Mass General Brigham
Mass General Research Institute

A Resource Guide:
Digital Health Research Tools
at Mass General Brigham

Part 2 of the Digital Research Education. A guide designed for research investigators and study staff to better understand how to utilize the research **tools** available at Mass General Hospital.

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How to Use this Guide

This guide is meant to be used with a larger three-part class designed to help researchers and staff navigate digital health research at Mass General Brigham (MGB). This guide is a detailed overview and is not meant to be fully comprehensive. Information has been compiled from several information sources, and thus some material may need to be updated.

Please refer directly to each individual team's online materials for the most up-to-date content.

The Digital Research Education (DRE) series is composed of three educational courses:
Course 1 - Research Support Teams at MGB (mission, contacts, URLs, and FAQs)
Course 2 - Research Tools (Info sources, training, software)
Course 3 - Digital Health Research Process

What is Digital Health?

Digital health methods include the collection, transmission, and/or dissemination of private or non-private, actively or passively collected health 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

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Information Sources

COVID-19 Tools for Researchers

New and enhanced research data tools and data sets are now available to support the fast-growing number of COVID-19 research projects. The goal is to support the rapid turnover of analytics to help researchers understand the signs and symptoms, comorbidities, and treatments of COVID-19. Researchers can leverage the following:

- COVID-19 Data Mart housed in the Data Enclave
- COVID-19 Detailed Data Files housed in the Enclave
- COVID-19 Vaccine Registry
- COVID-19 Summary Table
- COVID-19 External Data Sets
- DICOM Images for Chest X-Ray with eUnity Viewer
- RPDR (Research Patient Data Registry) -- COVID-19 patient data updated daily

COVID-19 Research Support email: MGBCOVIDResearchRequest@partners.org
https://rc.partners.org/about/projects-initiatives/new-covid-19-research-tools-researchers

Digital Service Hub: Information Services or the IS Digital Service Hub can be used to browse knowledge such as how-to instructions and troubleshooting information.

- Make a Help Desk 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

https://partnershealthcare.service-now.com/isservicehub/

Knowledge Base: Provides articles for programming and tech teams on topics such as Data Analysis, Applications, Computers, Printers, Mobile, IT Service Management, Information Security, Networks, Remote Access, Servers, Storage, Data, and more.
https://rc.partners.org/kb

Mass General Research Institute (MGRI) Intranet: Assists researchers and administrators in navigating the research process and contains a comprehensive source of research information at Mass General.
https://researchintranet.mgh.harvard.edu/

Areas of focus: Organization, Support Offices, Grants and Funding, Research Resources, Research Admin, News, and Events. Phone: 617 724-0200. Email: researchinstitute@mgh.harvard.edu

The How To information page on the website: Covers Billing and Purchasing, Communication Links, Compliance and Integrity, Conference Room Booking, Computing, Core Facilities, ECOR, Grants, and Contracts, Help Desk Links, Human Resources, ICD, Innovation, Insight, Interactions with Industry, Isuggest, Legal, Library, Policies and Procedures, Security, Training and Guides, Travel and Visas.
https://researchintranet.mgh.harvard.edu/research-help-and-how-to

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The Resources Tab includes information on ECOR Grant Portal, Pivot Funding Tool, Isuggest, Guidelines for ECOR and NIH Applications, MGH Research Proposal Cover Sheet, FMD-Clinical Application Chief Statement, ECOR No Cost Extension and Exception Requests, MGH Research Email Distribution Subscribe Link, and more. https://ecor.mgh.harvard.edu/Default.aspx?node_id=312

- 12 Things Every Researcher Should Know
- MGB Phone Directory
- Hospital Policy Manager
- Research Space Management
- Useful Tools: links to Common Sites: Peoplesoft, UKG, Insight, Supply Chain, and more

MGB Innovation Digital Education Academy (IDEA): IDEA includes a series of educational webinars and events and provides resources to support ongoing digital health initiatives and continue to engage our MGB community in digital health innovation.

