

- Review, prior to its initiation, all research involving human participants.
- Authority to approve, disapprove, monitor, and require modifications in all research activities that fall within its jurisdiction as specified by federal regulations and institutional policy.
- Brigham and Women's Hospital (BWH), MGH, Mass Eye and Ear Infirmary, Spaulding Rehab and Wentworth-Douglass Hospital combined their respective IRBs into a single integrated IRB system.
- The integrated IRB operation is managed by staff of MGB Human Research Affairs, which is a centralized department responsible for supporting human subject research services.

NOTE: Some quality improvement programs are not considered research and do not require IRB approval. To determine if your quality improvement (QI) program can avoid a full submission, contact the IRB directly to assess or submit a Not Human Subject Research determination form in REDCap (Not Human Subject Research Determination (partners.org)).

IRB Policies and Forms:

- https://partnershealthcare.sharepoint.com/sites/phrmApply/aieipa/irb/Pages/MGB%20IRB-Policy-and-Guidance.aspx
- https://partnershealthcare.sharepoint.com/sites/phrmApply/aieipa/irb/Pages/IRB-Forms.aspx

Insight/Humans User Guide:
https://partnershealthcare.sharepoint.com/sites/phrmResources/t/Pages/InsightеIRB-Training.aspx

IRB Help Line for Insight/eIRB Help: Tel: 857-282-1900; Email: partnersirb@partners.org

MESH Network / MESH Incubator (MGB)

The Innovation MESH Network™ was created by the MESH Incubator, Mass General Brigham's technology and entrepreneurship incubator, and Mass General Brigham Innovation. It has created infrastructure and framework to aid in transnational innovation, through both core education and materials prototyping and manufacturing with direct pipelines to patent and licensing offices.

Mesh Key offerings:
MESH Core™ is the first integrated innovation curriculum in a medical training program, and has been featured by the American College of Radiology. To date, Core has graduated 26 MD alumni in their weeklong intensive bootcamp, including out-of-state attendees. Core runs on a rolling basis throughout the year in small group cohorts and spans one week.

Website: https://meshincubator.org/
Innovation courses: https://innovationmeshnetwork.org/courses/
Contact: Founder & Executive Director, Dr. Marc Succi -- msucci@mgh.harvard.edu

Mass General Research Institute (MGH MGRI)

The Mass General Research Institute comprises more than 9,500 researchers working across more than 30 institutes, centers and departments. The Research Institute Steering Committee is focused on establishing broader relationships with industry, government and community partners and finding new ways to connect them with our highly knowledgeable scientists and clinicians.

- Research Intranet
- Mass General Brigham Biobank
- Research Core Facilities
- Rally (Clinical Trials listing for MGB)
- ClinicalTrials.gov
- RSVP for health
- Promote Your Research

Website: https://www.massgeneral.org/research/

Contact: researchinstitute@mgh.harvard.edu

Office for Interactions with Industry (MGB OII)

Oversees, administers and educates staff about all policies relating to interactions with industry and conflicts of interest. The structure of OII brings together Board Members, MGB physicians and other clinical providers, senior management and outside community members to consider policy issues, manage relationships with industry and help staff participate in productive arrangements with industry within the confines of MGB policies.

- Reviews personal consulting agreements received by principal investigators (PIs)
- Negotiates education activity agreements incoming from for-profit entities
- Reviews conflict disclosures and manages Financial Conflicts of Interest reporting

Website: https://partnershealthcare.sharepoint.com/sites/phrmDepartments/opd/Pages/Office-for-Interactions-with-Industry-(OII).aspx

Important OII Documents:
https://pulse.massgeneralbrigham.org/resources_training/documents/resources_training_documents/office_for_interactions_with_industry
OII staff directory

For questions email: PHSOII@partners.org
For Consulting Agreements email: Lindsay Nangle lnangle@partners.org

Note: Contact the Center for Innovation in Digital Healthcare (CIDH) to determine which group should process your contract.
Contact: cobrien@mgh.harvard.edu

Office of General Council (MGB OGC)

The legal counsel that represents Mass General Brigham roles up to Human Resources, Compliance and Board of Trustees. Typically, OGC is engaged via the contracting process or during a protocol review of your research project. Commonly the Clinical Trials Office (CTO), Research Information Security Office (RISO), Office for Interactions with Industry (OII) or Research Management (RM) may trigger engagement with OGC to create and negotiate contracts, execute data sharing agreements, or help determine royalties in licensing agreements, and other activities including:

- Works directly with management and physicians with primary decision-making responsibility
- Engages outside counsel to work under its supervision when special counsel is appropriate
- Drafts and provides legal guidance on contracts, including Institutional Service Agreements (ISAs)
- Assists with Materials Transfer Agreements (MTAs) and Tissue Transfer Agreements with not-for-profit and industry entities supporting non-human subject's research
- Does not provide legal advice to employees or patients on personal matters

Contract Crossover Projects: When more than one of the six contracting groups above will need to be involved. Involvement of more than one office may be required to execute and manage an agreement. The Lead group is responsible for structuring and coordinating the negotiations and the Support group is responsible for providing guidance and agreement language relevant to an area of expertise.
http://pulse.partners.org/gc/

Note: Contact the Center for Innovation in Digital Healthcare (CIDH) to determine which group should process your contract.
Contact: cobrien@mgh.harvard.edu

Research Applications and Analytics Group (MGB RAA)

Composed of IS, analytics and contract staff, RAA is responsible for supporting the administrative systems required to manage the MGB biomedical research portfolio. The group's sponsored computer applications provide the core features necessary across research management, human studies oversight, grants and contracts processing and animal program management.

