INTRODUCTION: Unregulated Health Research Using Mobile Devices

Mark A. Rothstein and John T. Wilbanks

In recent years, new researchers have begun to complement investigators from academic medical centers; biotech, medical device, and pharmaceutical companies; non-governmental organizations; and government agencies. These independent researchers, citizen scientists, patient-directed researchers, DIY researchers, self-experimenters, and others have great potential to advance biomedical research, but they also present challenges with regard to such issues as informed consent, privacy, and independent review. Because the researchers are generally not federally funded or otherwise subject to federal research regulations, we refer to them as "unregulated" researchers.

Both regulated and unregulated researchers increasingly have utilized smartphones, tablets, and other mobile devices in recruitment, enrollment, data gathering and analysis, and dissemination of research findings. Mobile devices and their software applications facilitate the enrollment of large cohorts and enable participants to record a range of biometric and other measures. Both research platforms and health apps can play an important role in ensuring the scientific accuracy of the research and safeguarding the wellbeing of research participants. We investigated how the interests of participants, researchers, and the public can be addressed in an unregulated environment.

The study reported in this special supplement considered a wide range of issues. Our research plan contained the following four elements.

First, we conducted in-depth qualitative interviews to elicit thought leaders' perspectives on the risks and appropriate protections for participants in unregulated health research using mobile devices. We interviewed leaders in four categories: app and device developers, researchers using mobile devices, patient and research participant advocates, and regulatory and policy professionals. The interviews were conducted by our co-investigators from Vanderbilt University Medical Center, Laura M. Beskow, Kathleen M. Brelsford, and Catherine M. Hammack-Aviran. Their findings, reported in two articles in this symposium, helped to frame the issues for the study.

Second, we held four working group meetings to explore various aspects of the topic. In addition to the investigator team, the working group meetings involved the following three groups of individuals: working group authors (who participated at all four meetings and wrote articles for this symposium), working group discussants (who participated at all four meetings), and guest speakers (who presented at one of the working group meetings).

- **Working Group Meeting #1, La Jolla, CA, October 9-10, 2017**
  Surveying the Landscape: Technology, Researchers, and Participants
- **Working Group Meeting #2, Chicago, IL, April 24-25, 2018**
  Thought Leader Input and Regulatory Framework
- **Working Group Meeting #3, Atlanta, GA, October 25, 2018**
  Developing Ethical Guidelines and Policy Options
- **Working Group Meeting #4, Houston, TX, April 10, 2019**
  Formulating Policy Recommendations and Planning Publications

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Discussants:

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Cindy Geoghegan	Patients & Partners
Henry T. Greely	Stanford University
Steven Hershman	Stanford University
Katie Huber	23andMe
Marc Hurlbert	Melanoma Research Alliance
Gary E. Marchant	Arizona State University
Sally Okun	PatientsLikeMe
Kevin Patrick	University of California, San Diego
Patricia Spears	Alliance for Clinical Trials in Oncology

Guest Speakers:

Fuad Abujarad	Yale University
Sean Ahrens	Crohnology
Lori B. Andrews	Illinois Institute of Technology
Kevin Chaney	Department of Health and Human Services
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Steven Keating	Massachusetts Institute of Technology
Andrea M. Matwyshyn	Penn State University
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Third, we held two educational/informational workshops. On September 12, 2019, we hosted a workshop for mHealth app developers at the New York Genome Center in New York City. The purpose of the meeting was to discuss with developers the importance of incorporating principles of research ethics (e.g., consent, privacy, and transparency) into their apps. The workshop stressed that adding these features to health apps would not be costly or time-consuming, and the result would be a more valuable product. Video highlights of the workshop were posted online.

We also held a policy briefing at Georgetown University Law Center in Washington, DC, on November 12, 2019, which was hosted by the O'Neill Institute for National and Global Health Law. The purpose of the briefing was to inform policy makers and stakeholders about our study's findings and recommendations. Attendees included representatives of federal agencies, leaders from patient advocacy groups, IRB officials, unregulated researchers, and academics. Video highlights of the briefing were posted online.

Fourth, we published this open-access, special supplement of the *Journal of Law, Medicine & Ethics*. The articles include the results of our thought leader interviews, in-depth articles produced by our expert working group members, and a concluding article containing ethical considerations and policy recommendations developed by the investigators. The working group members are experts in diverse fields and have diverse views. Their articles represent their individual views, and they do not necessarily agree with all of the recommendations in the concluding article.

The investigator team included: University of Louisville: Mark A. Rothstein and Kyle B. Brothers; Sage Bionetworks: John T. Wilbanks and Megan Doerr; Cincinnati Children's Hospital Medical Center: Michelle L. McGowan; Vanderbilt University Medical Center: Laura M. Beskow, Kathleen M. Brelsford, and Catherine M. Hammack-Aviran; and University of Nevada, Las Vegas: Stacey A. Tovino. The investigators were aided by the excellent grant administration of Robert W. Klein.

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A final note. At the first meeting of the Working Group on October 9-10, 2017, the investigators and Working Group members were enthralled and inspired by Steven Keating, a brilliant and creative mechanical and materials engineer who responded to a brain tumor in graduate school by simultaneously earning a medical degree and dedicating his life to technological and societal innovations to advance health research and care. Steven died on July 19, 2019, at age 31. We are grateful that his powerful voice helped launch our research.

Note

The authors have no conflicts of interest to disclose.

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