- Stay up-to-date and informed on innovations within the MGB digital health space
- Explore, learn, and understand the potential of innovative digital health solutions to transform research, care, patient experience, and operations
- Learn the necessary skills, technologies, organizational enablers, and constraints for successfully identifying, verifying, and adopting new digital health solutions
- Monthly Digital Health Grand Rounds highlighting key individuals and innovations in the MGB digital health space

IDEA Symposium video recordings: https://web.microsoftstream.com/channel/54f1b50a-ab8c-4779-975e-2a0902cf3bc8

MGH Research Job Board: Find a new opportunity within the Mass General Research Institute or promote a newly posted job within your department. The Research Job Board, powered by the Division of Clinical Research, is available to all community members to submit postings or apply for positions. https://elasticwork.mgh.harvard.edu/

Rally: Rally, developed by MGB Research and MGH Laboratory of Computer Science, is an online platform that supports collaboration between the public and the research community. Investigators can upload information about their research studies such as a brief description, estimated time commitment to the study, eligibility, remuneration, and other necessary details for potential participants to review. If interested, participants can fill out a form to express interest. All eligible MGB research study investigators can submit a new project to the Rally website.
https://rally.massgeneralbrigham.org/
https://rally.massgeneralbrigham.org/manage/project/add#/

Researcher Support and Resources: Facilitates administration, financial and regulatory requirements of MGB's research efforts, and supports collaborations with external entities.

Research Support offices at MGB include:

- Research Management
- Research Core Facilities
- Research Applications and Analytics
- MGB Human Research Office/Institutional Review Board

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- Human Research Affairs Quality Improvement Program
- Research Information Science and Computing
- MGB Clinical Trials Office
- Research Support Services

https://www.massgeneralbrigham.org/researcher-support-and-resources

Research Navigator: The most comprehensive collection of research guidance, documents, and related resources. Research Navigator contains resources to guide Mass General Hospital employees through the administrative research process.
https://partnershealthcare.sharepoint.com/sites/phrmportal/

- Most Popular Pages Across Research Navigator
- Forms, Policies, Checklists, and SOPs/Procedures: content related to forms, policies, checklists, and SOPs
- Forms & Templates: simple list of MGB research forms and templates
- Overview for Obtaining IRB Approval of Human Subject Research
- Research Management: mission statement and administrative operations
- QI Study Management Tools: a starting point for regulatory documentation and subject files
- Funding Opportunities, Announcements, Deadlines

RISC Fees and Purchasing Information for Computer Support: Fees on desktops, laptops, backups, Server backups, MAD3 storage, RFAs, Cloud Services, Consultation, Web Development, Application Analysis, QA testing, Endnote, MATLAB SAS, Stata, and Server Provisioning. https://rc.partners.org/about/who-we-are-risc/fees-purchasing-information

Springer Journal Suggester**:** This site provides personalized recommendations and journal matching to find relevant journals based on your manuscript details. It includes over 2,500 journals. You can easily compare relevant journals to find the best place for publication.

Treadwell Library: Access to full-length research papers that you can't find on PubMed. Get access to the Treadwell library using your MGB account credentials. Complete access form at:
https://library.massgeneral.org/proxyreq.asp
https://library.massgeneral.org/

Vitals: Mass General's new intranet, Vitals, is now live! Vitals has replaced Apollo as the hospital's intranet site. This launch marks the completion of creating one unified systemwide intranet, which will provide a single tool for communication, collaboration and personalized content.
https://partnershealthcare.sharepoint.com/sites/Vitals

- Use the Departments, Programs & Groups, and Resources dropdown menus to find your specific department, group etc.
- Use the A-Z Directory for a comprehensive list of sites and resources.
- Use the search functionality

To view all tips and FAQs, visit the Vitals Quick Tips page.

