PARTNERS HUMAN RESEARCH COMMITTEE
Guidance Document
Digital Health Research

What is Digital Health Research?
Human subjects research involving the generation, use, and 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.

Of note, these technologies may be in development at PHS or elsewhere, commercially available, or provided by 3rd party, industry, or academic or other collaborators.

Studies using new devices and digital health methods are generally not considered quality improvement. However, if you are implementing their use as part of STANDARD CARE, under the purview of the hospital or appropriate clinical department or service, this may be considered quality improvement. This can be determined on a case-by-case basis by the IRB.

For studies using digital health methods, prior to submitting your IRB application or amendment:

1) Contact the Clinical Trials Office [CTO] (avital@partners.org) to determine if they need to review your planned use for research and determine the need for and/or details of contracts with 3rd parties, collaborators, or other groups. As necessary, CTO will work with you and any 3rd parties to determine what information will be gathered, shared, stored, and used for future uses. Contact them before you submit to the IRB – the outcome of these determinations can affect the informed consent and protocol documents. Provide their response with your submission.

2) Contact the Research Information Security Officer (RISO@partners.org) for data security assessment. Upload RISO approval email with your submission.

POINTS TO CONSIDER

Please address relevant points in your protocol and consent materials, and include supporting documentation with your submission:

- What data will go to the app developer/third party/industry or other collaborators/entity? Is it identifiable or coded, or anonymous (no link to subject exists)? What identifiers are sent? Participants should fully understand uses of their data. (Consult CTO and RISO if needed.)
- Is the app/digital device provided at no cost from the company to investigators and/or participants to use after study participation ends? Is it an "In kind" donation to your research team? What are costs to investigator and subject? Are licensing agreements needed? (Consult CTO or Innovations)
- Does the participant need to pay for the app/device? Does the participant need to share data to acquire or use the app/device? Will the device be given to participants? What happens if the device is not returned?
- What provisions are made for data security? What identifiers are used and collected/retained? (Consult RISO)
- Consider issues related to how information collected via digital health methods will or will not be used in clinical care or placed in electronic or other records. Which data collected go or should go into the medical record, if any? Which information is usually used in clinical care and therefore should be in the record and used in care? Which information is not clinically validated and/or for research only and should not be placed in medical records? When might information be shared with care providers (in or out of the PHS system), if both the participant and doctor agree? When is it appropriate to send information to others outside of PHS? When do you need consent/permission from clinical staff to receive data from the app/device? Be sure these issues are clearly discussed in the protocol summary and the consent form.

- Will the data from the app/device be linked to other data or information? Is data stored temporarily or permanently via the app/device? (Consult RISO)
- Consider whether it is important to you to work with RISO during the development stages of your project.
- Is it appropriate to provide or suggest the use of the app/device to participants on behalf of a company? Will the company be using the Hospital's or Harvard's name? Are you inadvertently advertising or "marketing" for a technology company? Should Public Affairs or CTO be consulted?
- When are clinicians who are getting research data from the app/device considered research subjects? For example, if they are using data in care, this may create some risk by participating in the research activities? Should clinician participants provide informed consent or formally agree to take part in some other way? Is any record created that could reflect poorly on or otherwise adversely affect clinicians later?
- How will serious and medically actionable information (e.g., high blood pressure, suicidal plans, etc.) be handled? What are the study staff responsibilities in this regard from a legal perspective? Will participants and others assume that you will act on such data? Will a health care provider be informed of actionable information? When is this appropriate and acceptable to that clinician? Will that health care provider be aware information may be shared? What will the investigator do if the participant is out of state, or out of the US? State laws vary.
- If informed consent is obtained via an app/device, how do you determine whether the documentation process is in compliance with IRB and legal requirements?
- Systematic investigation or evaluation of new apps, wearable devices and other digital health methods are generally not considered quality improvement. However, if you are implementing their use as part of STANDARD CARE, under the purview of the hospital or appropriate clinical department or service, such as a hospital or divisional Quality Director or Team, it may be considered a quality improvement activity. This can be determined on a case-by-case basis by the IRB.
- Include information about the manufacturer, the app/device, if applicable, such as a device brochure, screenshots, version dates, or other information that will be useful for reviewers. Please avoid use of web links to manufacturers' websites, which may change or outdate.
- Some apps/devices may be FDA regulated (for example diagnostic devices like an EKG app or apps that direct drug dosing). See: Mobile Medical Applications at FDA.

For additional information, contact: Melissa Abraham, PhD, mabraham2@partners.org