Mass General Brigham
Mass General Research Institute

A Resource Guide:
Digital Health Research Development Process
at Mass General Brigham

Part 3 of the Digital Research Education. A guide designed for research investigators and study staff to understand research **process** at Mass General Hospital.

MARCH 9, 2023

Table of Contents

Authors: Conor S. O'Brien, Remona Kanyat, and Dawei Jiang
MGH Center for Innovation in Digital HealthCare
*For comments and edit suggestions: cobrien@mgh.harvard.edu or djiang2@mgh.harvard.edu

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.

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

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

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

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 and Supports Digital Health Research?

Many research support teams and stakeholders are involved in the review and development of Digital Health Technologies for implementation in clinical research. This document introduces their involvement in the research development process.

What are the steps for Digital Health project development and implementation?
This document details the procedure to create, implement and manage a digital health research project and includes frequently used forms, documents, checklists, and URLs.

Overview of the Process

The research development process depends on your project type (i.e., human subject research, clinical pilot, quality improvement, etc.). For a quality improvement project, obtain a "Not Human Subjects Research (NHSR)" determination from the IRB by completing [this form on REDCap](). The IRB will review your project description and provide either a written confirmation that your project is "Not Human Subjects Research (NHSR)" or direct you to submit a full IRB application if you are conducting human subject research.

This resource guide is focused on describing the human subject research project development process:

1. Funding and Grants	2. Project Development	3. Contracts & Agreements	4. Project & Data Security Review	5. Project Implementation

1) Funding and Grants
    a) **New Project Idea.** Begin with a new project idea, clinical research protocol, or a funded clinical research project from an investigator
    b) **Consult with CIDH.** Investigator reaches out to Center for Innovation in Digital Healthcare (CIDH) for help with digital health research. CIDH will schedule a 30-minute interview intake and provide follow-up guidance and consultation
    c) **Industry Collaboration.** If an industry sponsor is needed, CIDH will help steward the collaboration and coordinate the contractual process

2) Project Development
    d) **Draft statement of work (SOW) and Protocol.** The investigator drafts a statement of work (SOW) and a research study protocol

3) Contracts & Agreements
    e) **Initiate Contracting.** Once a research study path has been established and an initial relationship opportunity has been identified with an industry sponsor, CIDH will reach out to the appropriate contracting office (i.e., Clinical Trials Office) and provide an SOW and protocol for review

4) IRB & RISO Review
    f) **Further Development of Study Documents.** In parallel, the clinical research team will further develop the protocol and study recruitment materials for IRB submission

g) **Executing Contract.** Clinical Trials Office (CTO) executes the contract and creates an agreement number

h) **Submit to IRB.** PI and Clinical research team submit the protocol and supplementary materials via Insight to the Institutional Review Board (IRB)

i) **RISO Review.** IRB may trigger a Research Information Security Office (RISO) review
*note: complex projects or others that include sharing Protected Health Information (PHI) on third-party servers may require additional review time; these protocols should be submitted to the RISO team prior to IRB to avoid potential delays

j) **Reach out to RISC and other research support teams.** The research team reaches out to Research Information Science and Computing (RISC) for software licenses, for study-related works, and to get cohort query analysis; other support teams include Division of Clinical Research (DCR) for research staff training support, Human Research Affairs Compliance and Education Office (formerly the QI office) for study procedure and regulatory compliance review

5) Project Implementation

k) **Study Implementation.** Research team utilizes standardized project management tools to maintain study records, meet regulatory requirements, and complete all research activities

l) **Study close-out.** Complete data analysis, regulatory monitoring, and publication

1. Funding and Grants

Listed below are some of the common funding sources for digital health projects.

1.1 MGH Executive Committee On Research (ECOR):

ECOR is the central planning and policy-making body of MGH. It provides guidance on awards and grants. 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

1.2 Pivot - source for global funding information:

A library database that indexes funding announcements from government agencies, private foundations and nonprofits, and international sponsors.