*All Apollo site homepages now redirect to their corresponding Vitals homepage. Some pages within sites still open to Apollo. Staff will see an alert on these pages instructing them to visit Vitals, as Apollo is no

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longer being updated. From the Vitals homepage, there are numerous ways to find, and re-bookmark your desired page.

Software

Advarra (Forte) Participant Payments: Offered by the CTO, Participant Payments is a cloud-based application that simplifies the process of paying subject stipends. Participant Payments provides subjects with a reloadable Visa card credited with the stipend when a visit has been completed. This is an alternative to the existing eCheck request system.

- Study team members access the system via a web portal to register study subjects and initiate stipend payments
- The first payment per-subject requires a secondary approval, but all subsequent payments may be made with the click of a button
- Payments are credited to a subject's reloadable Visa credit card within five minutes. This offers a greatly improved subject experience when compared to other methods of payments

https://www.massgeneralbrigham.org/en/research-and-innovation/centers-and-programs/clinical-trials-office/investigators-staff#accordion-2a5b692f7e-item-1b3bdf04ed

Biobank Portal: A tool that links consented subjects from the Mass General Brigham Biobank (turn on VPN before accessing) with their electronic health record (EHR), as well as health information survey and genomic data. Researchers can query this database for aggregate totals and to request individual blood and plasma samples, genomic data, and EHR data. You must have a valid MGB logon and be a registered Research Patient Data Registry (RPDR) user to use the Portal. In addition to comprehensive EHR data, the Biobank Portal includes:

- **Biobank Health Information Survey:** patient-reported lifestyle, environment, and family history information
- **Curated Disease Populations:** sets of subjects that have been statistically determined to have a particular disease (disease phenotypes)
- **Healthy Populations:** an index that statistically groups patients by co-morbidities to help select relatively healthy controls
- **Biobank Sample Types:** including DNA, plasma, and serum (requesting identified samples requires a valid Mass General Brigham IRB protocol)
- **Biobank Genomic Data:** genotyped and imputed genomic data are available for a subset of the Biobank population
- **Querying by Genomic Data:** single nucleotide polymorphism (SNP), and insertion and deletion (indel) variants and their related annotations are available on a subset of genotyped subjects
- **Download of de-identified patient data:** enables the creation and download of data-obfuscated limited data sets (LDS) for further analysis

Contact the Biobankportalhelp@partners.org mailbox with any questions or support.

Grammarly: A cross-platform, cloud-based writing assistant that reviews spelling, grammar, punctuation, clarity, engagement, and delivery mistakes. It offers suggestions for clearer, more concise wording/phrases and is an ideal tool for anyone whose first language is not English. Grammarly can be used on multiple platforms, including Microsoft Word, Outlook, Safari, etc. Grammarly is now free for MGH researchers. Start all your Grammarly activities at: https://go.grammarly.com/MGB

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Insight: A web-based administrative portal to review, monitor, and manage research portfolios. Insight is the primary way the research teams and the IRB communicate and share documents. Insight is comprised of ten different modules in all and cover the broad function of research administration from award management, effort reporting, IRB, BioSafety, IACUC submissions, and reporting.

Insight/Humans is where individuals request a determination from the MGB Human Research Committee (PHRC) on their research protocol. Research teams submit the appropriate PHRC forms in Insight, describing the activity in sufficient detail to make the required determinations. When an Insight/eIRB application form is submitted to the PHRC, the PHRC staff will provide the individual making the request with written documentation of the determination and the basis for the determination. Timelines vary from weeks to months for the initial review of protocol based on the complexity of the project and IRB capacity. Please plan accordingly.
https://insight4.partners.org/
https://insight4.partners.org/help

LabArchives: Electronic Lab Notebooks for Researchers. Enterprise Research Applications (ERA) manages an enterprise license for LabArchives for all researchers to use at no cost. LabArchives is a web-based application designed for organizing, documenting, and sharing research data with teams, departments, and collaborators. Document sharing features may be helpful for meeting NIH Data Sharing requirements.