Contact: RAA Director, Scott McNeal -- 857-282-1948; smcneal@partners.org
Research Analytics Manager, Jonathan Kutrubes – 857-282-1825; jkutrubes@partners.org

Research Compliance (MGH)

MGH Research Compliance helps navigate the regulatory landscape by providing answers to regulatory and compliance questions, regulatory interpretation, training, compliance assessments and audits, as well as investigating areas of concern.

- Researchers should ideally approach the MGH Research Compliance office first, and that office will determine if MGB Research Compliance also needs to be involved
- Supports all areas of research, regardless of the funding or the nature of the project
- Partners with the research community to promote responsible and ethical research conduct, collaboration between programs, and a culture of compliance at MGH

Website: https://mghresearch.partners.org/research-compliance-homepage/
Resources and training: https://mghresearch.partners.org/compliance-resources-and-training/

MGH Director of Research Compliance – Kelé Piper, kkpiper@mgh.harvard.edu
MGH Research Integrity Officer (RIO) – Dr. Harry W. Orf, horf@mgh.harvard.edu

Research Compliance Office (MGB)

Supports the research mission of MGB and its affiliates by promoting adherence to research regulatory requirements and the development of ethical business practices throughout the MGB research community.

- Supports MGB Research Management, MGB Human Research Office, Clinical Trials Office and Research Finance through development of policies and procedures
- Oversees and monitors high-risk Research Management and Research Finance activities to ensure compliance with sponsor requirements
- Responds promptly to incidents of non-compliance and assists the development of corrective action plans
- Manages Responsible Conduct of Research (RCR) Program for all trainees, postdoctoral fellows, students and career-development recipients under award mechanisms (e.g., T32, F32, K08)
- The RCR Training Program Consists of Three Parts:
    1. MGB Seminar – offered three times per year
    2. On-line training through the CITI (Collaborative Institutional Training Initiative)
    3. Participation in no less than four lecture/discussion offerings eligible for RCR credit at local institutions

Partners Research Data Management Requirements
https://partnershealthcare.sharepoint.com/sites/phrmdepartments/poc/rco
https://www.massgeneralbrigham.org/researcher-support-and-resources/research-compliance-office

Chief Research Compliance Officer – Heather Cosier, JD, MA: hcosier@partners.org
Biosafety and Export Controls Program Manager – Claire Moretti: crmoretti@partners.org

Research Core Facilities (MGB)

There are over 125 Research Cores spread throughout the shared interdepartmental facilities of MGB. These paid service cores bring state-of-the-art instrumentation, methodologies and expertise crucial to the promotion of research. They allow for more efficient use of resources, promote collaboration among investigators, and further enhance the competitiveness of MGB investigators to secure research funding.

Examples of Research Cores include:

- Admin Core
- Animal Resources
- Biorepositories
- Cell Biology
- Databanks
- MD PnP Medical Device Interoperability Program
- Physiological Chemistry
- Research IT
- Sequencing and Omics and Translational Research
- Microbiology

Website: https://researchcores.partners.org

Research Information Science & Computing (MGB RISC)*

Research Information Science and Computing (RISC) 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 across the academic medical centers of MGB. Many of the services are at no cost to researchers. Additional services such as dedicated consultation, software licenses and data storage are offered on a fee-for-service basis:

- Desktop and Mobile Service
- Remote Access
- Systems Development and Consulting
- Developer Tools
- Website and Server Hosting
- Computational Resources
- Storage and Backup
- Database and Data Services
- Training on Technical Tools, Computing, Infrastructure

Additional Services and Support:

- Identifying Subjects, Requesting, Collecting and Analyzing Data
- Digital Health Review
- Data Security
- Research Computing Core
- Boiler plate descriptions of resources for use in grants, contracts and IRB applications
- Research Information Security Office (RISO)
- Research Patient Data Registry (RPDR)

Website: https://rc.partners.org/
RISC computer support: https://rc.partners.org/about/who-we-are-risc/fees-purchasing-information
IT Services: https://rc.partners.org/it-services
Information Security Program, Secure your Computer, and FISMA Security Documentation Programs: https://rc.partners.org/security
Antivirus, Encryption, Firewall, and Secure Log in: https://rc.partners.org/kb/information-security
*This group may be reorganized within the structure of MGB Digital, to be determined at a later date.

Research Information Security Office (MGB RISO)

Part of the larger Mass General Brigham Enterprise Information Security & Privacy Office (ISPO), RISO ensures that the confidentiality, integrity and availability of our research data is protected.

