IRB Review Process:
Submitting a Digital Health Research Project

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Digital Health Research-IRB Review

• USUALLY Minimal risk
• Privacy
• Data use and sharing
• Passive vs. active data collection
• Wearable sensors/devices

• Snapshot or ongoing data collection
• Consent/terms of agreement
• Return of results
• FDA Oversight
Digital Health Review

• Research Information Security
• Clinical Trials Office
• Partners eCare?
• Biomedical Engineering
• FCC Regulations

• Departmental Leadership
• Innovation/Research Management
• FDA?
• Office of Interaction with Industry
• Public affairs?
Digital Health Methods

**Digital health methods** include collection, transmission and/or dissemination of private or non-private actively or passively collected data or private information using software or technology that collect information at a point in time or over a period of time.

**In Scope Examples:**
- Clinical technologies that are part of a human subject research study, both new IRB submissions and amendments
- Mobile applications and/or surveys – whether home grown or commercially marketed, using their own devices or study sponsor provided
- Wearable technologies, including pervasive data collection using multiple sensors or devices placed in an individual's or group's environment (ie Fitbit)
- Patient facing and/or study team facing

**Out of Scope Examples:**
- Non-clinical applications
- Applications that are not utilized on a mobile device
Mobile Application Program Coordinator (MAPC)

• New as of April 2018
• Supported by Academic Research Leadership
• Funded by IRB, CTO and ERIS
• Provides connections between Researchers and relevant Stakeholders
• Tracks Insight progress of IRB / IRB Ancillary Reviewers required approvals
• Docked into IRB to stay apprised of issues/concerns/questions
• Optimizes timing of requests to relevant Partners IS teams

Contact: IRBDigitalHealth@partners.org
Research Team Work Flow

https://rc.partners.org/digitalhealth
Have an Idea?

“Can I do this?” “How do I do this?”

- Contact your Site Innovation Team
- Contact IRBDigitalHealth@partners.org

Where possible, do not “reinvent the wheel”

MAPC collaborates with the Site Innovation Teams.

Together, they compile information on successful applications for vendors, platforms, technologies.

These known solutions might meet your needs, or could be modified to meet them.
Innovation Teams

- Innovation Hub at Brigham Health (DHIG) - https://www.bwhihub.org/
  - Connected with start ups working to disrupt innovation
  - Connected with companies who will provide custom development on existing platforms – Brigham Mobile Research Program
  - Will work with teams from across the enterprise
  - Can provide guidelines for best practices

- MGH - Center for Innovation in Digital Healthcare (CIDH) http://healthcaretransformation.org/1183-2/

- MGH - the MD PnP program http://mdpnpmgh.harvard.edu/
  - Recognized leader in the development of the concepts and capabilities for integrated clinical environments. We have been working to accelerate the adoption of medical device interoperability by providing interoperability building blocks (use cases, standards, a neutral lab "test bed" environment, and open research tools)

- McLean Innovation for Technology in Psychiatry (ITP) https://www.mcleanhospital.org/research/mclean-institute-technology-psychiatry
Prior to IRB Submission

Preparing for the submission process, or moving forward on an idea

1. Gather all information about the technology as possible. Includes user manuals, or technical manuals with information related to:
   • the device and how it's used
   • how data is transmitted (via the internet, using cell service, bluetooth, etc)
   • where data is transmitted and stored (to the vendor servers/study sponsor servers/cloud)
   • operating system, version, model, form factor
   • number of devices
   • who is acquiring them
   • Vendor contact information
Prior to IRB Submission (cont.)

2. Write use cases

Describe how the study subject is interacting with the technology, and/or how study coordinators will work with the subject.

Examples include:
- Is the subject adhering a wearable? Putting it on their wrist?
- What data is the technology collecting?
- Is the subject using an application? If so, where will it be installed and how?
- Will they use sponsor provided device or their own? If their own, will it be transmitting data or receiving data from another device?
- What data is it collecting or is being entered? Where is the data going?
- What data elements are involved? PHI/PII, study subject cell phone number or email address. If deidentified, how?
During IRB submission in Insight (specific to Digital Health):

1. Answer YES to this question on the pre-submission screen:

   **Will you be using any applications, systems or technology as part of your study to collect, store or share data?**

   ☐ Yes or No

2. Complete Technology Form (new as of Insight v4.0)

3. Submit CTO approval letter as an attachment
Technology Form > Digital Health Question

Digital Health
Does your research involve the generation, use and/or dissemination of health information or physiological data using mobile and wireless devices, wearable devices, smartphone apps, digital health tools, health-related IT, new healthcare software and related new technologies?

◉ Yes or No. Please send an email to IRBDigitalHealthReview@partners.org with protocol number and Digital Health Responses.

Indicate type of digital health technology being used in the study (check all that apply):

X Mobile devices

iOS
Android
Devices owned by Partners
Devices purchased external to Partners or study-sponsored
  Devices owned by study subjects
  Devices will be enrolled in PHS Mobile Iron
  Devices will not be enrolled in PHS Mobile Iron
Wireless device
Wearable device
Smartphone application
Digital health tool
Healthcare / IT software
Other List name and manufacturer of all digital devices
3. Email Irbdigitalhealthreview@partners.org to receive instruction on how to complete the Clinical Trials Office (CTO) form.

