Guidance for Research Involving Mobile Apps or Mobile Medical Apps

Overview:
The IRB recognizes that mobile apps may be valuable research tools and methodologies, yet their use presents special challenges to ensure that the research is conducted both legally and ethically.

The purpose for the guidance on the use of mobile apps or mobile medical apps is to provide researchers, IRB staff, and IRB panel members with a common understanding of the following:

1. Definition of mobile apps and mobile medical apps
2. Regulatory requirements pertaining to mobile apps and mobile medical apps
3. Regulatory review flow and points to consider when utilizing mobile apps or mobile medical apps in research

What are mobile apps and mobile medical apps?
Mobile apps are software applications downloaded to a mobile device, such as a cell phone or tablet, which provide the mobile device user with software that can be utilized on their mobile device in many different ways. For example, web browsing, social media connections, ridesharing applications, and many more. Many of these mobile apps also collect information about the user via the user's device.

Medical Device, as defined in Section 201(h)(1) of the Food, Drug & Cosmetic Act, is an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part, or accessory which is intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, or to affect the function or structure of the human body.

Mobile medical apps, as defined by the FDA, are medical devices that meet the above definition and are mobile apps that are either an accessory to a regulated medical device or transform a mobile platform into a regulated medical device. For example, mobile apps that alter the function or settings of an infusion pump, such as turning the pump on or off; mobile apps that use a microphone or speaker within a mobile platform to serve as an audiometer to allow healthcare providers to determine hearing loss at different frequencies; mobile apps that use an attachment to the mobile platform to measure blood glucose levels; etc.

What are the regulatory requirements pertaining to mobile apps and mobile medical apps?
Mobile Apps: There are no research-related regulatory requirements for mobile apps, in general, except for ensuring that the utilization of mobile apps adheres to the 45 CFR 46.111 criteria for IRB approval. However, many mobile apps have Terms of Service, User Agreements, etc. that researchers need to be aware of when utilizing mobile apps in a research study. Although not regulatory, ethical considerations, such as those described in The Belmont Report, also need to be considered.

There are many mobile apps that do not meet the regulatory definition of a medical device, which the FDA will not expect manufacturers, or investigators to submit premarket review applications or to register and list their apps with the FDA. For example:

- mobile apps that help patients/users self- manage their disease or condition without providing specific treatment suggestions;
- mobile apps that provide patients with simple tools to organize and track their health information; mobile apps that provide easy access to information related to health conditions or treatments;

- mobile apps that help patients document, show or communicate potential medical conditions to health care providers;
- mobile apps that automate simple tasks for health care providers; or
- mobile apps that enable patients or providers to interact with Personal Health Records (PHR) or Electronic Health Record (EHR) systems.

For more information and examples of software functions that are NOT medical devices, please refer to the FDA guidance, and Appendix A: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/policy-device-software-functions-and-mobile-medical-applications.

Mobile Medical Apps (MMA): Mobile medical apps meet the regulatory definition of "device" and are intended to be used as an accessory to a regulated medical device, or transform a mobile platform into a FDA regulated medical device. The FDA will apply the same risk-based approach the agency uses to assure safety and effectiveness for other medical devices. For more information about these types of apps, please see the FDA's website.

FDA medical device regulations apply to you if you are studying the safety and/or effectiveness of a mobile medical application in a human research study.

Non-Significant-Risk (NSR) medical device: The FDA does not require a Pre-Market Approval (PMA) and does not need to approve the study of NSR device, but the FDA does require an abbreviated Investigational Device Exemption (IDE). However, the FDA requires a convened IRB to make the Significant Risk/Non-Significant Risk determination of the device as it is being studied. This also requires IRB oversight, which effectively makes the IRB serve as the surrogate of the FDA and have oversight of that study. Informed consent is required, unless the criteria for a waiver are satisfied, so that participants in the study know that this is an unapproved medical device. Participants must also be made aware of the benefits, as well as the risks of participating in the study. (https://www.fda.gov/regulatory-information/search-fda-guidance-documents/significant-risk-and-nonsignificant-risk-medical-device-studies)

Regulatory flow and IRB review:

1. Does this mobile app meet the FDA's definition of a medical device?

Yes- continue to the next question.
No- FDA regulations do not apply. Continue to the "points to consider", below.

