**The Multi-Regional Clinical Trials Center of Brigham and Women's Hospital and Harvard Bioethics Collaborative**

Thursday, May 02, 2019 | 10:00am- 3:00pm
Ropes & Gray LLP | 800 Boylston Street, Boston, MA, 02199

# Impact of Mobile Technologies on Clinical Research
# Executive Summary

The May 2, 2019 meeting of the MRCT Center Bioethics Collaborative convened thirty-four stakeholders from academia, industry, patient advocacy organizations, foundations, and Institutional Review Boards (IRBs) to examine the topic of the **Impact of Mobile Technologies on Clinical Research.**

## *Introduction*

The widespread use of mobile smart devices and wearables (together, "mobile technologies") has the potential to change how clinical research is conceptualized and conducted. Participants' data may now be leveraged for a variety of health purposes, including the development of remote screening and diagnostic tools, early intervention programs, and the promotion of public health. While these developments can make research participation less burdensome, they also raise ethical and regulatory challenges around acceptable levels of privacy risk, necessary precautions for safeguarding participants' confidentiality, and the optimal approach to risk mitigation. The promises and potential barriers to integrating mobile technologies in clinical trial workflows was the focus of the May 2, 2019, meeting of the MRCT Center Bioethics Collaborative.

## *Meeting Summary*

The MRCT Center Bioethics Collaborative meeting began with an overview of the varied ways in which mobile technologies interface with clinical research. For purposes of clarification, the term *mobile technologies* includes mobile *devices* often used in reference to software applications for smartphones, tablets, and/or web-based platforms and *wearable technologies* referred to monitoring devices or sensors, activity trackers, and drug delivery devices. It was

noted that the use of mobile technologies has grown exponentially over the past five years; as of 2017, over 318,000 health-related apps were available for download and over 340 consumer wearable devices available for purchase worldwide.[1]

Following an exploration of the promises and challenges of using mobile technologies in clinical research, attendees considered whether distinctions could, and should, be drawn between the various types of mobile health technologies. It was argued that there is a meaningful difference between mobile health technologies that gather data passively (data collection is ongoing without input from participant) versus actively (participant enters data in real-time). Because passive data collection does not require direct interaction and/or input from the user, research participants may not be fully aware of the types of data collected and the extent to which their activity is monitored and shared. Sensors that utilize passive data collection therefore raise a number of questions with respect to data privacy and confidentiality. In particular, what is the best way to inform participants of privacy/confidentiality risks? What access should the "wearer" of the mHealth device have to passively collected data? What protections are needed to guard third parties from using the data in a way that may harm participants? Who is responsible for acting on signals that might arise from these data?

An additional foundational question is whether the mobile technology is the focus of the research or whether the research is leveraging the technology as a means of gathering data. If the latter, are the de-identified data being collected by a third party (generally the developer) for purposes related to the research – and transparent to the participant – or for other, unrelated purposes? What degree of transparency and clarity is afforded to the participant in the informed consent, including who will have access to what data and where the data will be stored?

Attendees shifted their focus to the jurisdictional scope of the FDA and the Common Rule. Bioethics Collaborative participants recognized a tension between the regulatory conception of private information and the ways in which individuals' data are used by mobile technologies in the context of clinical research. The determination of whether the research is minimal risk or greater than minimal risk is important because minimal risk studies are often subject to less oversight and impose fewer burdens on researchers. Pertinent regulations tie 'minimal risk' to the level of risks encountered in one's daily life, but determining whether the risks of mobile technologies meet or exceed that threshold is challenging. If the research involves "bring your own technologies," then the participant has already agreed to any third-party collection of data

[1] 42 Matters, Jul 2017; Mevvy, Jun 2015; IQVIA AppScript Database Jul 2015; IQVIA Institute, Jul 2017

and only the new risks of the research need be considered. Of course, the participant will have signed the user agreement without the research in mind. If the technology is the subject of the research, or new to the participant, however, the assessment of the threshold of minimal risk may be difficult, compounded by the fact that the traditional regulatory view of risk is largely calibrated to physical harms, as well as by the fact that the risks of mobile technologies are routinely accepted by members of the public and may now be 'everyday.' In the digital age, while the risks to privacy and confidentiality are well appreciated, the actual evidence of harm is not. IRBs may be overestimating the risk of harm. Conversely, it may be argued that, from an ethical perspective, the public's seeming willingness to accept the risks of mobile technologies does not necessarily mean that those risks are acceptable or that more should not be done, both within research and without, to mitigate and address the risks and potential for abuse.

For any research that utilizes mobile technologies, the terms of service (ToS) and end user licensing agreements (EULAs) should be reviewed by the sponsor, the investigator, and the IRB. The agreement provided to the participant should be written in plain language. Guidelines for the essential elements to be included in both the sponsor summary and the participant informed consent were suggested.

It was acknowledged that many apps used in research require participants to agree to EULAs/Privacy Policies that contain exculpatory language, which plausibly (assuming these agreements count as part of the study materials or informed consent) conflicts with the regulatory prohibition on exculpatory language in the consent process. More work and guidance from regulatory bodies is needed to address this tension.

After discussing the risks associated with both "Bring Your Own Device" trials and trials that utilize commercially-available technologies, attendees engaged in a discussion about the relationship between personalized medicine and surveillance. In an increasingly technology-dependent world, there is an argument for moving away from the idea of data ownership and toward the idea of data stewardship.

Participants discussed the approach of the IRB to clinical trials involving mobile technologies. Data privacy and technology experts are now needed to assist the IRBs in assessing risk and benefit of protocols using mobile technologies. IRBs are increasingly considering the current social rules surrounding privacy and data sharing and whether the collected data are "chart-worthy," in other words, sufficiently reliable and usable as to belong in the participant medical chart. Together, attendees recognized the importance of providing additional information, such as device brochures, photos of the proposed device, and descriptions of the device's features,

to IRBs at the time of protocol submission so that an accurate assessment of the risks and benefits can be made, and the IRB can determine whether and what information should be communicated to the participant.

***Potential Future Work***

To advance and operationalize discussions of the impact of mobile technologies on clinical research, the following ideas were suggested as potential next steps:

- Foundational ethical work is needed on estimating risks and benefits of mHealth, balancing researcher obligations to act on incoming safety signals versus maintaining equipoise, and best practices for returning individual results in mHealth studies.
- Develop a training resource and a guidance document for IRB members that summarize the potential risks and benefits of mobile technologies in clinical research. Included in this document could be a set of questions to consider when reviewing mobile health protocols.
- Similarly, develop a training resource and guidance document for individuals with information technology in the organization charged with reviewing protocols that involve the use of mobile technologies. Develop a set of questions that will guide how to perform a technology assessment.
- Define a core set of information that sponsors could provide to investigators and IRBs at the time of protocol submission to assist in the review of mobile health trials.
- Develop educational materials for research participants with respect to mobile technologies.