Create Your Pivot Account: go to https://pivot.proquest.com/register#

- Use your *partners.org* or *harvard.edu* email address and select *Harvard University* as the affiliated institution
- Once you've created a password, you'll receive an automated email message. Click on the link provided to confirm your account
- Log in to the database using your email and password
- For more information and training materials, please see: https://pivot.proquest.com/contact_us

You may also schedule an individual research consultation or group workshop on the use Pivot with **Amy Robb** in the MGH Office of Development. **Schedule a consultation** through the Center for Faculty Development or email arobb@mgh.harvard.edu.

https://ecor.mgh.harvard.edu/awards-and-grants/cos-pivot----external-funding-search-engine
https://ecor.mgh.harvard.edu/awards-and-grants
https://www.grants.gov/

1.3 Harvard Catalyst
Also known as Harvard University's Clinical and Translational Science Center, Harvard Catalyst supports training of the next generation of researchers and provides pilot funding for novel, high-impact projects. Contact: https://catalyst.harvard.edu/

1.4 Medicine Innovation Program (MIP) Pilot Grant Award (MGH DOM only eligible)
Takes research projects with the potential and provides resources, e.g., structured project management support, milestone-based stewardship of resources, focused mentorship, and access to networks that can move the project to the next step in development. MIP actively supports projects for one year to 18 months.
- At least two projects will be funded for direct costs of up to $75,000 for the 2021-22 cycle. Projects must demonstrate a new way of thinking about an existing challenge that falls within one of the following four categories: Technology and Equity, General Innovation (Device, Therapeutic, IT, Digital Health), Digital Health, Artificial Intelligence in Medicine
- https://www.massgeneral.org/medicine/initiatives/medicine-innovation

1.5 Mass General Brigham Innovation Discovery Grants Program
The Innovation Discovery Grants (IDG) program aims to enhance the commercial outcomes of the MGB community and increase its innovative potential.
- https://innovation.massgeneralbrigham.org/about/special-programs/partners-innovation-development-grants-program

2.   Project Development
The following sections describe the project development process of an intervention/interaction type human subject research study.

2.1 Start your protocol development by using the IRB detailed protocol template, sections required:
a)   **Background and Significance**: describe the rationale behind the proposed research and its significance to patients, society, and science

b)   **Specific Aims and Objectives**: the purpose for performing the study in terms of the scientific question to be answered and the hypotheses being tested

c)   **General Description of Study Design**: explain the basic study design, (e.g., parallel group, randomized controlled trial, open-label single arm study, cross over, adaptive, etc.)

d)   **Subject Selection**: describe sources of subjects and procedures for subject selection, inclusion/exclusion criteria, recruitment methods

e) **Subject Enrollment**: describe any pre-screening procedures as applicable, a step-by-step description of the consent process, number of subjects to be enrolled and included in the analysis, withdrawal criteria

f) **Study Procedures**: provide a detailed description of all study visits, procedures, and data collections; description of study drugs, devices, or other interventions/exposures administered; description of specific data variables to be collected, including data collection methods, assessments, data collection sheets, and/or schedule of assessments

g) **Risks and Discomforts**: provide a detailed description of potential risks of each study-related procedure/intervention and steps taken to decrease relevant risks

h) **Benefits**: describe potential benefits to participating individuals or clearly state that there is no direct benefit to individuals; describe potential benefits to society

i) **Statistical Analysis**: describe plans for statistical analysis, including statistical methods/data analysis plan and power analysis (e.g., sample size, evaluable subjects, etc.)

j) **Monitoring and Quality Assurance**: describe the plans that will be followed by study staff for monitoring and quality assurance, including procedures for assessing and reporting adverse events, safety, and data monitoring plans, etc.

k) **Privacy and Confidentiality**: depict the privacy and confidentiality measures that apply

l) **References**: include references to any studies/materials referred to in the protocol

2.2 Develop the following study materials:
a) **Consent:** use the MGB template and the following tools:
        Consent Form Preparation Worksheet
        Consent Form Reviewer Worksheet and Checklist
        Tools & Tips (writing in plain language and terminology)

      Use the following link for other templates (children's Assent Form, other languages, drug trial consent, Tissue Bank Consent Form, etc.):
      https://partnershealthcare.sharepoint.com/sites/phrmApply/aieipa/irb/Pages/IRB-Forms.aspx

b) **Recruitment materials (Flyer, Rally page, emails, FAQs, etc.):** must be reviewed and approved by the IRB

c) **Study schema:** outline the step-by-step workflow of the study procedures

d) **Data collection instruments (i.e., surveys)**

e) **Data flow diagram:** depict the life cycle of study data collection, transfer, storage, and security measures

2.3 Epic integration process:
Research project needing any Epic integration or Epic functionality: submit a request via email to Holly Barr Vermilya and Jasmine Ha for intake of new Human subject research projects.