4. Complete the CTO questionnaire

CTO Reviews manufacturer's agreements (e.g., End-User License Agreement, Terms of Use, Privacy Policy, etc.) for clinical trial protocols that require subjects participating in the trial to use a smartphone application, wearable device (e.g., an activity tracker, monitor, or sensor), and/or a web-based service

CTO does not review agreements if subjects have already accept the agreements in order to use the manufacturer's smartphone application, wearable device, or web-based service prior to enrollment in the clinical trial (e.g., trial subjects have already downloaded the smartphone application under investigation and accepted the manufacturer's Terms of Use prior to participation in trial)
During IRB submission in Insight: RISO Review Process

• RISO = Research Information Security Office
• Insight 4.0 will alert RISO when an action is required on an IRB application.
• RISO continuously monitors the riso@partners.org mailbox for any direct security review requests received by the research community
• RISO will contact the research staff to acknowledge receipt of the notification and kickoff the review process
• The research coordinator and/or PI will be instructed to complete an ISPO Risk Assessment Request Form in ServiceNow
• Depending on the complexity of the systems/technologies used for research, and what will be involved in the full scope of our assessment, average time to complete a review is 2-6 weeks.
  » RISO will work with the research staff if a review is needed sooner due to specific deadlines
  » If it is known that a specific technology has already been assessed and approved for another research study, share the protocol number with RISO.
What is an Information Security Risk Assessment?

- The process of identifying risks to Partners HealthCare electronic confidential data and creating action plans to lower or manage risk to an acceptable level.

- An Information Security Risk Assessment is required for:
  - IT Systems that store, process or transmit confidential data.
  - IT Systems that are remotely supported on the Partners HealthCare network by a third party.
  - IT Systems that require special assessments in accordance with regulatory (i.e. GDPR), industry specific, or contractual obligations.

- Some security risk assessments will require a full vendor/third-party assessment (VISP) on their security controls, which is dependent on the data classification (i.e. confidential)
  - VISP’s are generally renewed every few years or when there is a substantive change in project scope, whichever comes first.

- Many systems, applications and technologies have already been assessed by the Information Security department.
  - For research, technologies are evaluated based on how they are used for each study. For example, using a technology for de-identified data will not be assessed in the same manner as the same technology being used for confidential data.
The Secure Data Life Cycle

• When submitting your IRB application, incorporate details specific to:
  » What type of data is involved (i.e. confidential/identifiable, de-identified, anonymized)
  » How data is created and accessed
  » How data is being transmitted (send and receive)
  » Where data is being stored
  » How data is being backed up and destroyed

• RISO will work closely with researchers and third party vendors to help fill any gaps pertaining to the data flow, data management and how data will be secured
RISO Review Process Continued

- At completion of the review, RISO will document an approval letter and send to the research staff via email for uploading into Insight. RISO will also complete the following task in Insight, which will trigger an alert to the research staff to inform them that a specific action was taken:

  ![Actions](image)

  - I have carefully reviewed the protocol and confirm my sign off.

- PI/study staff will be responsible for reviewing the security recommendations outlined within the approval letter and ensuring the necessary security controls are implemented to align with Partners Enterprise Policies & Procedures.
Helpful Policies, Resources & Contacts

- Research Computing Website (ERIS)
- Digital Health Review Process
- Research Data Classification
- Data Classification Reference Guide
- Partners Research Data Management Requirements
- Guidelines on Retention of Research Data, Materials and Records
- General Data Protection Regulation (GDPR)
- IT Asset Management Standards for Risk Management
- IT Asset Management Standards for Data Classification
- IT Access Control Standards for Users
- Enterprise IT Acquisition, SDLC and Maintenance Policy

For any questions related to data security for your research, please contact the following:

- riso@partners.org
- Fabio Martins, Research Information Security Officer: fmartins2@partners.org
- Heather Carter, Associate Research Information Security Analyst: hcarter@partners.org
During IRB submission in Insight: Additional Ancillary Approvers

Additional Ancillaries will be triggered in Insight, where relevant:

- Biomedical Engineering*
- Pharmacy
- Radiation
- Nursing

*Ancillaries working with other technology reviewers
Ancillary Approvers: BioMed

Biomed Reviews
1) Research activities involving clinical investigations of electrically powered devices
2) Research activities involving non-standard use of hospital inventory electrically powered devices
3) Research activities involving the use of non-hospital inventory electrically powered devices for research purposes. There are specific “triggers” in the submission process that the PI answers that will initiate a request for review to Biomed via Insight.