2. Is the mobile medical device what is being investigated?

Yes- then FDA regulations likely apply. The **convened IRB panel** will review studies that are believed to meet the abbreviated IDE regulations and make a risk determination of the device.
No- FDA regulations do not apply, but OHRP regulations do apply (additional federal and state regulations may also apply). Continue to the "points to consider", below.

Points to consider and address in your IRB application (protocol) when utilizing mobile apps or mobile medical apps in research

Purpose of the app:

1. What is the purpose of the app and how is it being utilized in the research?
    a. To determine validity of the app to do something?
    b. To collect information from participants and store it, such as through surveying?
    c. To engage participants in activities, such as to send reminders, motivational messages, etc.?
2. Is the app appropriate for the study population (e.g., content, age appropriateness, font size/color)?
    a. If minors are involved, is the content appropriate for the age group?

App functionality:

1. What is your plan to address issues related to the app not working?
2. Will downloading or using the app cost the participant anything?
3. Will the app only work on certain devices (e.g. iOS, Android)?
    a. Will participants use their own devices or will the study provide them to participants?
        i. If they use study devices, what are the requirements for returning the devices and are there consequences for not returning them?
4. When a device's operating system is updated, how will the app's functionality be impacted?
5. When the study is over or when a participant withdraws, how will you ensure the removal of the app from the participants' phones?

Participant/user support:

1. How are participants being trained to use the app?
2. How will participants get support if they need help with the app?
3. How is the app being monitored to ensure it is working properly? How often and when?

Obtaining consent and the app's Terms of Service:

1. How are you obtaining consent?
    a. Written consent? Consent via the app?
        i. If consenting via the app, what are the limitations to consenting using the app versus the standard written consent?
    b. Waiver of Written Documentation of Consent? Waiver of Informed Consent?
2. Does the informed consent tell the participants about what data will be collected, what identifiable data will be collected, where it will be stored, and who has access to it?
3. The app's Terms of Service will need to be uploaded in your IRB application.
4. Is the consent form in-line with the Terms of Service for the app, if applicable?
    a. Do the Terms of Service indicate data ownership?
        i. Does the owner of the app own the data?
    b. Does the researcher own the data?
    c. Does the user own the data?
5. How are the Terms of Service being explained to participants?

6. Are the Terms of Service compliant with research regulations, local/state/federal law, etc.?
7. What is your plan for monitoring the Terms of Service for updates or changes?

Privacy and confidentiality protections:

1. What data will be collected?
    a. Research data? Other data captured from the device the app is installed on?
2. Will the data being captured be identifiable?
3. How will the data be obtained? Data sent from the app or device via the internet? Or will it be a manual export of data?
4. Where is the data being stored and how?
    a. Is encryption utilized?
    b. Are university devices, firewalls, etc. utilized?
5. If the app is a commercial app, will the app have access to the research data?
6. Do the apps require usernames and passwords?
    a. Are they generated by the user or by the researcher?
    b. What if a participant forgets their username and/or password?

Risks related to app use:

1. Are the privacy and confidentiality risks stated in the protocol?
2. What if the app does not work as intended or malfunctions? Whom will participants contact?
3. Who is monitoring the app for potential risks and how often (e.g., questions or functionality within the app that monitors for emotional distress, such as suicidality)?
4. What about risks to third parties (e.g., social media engagement app that encourages communication between participants in the study and non-participants)?

Resources:

- Mobile Apps and Mobile Medical Apps Worksheet
    - HRP-336 WORKSHEET
- Devices Worksheet
    - HRP-307 WORKSHEET DEVICES
- Northwestern University
    - Institutional Review Board (IRB)
- United States Food and Drug Administration (FDA)
    - Mobile Medical Applications
    - Policy for Device Software Functions and Mobile Medical Applications
- Federal Trade Commission (FTC)
    - Understanding Mobile Apps