*If the project is NOT research (quality improvement) and requires Epic: submitted the application or "new technology" to the Enterprise Architecture Council (mgbarchitecturecouncil@PARTNERS.ORG). The requests will be vetted against the business capability model and reviewed. They are working on a Request Form but that is in progress.

**If the project is NOT research (quality improvement) requiring Epic INV environment: there is a request form in Service Now and within the form, there is a check box for the Epic INV environment, the requestor will be required to provide a reason for the access. The security team will receive that request and then send it to Julie White for approval. If further conversations are needed with the requestor, the reviewer will bring in the appropriate people for discussion.

2.4 Common Pitfalls and Tips:
- **Develop a protocol that is understandable** and can be operationalized
- **Nailing down key elements of the protocol early** is important - interventional or observational, clinical trial or pilot, investigator-initiated or sponsor-initiated
- **Using internal MGB processes** (i.e., REDCap, Dropbox, LabArchives, MGB Secure File Transfer, MS Teams) improves work efficiency
- **Clearly define the study procedure** and data collection time window in the protocol
- Consider consulting a biostatistician
- Ensure protocol, ICF, and IRB application are **consistent** with each other
- All subject-facing documents/forms must be reviewed and approved by IRB
- Recruitment of staff as research participants needed much more consideration (e.g., steps, procedure, surveys, payment)
- **Participant payments and participation** needs to be clearly defined and detailed via spreadsheets/charts/graphs/diagrams
- **Ensure business owners** (both MGH and sponsor) **review protocol** (e.g., financial disbursements, ensure budget/fees and financial disbursement process is finalized)

3. Contracts & Agreements
Once a draft protocol has been created, and the sponsor relationship has been established, the next step is to work on the study contract and agreements as needed. Refer to **Section B of the Groups document** for the contracting groups and guidelines for determining which MGB entity you need to interact with. Contracting checklist: Research Agreement Quick Reference

3.1 Overview of the process
For projects involving industry sponsors, work with the Clinical Trials Office (CTO) to develop a Scope of Work (SOW) to define the overall project goal, specific aims, key personnel, deliverables, responsible parties, timeline, budget, etc.
- Contact CIDH if you need guidance and support on this process
- Fill out CTO's PI questionnaire to help with the content preparation

- This will help the CTO to first understand the objectives/scope of the project and to determine the agreement type
- From there, CTO can provide advice on agreement type, format, and other requirements to be defined as part of the SOW

Based on the SOW and the protocol, CTO determines the right agreements to be used for the collaboration:
- A Clinical Trial Agreement (CTA) is needed for a clinical trial
- If any SOW calls for the Company to access or receive any Patient Data from MGH, then a Business Associate Agreement (BAA) is needed
- Also check with CTO to see if another SOW or amendment is needed if an additional party is involved and participating in the study design

3.2 Links to common legal, contractual agreements:
a) **Industry-Sponsored Basic Research Agreements**
https://partnershealthcare.sharepoint.com/sites/phrmInitiate/iian/Pages/Industry-Sponsored-Basic-Research-Agreements.aspx

b) **Industry-Sponsored Clinical Research Agreements**
https://partnershealthcare.sharepoint.com/sites/phrmInitiate/iian/Pages/Industry-Sponsored-Clinical-Research-Agreements.aspx

c) **Non-Industry Agreements**
https://partnershealthcare.sharepoint.com/sites/phrmInitiate/iian/Pages/Incoming-Contracts.aspx

d) **Contract Terms**
https://partnershealthcare.sharepoint.com/sites/phrmInitiate/iian/Pages/Customary-Contract-Terms.aspx

e) **MTA's, CDA's, DUA's, RSA's IP Disclosure and Acknowledgement**
https://partnershealthcare.sharepoint.com/sites/phrmInitiate/imcdc

3.3 Common Pitfalls and Tips:
- **Clearly define the responsibility** of the study sponsor, principal investigator (PI), vendors, and the study team members
- **Deciding early in the process** who/what and when clinicaltrials.gov registration will be conducted
- **Identify a primary contact** for each of the tasks, deliverables, and responsibilities