Lab Archives Mass General Brigham Policy Note: Principal Investigators (PIs) must use LabArchives to document Research Data and other record keeping activities for active research projects.

https://rc.partners.org/research-apps-and-services/collect-data#electronic-laboratory-notebook
Use the Login or Create Account link to create an account if you don't have one already.

Oncore: is an enterprise-level clinical trial management systems (CTMS) designed to support trial management throughout the life cycle of a study. Oncore focuses on protocol and subject management, financials, and reporting, providing a tool for departments to generate invoices and reconcile payments for industry-sponsored clinical trials, and can automate much of the invoicing process for financial managers. There is a fee associated with this service.

OnCore use is currently limited to those clinical trials that meet specific criteria, such as industry-funded studies and more. Clinical Research Coordinator usage of OnCore includes subject registration, subject visit tracking, adding non-scheduled visit procedures, and protocol event tracking. Financial Coordinator usage of OnCore includes creating invoices, managing invoice lifecycles, monitoring funds for sponsor payment, and payment reconciliation.
https://www.massgeneralbrigham.org/en/research-and-innovation/centers-and-programs/clinical-trials-office/investigators-staff#accordion-6044b2d522-item-8dcc7c3e00

Patient Data Science Repository (PDSR): The new Complete Patient Data Science Repository (PDSR) Curated Data Set was recently made available to researchers across Mass General Brigham.

- Provides the opportunity to access and analyze over 5 billion observation facts on the entire Mass General Brigham patient population
- Within the secure MGB Data Enclave platform protects patients' information by prohibiting the export of any raw data

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- Available to all Mass General Brigham RPDR Faculty Sponsors and faculty approved workgroup members
- No IRB required! Because the data set contains limited PHI (Protected Health Information) with removed identifiers per MGB policy an approved IRB Protocol IS NOT required
- Upon requesting access, users will attest to a Data Use Agreement (DUA) for the Complete PDSR Curated Data Set
- Direct access to the full patient database
- Computational tools available with the data

Website: Complete PDSR Curated Data Set
Contact: MGBRISCDataSolutions@partners.org

Patient-Reported Outcome Measures (PROMs): Questionnaires that explore patients' symptoms and outcomes in a way that is unfiltered and direct from the patient. PROMs measure patients' symptoms, functional status, quality of life, and/or mental health. Individual and aggregated PROMs patient data, integrated into the patient's medical record, are used to provide improved and more responsive individual patient care, inform shared decision making, support quality improvement, and aid in demonstrating the value of MGB care. There are about 300 programs that use PROMs across MGB. Clinicians can choose from validated questionnaires or submit their requests for questionnaires. Questionnaires are then pushed through Patient Gateway or can be completed in clinic on iPads. Clinicians are also able to see which other PROMs questionnaires have been completed in other clinics.

Website: https://partnershealthcare.sharepoint.com/sites/VitalsOCMOPROMS
Contact: Marc DeAngelo, Sr. Program Manager, mdeangelo1@mgb.org

REDCap: A free tool for creating surveys and databases for use in research and hospital programs without programming knowledge necessary. It is an IRB approved, secure web-based software for electronic collection and management of research and data. https://rc.partners.org/research-apps-and-services/collect-data

- Build online surveys and databases quickly and securely in your browser - Create and design your project using a secure login from any device. No extra software is required. Access from anywhere, at any time.
- e-Consent - Perform informed consent electronically for participants via survey.
- Diverse and flexible survey distribution options - Use a list of email addresses or phone numbers for your survey respondents, automatically contact them with personalized messages, and track who has responded. Or create a simple link for an anonymous survey for mass email mailings, to post on a website, or print on a flyer.
- Data-based triggers and alerts - Send real-time alerts and notifications to your team or other stakeholders via email, text, or phone based on certain data being entered or specific questions having a particular answer.

