

Report on Research Compliance Volume 21, Number 7. June 06, 2024 NIH Informed Consent Guide Focuses on Digital Health Technologies in Research

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“If you join this study, there is a potential risk that data you share may be accessed by someone without your permission or that someone may be able to identify you. These people may misuse the data you share with us in a way that leads to personal harm (e.g., discrimination). There may also be other risks that are not currently known. While we will do our best to protect your data, we cannot remove all risks.”^[1]

This is a paragraph that investigators could insert in informed consent documents for research involving digital health technologies, such as wearable devices, sensor technologies and mobile software applications—apps—accessed through phones, tablets and watches.

Biomedical and behavioral health researchers are increasingly using digital technologies, and while valuable, these may also pose atypical risks to participants related to third-party ownership and control of data, “including by commercial companies.”

Researchers and institutional review boards (IRBs) could use assistance and guidance with digital technologies, but the HHS Office for Human Research Protections, which has primary oversight of the ethical treatment of participants in NIH-funded studies, has not offered any insights on this topic. But now NIH has.

With these concerns in mind, NIH’s Office of Science Policy (OSP) issued a resource guide addressing risks and providing sample informed consent language for such studies. Timed to coincide with Clinical Trials Day (May 20), *Informed Consent for Research Using Digital Health Technologies: Points to Consider & Sample Language*, finalizes a draft NIH released for comment in October.

“Today, May 20th, is Clinical Trials Day; a day to reflect, recognize, and celebrate all that has been achieved through clinical trials and the participants, communities, researchers, clinical staff, and others who make these accomplishments possible. Clinical trials are at the heart of all medical advances. On behalf of OSP, thanks to all those who make clinical research possible,” officials said.^[2]

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