4. IRB & Data Security Review
For all digital health research protocols to be submitted to the IRB, first contact the Clinical Trials Office (CTO) and the Research Information Security Office (RISO) so they can evaluate the methods to be used. These approvals will be required before the study can begin, and it is most expeditious to discuss your study with them before sending it to the IRB. For example, the IRB can't opine as to what the consent form should say, if the RISO office has not yet agreed that data security is acceptable, and the CTO has not agreed upon what subject level data are being shared with for-profit concerns.

https://partnershealthcare.sharepoint.com/sites/phrmApply/aieipa/irb/Documents/Digital%20Health%20Research.pdf?CT=1624308242388&OR=OWA-NT&CID=043b38eb-a050-6f14-8990-4e10aeaac0b2

4.1 IRB Review Preparation
Develop IRB Protocol submissions according to the type of project:
- Intervention Interaction
- Health Medical Records
- Excess Human Material and Related Health / Medical Information
- Secondary Use of Research Samples / Data
- Research Data Repository
- Tissue or Sample Repository
- Coordinating Center / Core Labs
- Emergency Use for Single Patient

For information about IRB Forms and Templates, Policy and Guidance, as well as Insight instructions, please use the links below:
- IRB Forms and Templates
- Policy and Guidance
- Insight Quick Reference Guides

*Cede review occurs in a multi-site study when one IRB will lead on approving all procedures and documents, and the other participating sites will be ceding or giving over their review to that external central IRB. PI and the research team can create a CEDE Review Request Form in Insight and provide related documents upon IRB's request. Contact the single IRB (sIRB) team: mgbsingleirb@partners.org

4.2 A Review of Groups Most Often Needed to Conduct Digital Health Research
The following webpage contains the list of research support teams commonly involved in reviewing digital health technologies and the Toolbox that can be useful when developing the project:
https://rc.partners.org/node/3448?destination=/research-apps-and-services/digital-health-review

4.3 Digital Health Research Review Process and Regulations
When you submit a new research protocol (or an amendment) to the IRB, the IRB may require a RISO review. A RISO review or IRB Data Security Review will look to understand the technology you have in place and its surrounding data flow to ensure that your research data, intellectual property, and study participants' data are secure.

For details regarding the RISO process, refer to the Research Information Security page.

4.3.1 RISO Review – IRB Data Security Review
Examples of studies where RISO review will be required include, but are not limited to:
- Use of digital technology to collect, store or share PHI
- Use of digital technology to collect, store or share data internationally
- Use of cloud-based computing to collect, store or share data
- Use of wearable devices to collect, store or share data

RISO aims to understand the data from the moment of its acquisition, how data are transferred to the system that will store and process it, how and where data are stored (both internally and externally), how data are accessed, and how access is controlled if data will reside in multiple systems if data will be shared and finally how it will be archived and disposed of. The objective is to understand how to secure data in every step of the life cycle.

4.3.2 RISO Review Steps

- The **IRB will inform RISO directly** of a protocol that they are requesting a RISO review and approval for during the IRB's initial review period
  *You could also reach out to RISO directly (riso@partners.org) to initiate the discussion in parallel with your IRB protocol submission.
  - To submit a Research Information Security Request: https://partnershealthcare.service-now.com/isservicehub/?sys_id=70a999c11b1424189f83986cbc4bcb28&view=sp&id=sc_cat_item&table=sc_cat_item

  **The review process may be different if it is an institutional collaboration with an external entity or part of a multi-site study. Follow the specifics in the collaboration agreement and guidance from IRB and RISO to proceed

- The assigned **RISO reviewer will reach out to the PI** and/or Research Coordinator to make an introduction

- As the review of the IRB protocol documentation commences, the **RISO reviewer will follow up to request an initial 30-minute call or send questions via email**, depending on the scope and complexity, to gather information about the data flow/data life cycle for your study

- Research departments can expect that the RISO reviewer will **touch base as a check-in** if responses to data flow questions have not been received or there are items awaiting the department's action following a phone call
  *Additional calls may be necessary based on the complexity of the infrastructure

