

Research Ethics and Oversight in the Digital Age of Evolving Privacy Norms

By Sangy Panicker and Elisa A. Hurley

Over the last decade, advances in digital technology and the proliferation of mobile devices have afforded researchers unprecedented access to massive amounts of data generated by users. These developments have also provided researchers with access to a more diverse group of potential participants than was possible in traditional laboratory or clinic-based research. As a result, the digital revolution has expanded opportunities for researchers to study a wide range of complex human behaviors unobtrusively, as they occur in real-time. The sheer volume, types, and ways in which data using mobile, pervasive sensing, imaging, and other emerging digital technologies can be collected, analyzed, managed, stored, and shared for research purposes differs significantly from data obtained through traditional in-person laboratory experiments or clinical trials.

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This new research landscape is situated within the larger context of our everyday experience. The ubiquity of digital and mobile technologies has had a tremendous impact on our personal, professional, and social lives. Examples of such technologies and devices include smartphones, wearable

computing devices, social networking platforms, digital body sensors, and health apps. Artificial intelligence is now commonly embedded in many of these routinely used technologies. Algorithms and models evolve based on the personal information that people provide, allowing for personalized experiences of daily activities such as shopping, reading news articles, and watching movies. With the pervasive use of these technologies, people’s perceptions and norms about personal privacy continue to evolve. Evolving societal norms regarding privacy in general have implications for how one might think about privacy in the research setting. In today’s digital age, however, there is a blurring of lines between participating in research and going about everyday life: the data we generate in our daily activities could end up as research data, unbeknownst to us.

It is important to note that the education and training of researchers in the biomedical, behavioral, and social sciences typically equips them to be sensitive to and to incorporate ethical considerations into the design and conduct of their research. Academic programs in fields related to the development of digital technologies, such as information sciences, computer science, and engineering, on the other hand, do not typically include training in the ethics of research with human subjects, even though professionals in these disciplines may engage in research with human subjects or their data when assessing the validity, efficacy, and effectiveness of digital tools and technologies.

Challenging Questions for Research Oversight

This radically transformed research landscape raises challenging questions for the current research oversight system, including:

1. Are the foundational ethical principles elucidated in the Belmont Report adequate for addressing contemporary and emerging research ethics issues in the digital age?

2. How can the scientific community address the shortcomings and constraints of current regulations with respect to addressing the societal impacts of research using digital technologies?
3. How can the scientific community work within the confines of the current regulations to ensure that the rights and welfare of individuals are protected when the research involves new and emerging digital technologies such as artificial intelligence/machine learning?

Adequacy of Current Ethical Framework

There are efforts underway to assess the current ethical framework for research with human subjects in the digital age. One effort involves a collaboration between Public Responsibility in Medicine and Research (PRIM&R) and Drexel University that is funded by the National Science Foundation. The goals of this collaborative project are:

1. to explore how the ubiquity of digital technologies in everyday life impacts canonical concepts of research ethics such as privacy, confidentiality, consent, and justice;
2. to develop an ethical framework and guidance for (a) biomedical, behavioral, educational, and other social science research studies using digital technologies and (b) studies conducted by developers of digital tools and technologies—information scientists, computer scientists, and engineers—to assess the validity, efficacy, and effectiveness of digital tools and technologies; and
3. to promote the development of discipline-specific courses in the ethics of such research, based on the ethical framework and related guidance.

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Given the sheer magnitude of the issue, and the range of efforts afoot to address it, it will undoubtedly be a long while before the scientific community reaches consensus. More information about this project is available at <https://primr.org/resources/ethics-of-research-with-human-subjects-in-the-digi>.

In the meantime, the use of mobile, pervasive sensing, imaging, and other digital technologies in research involving participants and their data has grown exponentially. Especially in these last few years during the COVID pandemic, digital technologies have allowed researchers to avoid in-person contact with research participants. Thus, researchers and institutional review boards (IRBs) could benefit from guidance on the oversight, as well as the conduct, of research using digital technologies. In the absence of updated ethical precepts, standards, regulations, and guidance, two efforts to address ethical issues are underway.

Addressing Societal Impacts of Research Using Digital Technologies

Current regulations for the oversight of human subjects research (HSR) unequivocally direct IRBs to not consider the possible long-range effects of applying knowledge gained from research (e.g., the possible effects of the research on public policy) as among those research risks that fall within the purview of their responsibility (§46.111(a)(2)). However, given the rapid pace at which innovative digital technologies are developed and adopted by consumers, as well as the potential for powerful societal impact

from the ubiquitous use of these technologies and resulting data, it is incumbent on researchers and research institutions to extend their civic responsibility to include some level of oversight of such research. For example, recognizing the need to compensate for this shortcoming in the regulatory oversight of research using digital technologies, a program titled Ethics and Society Review (ESR) was created within the Ethics, Society, and Technology Hub at Stanford University. The mission of ESR is to help researchers with “mitigating negative and societal aspects of their research.” As a condition for receiving grant funding, researchers from participating programs are required to submit—for review by an interdisciplinary ESR Board—a proposal that includes the proposed study’s potential risks to society at large, as well as efforts to mitigate those risks. For more information about the program see <https://casbs.stanford.edu/ethics-society-review-stanford-university>.

A Practical Guide for Oversight of Research Involving Artificial Intelligence

Artificial intelligence (AI) is now commonly embedded in Internet browsers and other applications on mobile devices such as smartphones; these mobile devices are used as sources of research data. Technology developers often rely on user data to fine-tune algorithms and models, which in some instances may meet the regulatory definition of HSR. However, applying the current ethical framework and regulations to research involving AI and other emerging technologies can be challenging to IRBs for several reasons, including the lack of clear definition of AI. Absence of a clear understanding of the technology impacts an IRB’s ability to determine which projects meet the regulatory definition of HSR, assess the adequacy of the consent process, and conduct a risk-benefit analysis. But resources are being discussed and developed to assist IRBs with navigating this new terrain, such as an open-source AI checklist and decision tree for IRBs developed by Tamiko Eto (2021) and potential guidance from the U.S. Department of Health and Human Services’ Secretary’s Advisory Committee on Human Research Protections (SACHRP).

The pace of innovation and adoption of digital technologies by the public, and their impact on societal norms, all but guarantee that this new research landscape will remain dynamic. Tackling these challenges will require policy changes; education of stakeholders across the research enterprise; and, importantly, sustained dialogue with the public. ■

Reference

- Eto, T. (2021, December 29). Artificial intelligence human subjects research (AI HSR) IRB reviewer checklist (with AI HSR and exempt decision tree. IRB in translation. <https://etohconsulting.com/2021/12/29/artificial-intelligence-human-subjects-research-ai-hsr-irb-reviewer-checklist-with-ai-hsr-and-exempt-decision-tree>



Sangy Panicker, PhD, is the Director of Public Policy at Public Responsibility in Medicine and Research (PRIM&R). Prior to joining PRIM&R, she was the Director of Research Ethics at the American Psychological Association (APA).



Elisa A. Hurley, PhD, is the Executive Director of Public Responsibility in Medicine and Research (PRIM&R), leading the organization in executing its mission to advance the highest ethical standards in the conduct of research through educational, professional development, and public policy programs that serve the human and animal research communities.