REDCap Partners Login: https://redcap.partners.org/redcap/

Research Patient Data Registry (RPDR): A centralized clinical data registry or data warehouse. The RPDR contains data on current and legacy hospital clinical systems and stores it in one place. This repository and its related tools bring clinical information to the researcher's fingertips and ensure the security of patient information by controlling and auditing the distribution of patient data within the IRB guidelines and using several built-in, automated security measures.
More information on RPDR: https://rpdrssl.partners.org/information# (turn on VPN before accessing)

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FAQ's page: https://rpdrssl.partners.org/help/faq
Contacts: https://rpdrssl.partners.org/contact
Email: RpdrHelp@partners.org

SharePoint: A cloud-based service hosted by Microsoft, which provides a secure place to store, organize, share, and access information from any device. Integrated with MS Teams, you can share files with team members. Log in using your MGB credentials.
https://partnershealthcare.sharepoint.com/_layouts/15/sharepoint.aspx?

Studytrax: An electronic data capture (EDC) system that runs clinical trials, observational studies, surveys, and patient registries. Participants can enter outcomes, securely communicate with staff, and receive personally relevant disease information and educational materials using a portal. Clinical and research staff can tightly coordinate activities, incentivize subject participation, visualize data for better decisions, and facilitate data analysis to publish results faster.

- HIPAA compliant
- Personalized content
- Secure communication
- One-click surveys
- eConsent
- SSL enforced access
- Access your data from anywhere in the world

https://www.studytrax.com/
Studytrax support: info@sciencetrax.com
MGB support: edcsupport@partners.org

Veeva SiteVault: An electronic research study and regulatory manager software. It manages regulatory and source documents in a system that supports 21 CFR Part 11, HIPAA, and regional data privacy requirements. It allows the exchange of documents and study information between sponsors and CROs, remote monitoring, single enterprise sign-on, reduces data duplication, custom workflows for eSignatures and certified copies, and more.
https://sites.veeva.com/products/sitevault-enterprise/

Training

GCP training requirement at MGB

CITI human research training courses are no longer required by MGB. Investigators who are employees of Mass General Brigham and members of their research teams must complete two comprehensive training courses in human research protections training prior to their involvement in research:

- HRA Clinical Research Boot Camp
- HRA Good Clinical Practice

Users will need to register for the courses in HealthStream. There are live webinars and pre-recorded on-demand versions of these courses available. You may complete either version of the courses to meet the requirement. The courses should be completed prior to current certification expiration. These training courses must be completed every three years.

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It takes up to two (2) business days for training completions to post in Insight. Each weekday the HRA Compliance and Education Office receives a HealthStream Course Completion Report that is uploaded to Insight that night for posting. This is consistent with the process in place with CITI training. If you are new to MGB and will be involved in the conduct of human subject research, then these courses will be required prior to your involvement in the research.

Detailed instruction:
https://partnershealthcare.sharepoint.com/sites/phrmInitiate/iqore/Pages/QI-Education-Activities.aspx

Current MGB policy:
Human Subject Protection Education and Training Requirements for Investigators and Study Staff

Memo to provide sponsors or other external entities:
MGB Human Subjects Training Requirements statement from VP HRA

FAQs:
CITI Transition FAQs (Flipbook) (PDF)

HealthStream Training: HealthStream is a learning management system that enables the hospital to administer and manage annual trainings required by all employees (e.g., fire extinguishers, codes, sexual harassment training).
https://www.massgeneralbrigham.org/healthstream

MGB Innovation MESH Core: Healthcare Innovation Bootcamp: The official innovation course of Mass General Brigham. In this curriculum, you will systematically learn foundational knowledge, such as the process of creating a new company, digital health, building artificial intelligence demos, basics of the invention process, patents, and more. The Innovation MESH Network also offers a la carte courses. This course has been run yearly at Mass General Brigham since 2018 and is directed by Marc Succi, MD.
https://innovationmeshnetwork.org/courses/mgb-innovation-mesh-core-2/
Innovation courses: https://innovationmeshnetwork.org/courses/
Contact: Marc Succi msucci@mgh.harvard.edu

MGH DCR Courses: The Division of Clinical Research (DCR) works to promote science at the clinical—research interface. The division sponsors a total of 10 centers and 15 units, each of which has a specific mission to assist investigators conducting clinical research.