- At the time the data security review is complete, RISO will send **an approval letter** and formally sign off on your approval in Insight

4.3.3 Documents needed for RISO Review

- **Hardware/asset inventory**: list of all hardware devices used for the project
- **Data inventory**: list of where data are stored
- **Data workflow diagram**: a schematic view that outlines the flow of data between devices across the lifecycle
- Depending on the complexity, there might be **other documents,** such as implementation plans, configuration baselines, security scans, etc., that will be pertinent to inform the RISO review. Other documents that may be asked for include:
- **Software in use** — installed in which devices
- **Vendors used**

4.3.4 Cybersecurity Risk Assessments
A cybersecurity risk assessment is required if...
- Your IT solution stores, processes, or transmits Confidential data
- A third party connects to the Mass General Brigham network to provide support
- Your IT solution requires specific assessments in accordance with regulatory, industry-specific, or contractual obligations
- There are significant changes in the application or infrastructure

If systems/technology in your study meets the criteria above, follow the steps outlined in the [Information Security & Privacy Office Risk Management](#) page to submit a risk assessment request. For additional information, you may also refer to Mass General Brigham's Enterprise IT Asset Management Standards for Risk Management.

4.3.5 Examples of common RISO review questions
Mobile Apps:
- Does the App require a username/password or PIN code?
- If username, is this a unique ID or email address?
- (suggest using unique IDs instead of emails to reduce PHI exposure)
- Does the App cache information locally (temporarily or if there's no connectivity)?
- Is the data stored locally (cache or otherwise), if any, encrypted at rest within the app container?
- When the App is deleted, is any data stored locally also gone, or does it keep any information?
- What type of encryption is used for data in transit (i.e., TLS v1.2)?
- When data are sent to central servers, how is the device identified?
- Is the App collecting any data in the background when not in use (i.e., telemetry, GPS coordinates, audio, messages, etc.)?
- Does the App use any type of background data synchronization?
- Does the App integrate with other Apps (i.e., iCloud, Photos, OneDrive, Dropbox, etc.)?
- Are App updates configured to be applied automatically?

Wearables:
- Vendor and the name (and version number) of the wearable device?
- Is the device developed alongside the App or made by a separate manufacturer/vendor?
- If a separate vendor, how does the app integrate with the device?
- What data elements will be collected from the device itself?
- Will any of these data elements include PHI?
- Are all the HIPAA identifiers to be collected minimally necessary, or can some identifiers be omitted?
- Will the app/device communicate with participants via text message or push notification?
- Will the device transmit any data via Bluetooth to the mobile app? If so, will any study activities be conducted where data will be transmitted on the MGB campus, or will the wearable device only be used in the participant's home?
- Is the sponsor requiring to use the app and wearable device, or did MGB identify the app and device for the research?

4.3.6 RISO Review Timeline

Timelines for RISO review can take from 1 hour to many months, depending on the complexity of the study. On average, it could take up to a few weeks from the start of the risk assessment process. If your study has specific deadlines associated by which you need to obtain IRB approval, please inform your RISO reviewer as soon as possible. The Information Systems department, including ISPO, uses ServiceNow as the enterprise ticketing system for tracking and reporting purposes. The RISO reviewer may also ask you to submit a risk assessment intake form in ServiceNow.

RISO has established a RISO Ancillary Committee that meets every 1-2 weeks as a forum to discuss processes and questions related to IRB research assessments. Should the research study be complex, or a research department has a unique question or requests a consultation, a RISO reviewer may bring the topic to the larger committee to obtain input and guidance.

4.3.7 Agreement Reviews

The Information Security & Privacy Office (ISPO) can provide assistance reviewing specific aspects of data security plans, data management plans, contracts, and engagements with sections or clauses specifying how data Privacy & Security needs to be handled by MGB.

4.3.8 RISO Consultations

RISO provides consult services to research departments to answer general inquiries about systems or technologies that can be used to serve a specific purpose. RISO can also offer guidance on more complex research projects, including the steps that will need to be taken and items to consider for making your project as secure as possible based on what is in scope.

If your research involves using Mass General Brigham's Amazon Web Services, Google Cloud, or Microsoft Azure tenants/subscriptions, visit the Cloud Security website for more information.

