THE EVOLVING LANDSCAPE OF HUMAN RESEARCH WITH AI – PUTTING ETHICS TO PRACTICE

2024 EXPLORATORY WORKSHOP

By Marianna Azar

On September 19, 2024, the Office for Human Research Protections (OHRP) at the Department of Health and Human Services (HHS) hosted its 7th annual Exploratory Workshop focused on the use of artificial intelligence (AI) in biomedical and social and behavioral research.

The purpose of OHRP's Exploratory Workshops is to provide a platform for open dialogue and exchange of ideas among members of the regulated community. This workshop explored the ethical considerations and principles for governance pertaining to the use of AI in human research; considered some of the practical challenges of applying the Belmont Principles and the Common Rule to research involving AI; and contended with the challenge of maintaining public trust and aligning AI with human values.

The distinguished panel included speakers from industry, academia, think tanks, consultancy groups, and patient advocacy organizations. In setting the stage for the larger exploration of the topic, Kevin McKee, Staff Research Scientist with Google DeepMind, offered a myriad of ways in which AI can be defined and categorized. These definitions were interrogated in the presentations and discussions that followed, underlying the complexity of this topic and the challenge of identifying the right regulatory or policy approach to the use of AI tools in human research. In addressing the question of regulatory models and institutional practices, Stephanie Batalis, Research Fellow at the Center for Security and Emerging Technology at Georgetown University and Michael J. Pencina, Chief Data Scientist, Duke Health, both discussed key considerations for developing governance systems for the use of AI, stressing the need for flexibility, innovation, and inclusion of various research governance professionals, ethicists, and compliance experts into the process from the ground up.

As noted in the comments made by Craig Lipset, Co-Chair, Decentralized Trials & Research Alliance, the use of AI tools is changing the conduct of research and creating new opportunities and innovations in clinical trial design and conduct. The novel risks and the perceived magnitude of these risks have also prompted questions about activities that fall outside the Common Rule regulatory definitions of *research* and *human subject,* a subject explored in remarks by Iris Jenkins, Director of Research Integrity and Consultation, Virginia Tech. Benjamin C. Silverman, Senior Institutional Review Board Chair, Human Research Affairs, Mass General Brigham, addressed how the use of AI is testing the notions of personal privacy and identifiability of data and biospecimens. Expanding requirements for seeking and obtaining informed consent is a commonly suggested response to concerns surrounding the reach of AI. In her remarks, Sara Gerke, Associate Professor of Law and Richard W. & Marie L. Corman Scholar, University of Illinois Urbana-Champaign College of Law, reviewed the practical and theoretical implications for disclosing the role and use of AI in human research, concluding that such requirements may have the unintended consequence of further excluding people from research and potentially compromising the generalizability of research findings.

In the final session of the day, Reid Blackman, Founder and CEO, Virtue Consultants, and Karina Vold, Assistant Professor, Institute for the History and Philosophy of Science and Technology at the University of Toronto, debated the crucial question of how AI might impact autonomous decision-making and preference and value formation, ultimately shaping personhood. In a robust discussion, Dr. Vold argued for recognition of the unique and, in certain circumstances, grave danger posed by this technology and the need to align it with commonly held human norms and values that respect personal autonomy and authentic personhood, while Dr. Blackman underlined what he views as a common misunderstanding of what constitutes personal privacy and questioned what right any of us have to perceive our data as our own. In final remarks, Hugo Campos, Participant Ambassador, NIH All of Us Research Program, discussed the value AI holds for the patient and research participant and shared how his personal use of AI has empowered him to take more control over his medical care and wellbeing. Mr. Campos also suggested ways in which the research community could ensure that research participants and patients could be empowered through AI, including being transparent about its use and providing education and training to ensure proper use and recognition of the limitations of AI.

The event included three fruitful and rigorous panel discussions moderated by Jessica Vitak, Full Professor, College of Information, University of Maryland, Eric Mah, Associate Dean, Clinical and Translational Research, University of California, San Diego, and Jeffery Smith, Deputy Director, Certification & Testing Division, Office of the National Coordinator for Health IT, U.S. Department of Health and Human Services. In the opening address that Mr. Smith delivered, he spoke about HHS's efforts in technology and artificial intelligence and described the AI Lifecycle as a framework for public policy. This Exploratory Workshop follows past workshops on hot topics in research ethics, including Psychedelics Research, Payment for Participation, and Third-Party Research Risks.

The speakers' biographies, slides, event recording, and summary report are available on OHRP's website. Over 2,800 people have viewed the event as of the end of September.

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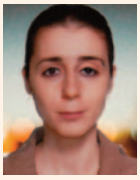

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