Biomed does not review -
1) The use of hospital inventory devices, i.e., devices with BME control numbers (BME stickers with bar codes affixed to the device), when these devices are used according to FDA-approved labeling indications
2) The use of devices being studied under an Investigational Device Exemption (IDE) that are not electrically powered (e.g., stents, catheters).
NOTE: Electrically-powered devices include devices that are line or battery-powered.
## IRB Approvers

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<thead>
<tr>
<th>Name</th>
<th>How to Request</th>
<th>Review Process</th>
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| CTO   | • Check Yes to Digital Health question in Insight  
      • Complete CTO form in REDCap [https://redcap.partners.org/redcap/surveys/?s=FP97YRCTTC](https://redcap.partners.org/redcap/surveys/?s=FP97YRCTTC): | • CTO approval sent to PI  
      • Uploaded by PI |
| RISO  | • Check Yes to Technology Question in Insight  
      • Request goes to RISO queue | • RISO signs off within Insight  
      • Approval letter sent by RISO, uploaded by PI  
      • PI follows up on all stipulations |
| Biomed| • Check on Ancillary Devices in Insight  
      • MAPC will initiate contact during review | • BME signs off within Insight |
Technology Stakeholders: IS and Vendors

EMM, Enterprise Mobility Management – For protocols utilizing tablets and smart phones (iOS, Android) on network, EMM provides assistance in the set up and configuration of newly acquired mobile devices or those provided by a vendor/study sponsor.

Mobile Devices – For protocols utilizing laptops or laptop/tablet hybrids on network, the mobile team provides guidance and assistance in the acquisition, set up and configuration of newly acquired devices or those provided by a vendor/study sponsor.

Network Engineering – For protocols requiring devices to be put behind the firewall, VLans

Server Teams – For protocols requiring Partners hosted servers

Partners eCare – For protocols requesting EMR integration

Vendors – For protocols utilizing vendor services, applications, devices, etc
Technology Stakeholders: Wireless

The Wireless reviewer looks at the following:
1) When something is using a wireless communications protocol like Wi-Fi, Bluetooth, two-way radio, etc.
2) With other not-so-common wireless communications protocols like IrDA, ultrasound, etc.
3) Things that use radio energy for non-communications purposes, like diathermy machines, microwave ovens, navigation systems, etc.
4) With medical devices when Biomedical Engineering isn’t involved (rarely, but it does happen)

The Wireless reviewer does NOT look at IS devices that are connected to the wired network.

Note – while Wireless is not an Ancillary Approver within Insight, a summary assessment and follow up recommendations is provided upon review completion. Any recommendations need to be executed upon implementation, including coordination with the Enterprise Mobility Management team where appropriate.
Technology Stakeholders: Vendors and Sponsors

MAPC will help you work with vendors and sponsors to obtain information that falls into the following categories:

- Data classification
- Data flow across the lifecycle
- Technical information for all mobile devices, wearables, etc being utilized in the study that relate to the security, transmission (ie bluetooth, wifi, cell) and storage of the data on that device
- Technical information for data transmission and storage outside of the PHS firewall, ie vendor/sponsor hosted servers, vendor/sponsor cloud services, their security controls, etc
Approvals aren't a sure thing

Sometimes:
- technology appears to be low risk,
- it may have been utilized/approved in the past, or
- is commercially available.

However, approvals from ANY/ALL Stakeholders are dependent on use cases since the technology or study may:
- interact with the user in a different manner,
- involve a different population,
- involve more/less/modified technology (ie a different version since last reviewed)
- require working with other technologies
- be using different data types, etc
Reviews and approvals require more time, if:

Technology doesn’t meet PHS standards for being on our network
  • Example: PIs being given hardware by the vendor that is not in line with our standards for putting on the network. There have been cases where the operating system was too old to update, and in one case technology was abandoned.

Use Case is complex
  • Example: Clinicians utilizing multiple devices/systems

Vendor is not providing support
  • Example: an OS that requires further understanding to ensure it will receive patches as it will be on our network for two years. Who will maintain this?

Technologies didn’t “seem” to require review
  • Examples: Inadvertently excluding technology; Technology that generates data that could have privacy issues, such as texts to study subjects no matter what the content, video/audio/photo files of study subjects
Research Ethics Consultation Unit

Mission
• Assist MGH investigators in considering and resolving ethical and IRB review issues
• Work with MGH faculty to improve the quality of IRB submissions

Consultation Service
• Guidance in planning and conducting human subjects research
• Assistance before, during and after regulatory review to address issues and discuss practical solutions

Examples of Service
• The Consent Process
• Appropriate and Effective Recruitment Plans
• Confidentiality or Handling Sensitive Information
• Disclosure of Findings or Results
• Enrollment of Vulnerable Subjects
• Using the Partners QI checklist and delineating care/research activities
• IRB review of survey/interview methods
• Digital Health/Social Media uses
• Risk/Benefit Assessment and Study Design (e.g. mitigating risks)
• Best Practices in IRB Applications, Communications and Responses to Review

Request at DCR site or contact Melissa Abraham, PhD:
https://www.massgeneral.org/dcr/CentersUnitsThink Tanks/Units/ResearchEthicsConsultationUnit.aspx
MAPC and Digital Health Review Process Website

https://rc.partners.org/digitalhealth
MAPC and Digital Health Review Process: Just Ask!

Contact: IRB Digital Health@partners.org

Website: https://rc.partners.org/digitalhealth