Helpful resources:
- Data Classification Reference Guide
- Overview of Cybersecurity Risk Assessment Process and How to Request
- List of Completed Vendor Risk Assessments
- Enterprise IT Acquisition, SDLC, and Maintenance Standards

For any questions, please contact riso@partners.org
Source: https://rc.partners.org/security/information-security-program/riso-ancillary-review

Digital Health Review
ISPO Risk Management
Risk Assessment Resources
Introduction to Information Security
Research Information Security Resource List

4.4 Billing for Research Procedures
- The IRB review process triggers the start of a **Medical Coverage Analysis (MCA) review**. This review determines if certain study elements can be charged via the standard of care vs research specific procedures that must be charged to a study fund number.
- All clinical research studies submitted to the MGB IRB are reviewed to determine if the study meets the definition of a **Qualifying Clinical Trial.**
- An MCA will be performed on studies that meet the Qualifying Clinical Trial definition.

- The Principal Investigator (PI) will be informed whether the study **meets the definition** of a Qualifying Clinical Trial. An MCA report will summarize which investigational services may be billed to Medicare. An MCA is not prepared if the study is not a Qualifying Trial. Nevertheless, the PI remains responsible for monitoring study related expenses.
- Typically, **informed consent documents describe** items that will be billed to insurance and items that the research study will cover.
- **Deviations from billing practices** described in the protocol and the informed consent document should be tracked on a minor deviations log and submitted to the IRB at Continuing Review.
- **Billing issues** affecting large numbers of research subjects should be reported to the IRB as soon as possible.
- **MGB Patient Accounts** - can help identify and correct charges billed to the subject or the subject's insurance in error.
- **MGB Research Finance** - can help identify and correct charges to a study fund.
- **Institutional Research Compliance** - can help develop the tools needed to ensure billing is directed appropriately.
- **Clinical Trials Office (CTO)** - can help develop and negotiate budgets and contracts with industry sponsors. CTO performs the MCA for all non-oncology clinical research protocols.
- **Research Management** - sets up the fund number at BWH or Special Billing Number at MGH for studies with a patient care line in the budget.

4.5 Common Pitfalls and Tips:
- **Involvement of additional 3rd party vendors** and not detailing in the protocol increased the complexity for IRB/RISO review and study workflow
- **Consider the pros/cons** of using a 3rd party vendor
- If conducting a RISO request in advance, double check that **all technical details are included**
- Additional regulations and compliance are required if your study involves collecting, processing, and storing **international data**

5. Project Implementation

5.1 Study Management Tools: quality improvement components used to ensure compliance with requirements and good recordkeeping. The tools in the following links are used as a starting point to meet site specific needs for regulatory documentation and subject files. They should be used in conjunction with other tools, such as the Virtual Regulatory Binder.

5.2 Recordkeeping and Record Retention: investigators must maintain records of their research activities to ensure compliance with requirements and optimal conduct of research. This page provides an overview of clinical research recordkeeping requirements, as well as record retention, transfer, and disposal requirements: Recordkeeping and Record Retention Requirements

5.3 Regulatory Binder: to organize all required Essential Documents as outlined in Good Clinical Practice (GCP) Guidelines, Section 8. A complete set of Essential Documents permits evaluation of the conduct of a trial and the quality of the data produced. It demonstrates compliance of the investigator and study team with the protocol and all applicable regulations.
- Each study should have its Regulatory Binder, but the contents may vary based on the protocol. Certain items, such as CVs/licenses/training records, may be stored centrally.

- Individual subject records/files, source documents, and signed informed consent forms are usually stored separately from the Regulatory Binder.
- A typical Regulatory Binder may include (some or all of) items in the following link

5.4 Subject Files: Each subject should have a separate file/binder. The subject file/binder should contain **all** the information (source documentation) used to complete the case report forms (CRFs) and substantiating documentation for notes, I/E criteria, and the quality of the informed consent process. (GCP 4.9.0, 4.9.1, 4.9.2, and 4.9.3). The subject file/binder should include the items in the following link.

5.5 Research Compliance
a. MGB IRB Policy and Guidance
b. Regulations and Regulatory Guidance
c. HIPAA Policies & Forms

5.6 Quality Improvement
MGB Human Research Affairs Compliance and Education Office, formerly the Partners Quality Improvement (QI) Program, 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.