The Division of Clinical Research promotes research by:

- Increasing Mass General's overall clinical research funding
- Expanding Mass General's pool of clinical research mentors
- Providing hands-on support to overcome the logistical challenges faced by clinical investigators

These centers and units provide a support structure for clinical, translational, and nursing research, and study support via biostatistics consultations and access to the Partners Biobank. Individual units in the DCR help with omics, patient-centered outcomes research, electronic health records research, qualitative research, and more.
https://dcr.massgeneral.org/

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Informational Documents or Forms

ClinicalTrials.gov: Clinicaltrials.gov is a web-based resource that provides patients, their family members, health care professionals, researchers, and the public with easy access to information about clinical research studies. The National Library of Medicine (NLM) maintains the website at the National Institutes of Health (NIH). Registering your protocol on Clinicaltrials.gov is very important and is required by law for some research studies. Additionally, failure to register your protocol before the study start could jeopardize your study team's ability to publish in a high-profile journal due to certain scientific research journal requirements.

Information on ClinicalTrials.gov is provided and updated by the sponsor or principal investigator of the clinical study. Studies are generally submitted to the website (that is, registered) when they begin, and the information on the site is updated throughout the study. ClinicalTrials.gov does not contain information about all the clinical studies conducted in the United States because not all studies are required by law to be registered (for example, observational studies and trials that do not study a drug, biologic, or device). See FDAAA 801 and the Final Rule for more information. ClinicalTrials.gov

Epic Integration and Innovation Environment (INV) Requests:
If your research project requires any Epic integration or Epic functionality, you can submit a request to Holly Barr Vermilya (hbarrvermilya@partners.org) and Jasmine Ha (jha3@mgh.harvard.edu) for an intake for new project requests.

If your project is not research but an innovation requiring Epic, a new technology application must be submitted to the Enterprise Architecture Council (EAC). The requests will be reviewed and vetted against the business capability model. To submit the request: https://partnershealthcare.service-now.com/isservicehub?sys_id=4c1918e61bf0e9109f83986cbc4bcb7b&view=sp&id=sc_cat_item&table=sc_cat_item

If the project is not research but is an innovation requiring Epic and you would like for it to be pursued using the INV environment: Complete the request form in ServiceNow within the DHeC catalog called the Epic Non Production & Project Team Access Request (make a request in Digital Service Hub > Digital Health eCare Catalog > Epic Security > Epic Non Production & Project Team Access Request).

- Within this form, there is a check box for the Epic INV environment. The security team will receive that request and then send it to Julie White (Senior Director) for approval.
- When selecting INV on the form, the requestor must provide a reason for the access.
- They will review the reason and inquire about the project that INV would be used for.
- If greater conversations are needed at that time with the requestor, they will bring in the appropriate people for discussion, whether clinical or technical review.

Human Research Protection Program (HRPP) Plan: The HRPP Plan is a document that guides Human Research Affairs in its conduct. It provides a general framework guidance for IRB and clinical research and may occasionally be used as a reference when designing and implementing studies. This plan does not include any checklists or other research process guidance. Document:
https://www.partners.org/Assets/Documents/Medical-Research/Clinical-Research/HRPP-Plan.1.11.pdf

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Website: https://www.massgeneralbrigham.org/researcher-support-and-resources/resources-collaborators-and-sponsors/human-research-protection-program-policy-guidance