1. When submitting your protocol to the IRB, depending on certain criteria (i.e., data type, methods of data management, technology in use, regulatory requirements) it is possible that your protocol will require a (RISO) review.
2. A **RISO review** or **IRB Data Security Review** means your protocol will go through a technology risk assessment. To ensure the technology in place will maintain integrity of all intellectual property (IP) and study data.
3. RISO Timing: A RISO review can take many months, depending on the complexity of the study; on average, review takes six weeks from opening a ticket in the Service Desk (ServiceNow) to complete.
4. RISO Process:
   a) Once RISO reviews the protocol, they will request an initial 30-minute call or send questions via email to review the data lifecycle for your protocol.

b) Once complete, RISO will send an approval letter and sign approval in Insight.
RISO areas of focus in the data lifecycle:
- How will data be acquired?
- How will data be transferred to the system that will store and process it?
- How and where will data be stored?
- How will data be accessed, shared, archived, and disposed, and how will access be controlled?

Three documents detailing your infrastructure are ideal to have for a RISO review:
1) Hardware inventory: list of all hardware devices used for the project
2) Data inventory: list of where data are stored
3) Data workflow diagram: a schematic of the data flow between devices across the lifecycle
4) Optional for more complex projects: Detail regarding devices, software and vendors used, implementation plans, security scans, etc.

Website: https://rc.partners.org/security/information-security-program/riso-ancillary-review
Email: riso@partners.org

Research Management / Research Finance (MGB)

Supports the research activities at MGB institutions by facilitating administrative, financial, and regulatory requirements of their research efforts.

Types of contracts they support:
- Government (federal, state, local) foundation and other non-profit sponsored clinical and non-clinical research agreements
- Any outgoing subawards and clinical site agreements issued under the above
- Research Confidentiality (CDA) and Data Use Agreements (DUA) with government and non-profits
- Other unfunded collaboration agreements with government

Pre-Award team provides support and assistance to Principal Investigators (PIs) and Department Administrators as they prepare proposals for external sponsors. This team works closely with Research Management's Post-Award Contracts and Research Finance teams to support research projects throughout the grant's lifecycle.

Post-Award team sets up accounts for new awards, serves as the liaison between PIs and sponsors once awards have been issued, executes award modifications and performs fund management and validates effort and personnel charges.

Contracts team reviews and negotiates incoming sponsored agreements from government, foundations and non-profit institutions, issues related subcontracts and reviews and negotiates research-related unfunded agreements such as Data Use Agreements (DUA) and Confidential Disclosure Agreements (CDA) with government, foundation and non-profit organizations.

Research Finance partners with PIs to manage the financial activity through control and review of all research-related transactions, including report preparation, grant and contract billing, receivables management, indirect cost (IDC) review and cash management, and acts as a liaison between Research Management and the broader MGB Finance organization.

Research Finance Systems PeopleSoft is an enterprise resource planning (ERP) system used to track and manage business resources. Modules allow for financial, procurement, grant and human resource/payroll management. PeopleSoft facilitates the flow of business functions between various internal departments, as well as managing connections to outside vendors and other MGB software applications.

Learn more about Research Management

Note: Contact the Center for Innovation in Digital Healthcare (CIDH) to determine which group should process your contract.
Contact: cobrien@mgh.harvard.edu

Research Space Management (MGB RSMG)

RSMG offers assistance with allocation of research office and lab space:

- Fosters a strategic, equitable and cost-effective use of research space and resources through data collection, analysis and project management while maintaining MGB policies
- Provides operational and client services including coordinating office and lab relocation, disposal of equipment, etc.

Website: https://mghresearch.partners.org/research-space-management-2/

Scientific Advisory Committee (MGH SAC)

The SAC meeting managed by ECOR is a two-day event that celebrates key accomplishments of MGH investigators:

- SAC examines strategies for meeting the challenges currently facing the academic biomedical research community at Mass General

Website: https://ecor.mgh.harvard.edu/MeetingsEvents/SAC

Supply Chain Management (MGB SCM)

Executes contracts with vendors and suppliers to procure items and/or services, including consultants, data management or lab tests including:

- Lab Agreements for the supply of consumable products
- Material Transfer Agreements (MTAs) that have an associated purchase cost
- Outgoing Consulting Agreements (to companies and individuals)
- Agreements for services (external lab, cores, vendors)
- Agreements for the purchase/licensing of computer hardware and software
- Purchase Agreements for capital equipment (including Try to Buy)
- Equipment Maintenance Agreements

Supply chain key contacts
Contact: mmcontracts@partners.org
Operations Support (617) 726-2142 or create a Supply Chain Inquiry ticket
https://www.massgeneralbrigham.org/supplier-vendor-information
FAQs https://www.massgeneralbrigham.org/supplier-vendor-information#faqs

Note: Contact the Center for Innovation in Digital Healthcare (CIDH) to determine which group should process your contract.
Contact: cobrien@mgh.harvard.edu