Data and Safety Monitoring Plans in Human-Subjects Research
See also, QI Program Monitoring Plan Template
Monitoring Log

Request Human Research Affairs Compliance and Education Office Services, complete this Service Request form to request a consult, audit, or education:
https://redcap.partners.org/redcap/surveys/?s=L7K3PH74NH

5.7 Study Close-out
• Complete data analysis, regulatory monitoring, and publication
• All data entered, and subjects notified and paid as necessary
• PI has signed everything required
• IRB and FDA are notified
• Study record storage plan compliant with regulations
Study Close Out Checklist

5.8 Common Pitfalls and Tips:
- **Define an organized folder structure** (Dropbox or Teams) and provide a project management tool to collaborate on documents to communicate efficiently
- **Align business and research practices** for efficiency (i.e., hourly tracking)
- **Create a spreadsheet** of all who will receive data (e.g., data type and level of identifiability)
- **Meeting agendas** - confirm who is responsible for sending meeting agendas and capturing the next steps. Ensure the appropriate owner takes responsibility
- Consider Clinical/Research Teams' **current tech platforms** in advance when designing study management/communication/storage tools

- **Iterate on the research participant enrollment process using role play** to ensure: 1) research staff understands the process, 2) polish recruitment language, 3) remove technical bugs, 4) remove inefficiencies, and 5) document a detailed step-by-step procedure prior to beginning

Links to Further Information

[Center for Innovation in Digital Healthcare (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. CIDH also helps guide and consult MGB internal innovators regarding next steps to further their digital health projects. Investigators and innovators can reach out to CIDH when they need support and guidance in areas such as scaling a solution, grants and funding identification, finding champions, creating networking opportunities, problem solving, and more. To reach out with to CIDH and conduct an initial intake with the team, please complete the form via this link: https://cidh.massgeneral.org/collaborate-with-us/

[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.

[Division of Clinical Research (DCR)](): provides a support structure for clinical, translational, and nursing research. It also provides 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.

*[Partners eCare](https://) **(MGB Epic team)**: implements an integrated electronic health record (EHR) at MGB. eCare also supports EPIC enhancements and integrations and assists researchers in identifying and recruiting patients from Epic EHR.

> *[Epic Software Integration Group (ESIG)](): is responsible for integrating non-Epic systems and applications with Epic. It deals with tight software integration primarily through Web Services but other forms of integration as well.
> - Work with non-Epic systems and applications to identify integration points and design the appropriate architecture
> - Assist in extracting and migrating data between Epic and non-Epic systems
>
> *[Enterprise Data Service Provisioning (EDSP)](): MGB utilizes Enterprise Data Services Provisioning (EDSP) to build an enterprise-wide catalog of reusable clinical IS functionality provided to multiple consumers over a simple interface. The EDSP request form in ServiceNow is used to communicate the need for the Application's project description, requested data and service(s), and the purpose of the request. When a request is submitted, it is reviewed by the following:
> - EDSP Enterprise Clinical Systems & Services Program
> - Service Provider and Infrastructure teams
> - Enterprise Data Access reviewers

EDSP Catalog (turn on VPN): http://clinical.partners.org/scripts/phsweb.mwl?APP=WSADMIN
When you are ready to submit a request to EDSP for service(s), complete the EDSP Request Form.
Helpful Hints and instructions on completing the EDSP Request Form are available from within the
EDSP Request Form, as well as the Online help for EDSP Requests in ServiceNow.

*The descriptions related to these research support teams and the web pages are under revision as of
March 6, 2023. This section will be updated once new information is available.

A list of "need to know" ("must-have") items about the digital research process

- **Keep an up-to-date accountability log** detailing who is responsible for all major research study tasks. The date range must be accurate for each task, and the log should be maintained and updated regularly.

- **All studies involving human research should have a regulatory binder** which is the collection of materials that provide the regulatory basis for the study. This will include the protocol, study staff documents, study tracking logs, Investigational products, Monitoring, etc. https://partnershealthcare.sharepoint.com/sites/phrmResources/rsm/rsf/Pages/study-management-tools.aspx

- In addition to the need to provide informed consent, you need to document the completed elements of the informed consent process. (i.e., the subject was given adequate time to consider the research study and provided a copy of their consent form).