Innovator's Commercialization Guide: A Guide for those interested in the MGB commercialization process, with policies and procedures, information on contracting, conflicts, and funding. This guide was developed to guide innovators through the commercialization process and to streamline their interactions along the way. It is meant to answer the question "Who do I contact" at any point. Achieving successful commercial outcomes that transcend the boundaries between the academic and industrial sectors, given their different missions and cultures, requires a clear understanding of processes, priorities, and challenges. The Guide: https://innovation.massgeneralbrigham.org/wp-content/uploads/2021/02/Innovators-Commercialization-Guide-FINAL-circulation-2-1-21.pdf

Invention Disclosure Form: One of the first steps in the innovation process is to submit a completed Invention Disclosure Form to Mass General Brigham Innovation. To best protect your ideas, it is critical that this form is filed with this office prior to publication, public discussions, or any other disclosures about your idea. Upon receipt of the Invention Disclosure Form, Innovation professionals will begin a dialogue with the inventors to better understand the novelty and utility of the invention. The form can be found at https://innovation.massgeneralbrigham.org/for-innovators

Research Communications Request Form: Once your team is ready to publish your research findings, the Research Communications Request Form is the new starting point for all requests to help promote your research findings. The form takes about eight minutes to complete and is crucial to helping MGH track and manage requests. Previously a research team would contact public affairs when preparing for public distribution of their research findings. This new form replaces that step as a new process.

More info on MGH Research Communications:
https://partnershealthcare.sharepoint.com/sites/VitalsMGHCommunications/SitePages/MGH-Research-Communications.aspx

Other

Mass General Brigham Password Help: to register or change your hospital credentials or password:
https://myprofile.partners.org

MGH Brand PowerPoint/Word Templates: Access branded templates – including letterheads, Word and PowerPoint templates, and backgrounds for virtual meetings – instructions for how to set up an email signature and FAQs.
https://apollo.massgeneral.org/branding/
https://partnershealthcare.sharepoint.com/sites/VitalsMGHCommunications/SitePages/Branding.aspx

Research Core Facilities

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.

A few examples of Research Cores include:

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- Admin Core
- Animal Resources
- Biorepositories
- Cell Biology
- Databanks
- Physiological Chemistry
- Research IT
- Sequencing and Omics and Translational Research
- Microbiology

Website: https://researchcores.partners.org

MGH Translational and Clinical Research Centers (TCRC)

Supports the conduct of patient-oriented research projects and serves as a human research laboratory in which investigators can perform their funded projects. It is composed of two major units: the Clinical Research Center, a federally funded part of the Harvard Clinical Translation Science Center, directed largely to support NIH and foundation-sponsored research and the Translational Research Center, which is specially directed to work with investigators performing industry-sponsored human research.

- Provides Clinical Research Coordination (CRC) services, which can be budgeted based on the study protocol (needs, activities, etc.)
- CRC services reserved for MGH Principal Investigators (PIs), or BWH PIs with an MGH Co-PI
- Translational Research Center offers services for industry-sponsored studies
- Clinical Research Center offers services for federally funded projects

Website: https://tcrc.mgh.harvard.edu/

* * * *

Hospital Directories: The three main directories for research information. It may be helpful to bookmark these informational resources:

- Vitals
- Research Navigator
- Research Intranet

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Additional Supplementary Information for informing the Innovation Process

Legal Terms You Should Know:

a. *Claims*: Define the scope of the protection (i.e., which subject matter is protected). A careful review of the wording of claims is crucial.

b. *Patent*: A legal grant that gives the holder the right, for a limited term, to exclude others from making, using, selling, offering to sell, or importing the patented invention.

c. *Patentability*: Essential to securing a patent is determining if an invention is truly novel (i.e., it has not been patented before nor is in the public realm). Lack of novelty is the most common reason for initial rejections.

d. *Provisional vs. Non-provisional Applications*: The first patent application filed is often a "provisional" and lasts for one year. Its less formal format is useful for quickly establishing an

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initial filing date to protect an invention while providing additional time to conduct research and add supporting data. Provisional patents are not reviewed by the USPTO and are not made publicly available.

e. *Inventorship Determination*: Inventorship must be correct for patent validity. If there are inventorship questions, Innovation should be promptly alerted. After an initial assessment, the Licensing Manager may engage in-house patent counsel to work with the inventor to assess the contributions made by multiple individuals to determine whether they meet the required level of inventorship. The standards for inventorship are different from and usually more stringent than for scientific authorship. Although an invention comprises both a complete performance of the creative part of the invention ("conception") and the carrying out of the creative part ("reduction to practice"), inventorship is limited to conception. Research records (e.g., lab notebooks, emails, grants, published papers, etc.) can be used in this determination. If needed, outside counsel may be consulted.

f. *Ownership*: Intellectual property (IP) discovered during employment and activities supported by Mass General Brigham and all its entities is owned by Mass General Brigham or its entities. Joint appointments should be disclosed to properly determine IP ownership.

g. *Inventor Compensation*: U.S. academic institutions distribute a portion of the net proceeds from commercialization to the inventor(s). The Mass General Brigham distribution policy includes 45% total to the inventor(s) and the inventor's lab or unit, 20% to the department or service, and 35% to the institution. The 45% to the inventor(s) and the inventor's lab is allocated between the inventor and the lab or unit, by the Principal Investigator with 30% maximum going to the inventors or the lab.

h. *Sponsored Research Agreements*: Sponsored Research Agreements (SRA) enable industry-funded, pre-clinical research. SRAs rely on hypothesis-driven research in furtherance of the hospital's medical and educational mission.

i. *Material Transfer Agreements*: An incoming Material Transfer Agreements (MTA) allows investigators to receive or share material or human tissue for pre-clinical research. These agreements are required by non-profits, the federal government, and industry alike and are also used to help track activities that might affect ownership or licensing of results. The Innovation Transactional Affairs Group (TAG) negotiates several thousand MTAs per year covering research materials provided by or sent to another academic researcher or company.

j. *Confidentiality Agreements*: Confidentiality agreements are ubiquitous in the life sciences business sector and key to protecting intellectual property rights and business opportunities. They cover meetings and other information exchanges with external entities, including companies, nonprofits, and academic organizations. Key focus areas are discussions about inventions or intellectual property, business strategy and sessions that could reveal undisclosed information, research outcomes, etc.

k. *Data Use Agreements*: Patient data entering or leaving Mass General Brigham must be accompanied by an agreement outlining how the data will be used, protected, and maintained through a Data Use Agreement (DUA). The Innovation Transactional Affairs Group (TAG) is responsible for developing, negotiating and executing data sharing agreements with industry for

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research or human data the IRB has determined to be de-identified. DUAs should be submitted to TAG through the Insight Agreement module.

l. *Consulting Agreements*: Faculty can consult with industry if the engagement follows organizational policies. All agreements for individual consulting are subject to review and approval by the Office for Interactions with Industry (OII). The agreement must not involve Mass General Brigham's resources, property, technology, information, or other assets. OII reviews agreements for compliance with institutional policies, not for the faculty's personal or business interests. The potential consultant should send an email, with the proposed agreement, to PHSOII@ partners.org to initiate the review process. The consultant will be asked to complete a Conflict of Interest questionnaire. After completion of the questionnaire, OII reviews the agreement.

m. *Institutional Service Agreements*: Outside parties (companies, government agencies, foundations, schools, etc.) occasionally ask staff to provide services for a fee. Examples of requested services include evaluation, feedback, or testing related to devices, software, or compounds; retrospective reviews of data or literature associated with research studies; demonstration of clinical techniques; development of training programs focused on specific disease states; and providing other consulting services. The Institutional Service Agreement (ISA) documents the terms and conditions for the services to be provided. An ISA usually must be prepared or reviewed by the Office of the General Counsel prior to finalization.

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

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