

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

## 2024 EXPLORATORY WORKSHOP

**Livestream on Thursday, September 19, 2024 | 9:45 a.m. - 4:15 p.m. ET**

*Registration not required | Access from event website*

The use of AI in biomedical and social and behavioral research raises fundamental questions about what impact these tools have on humans in the present and may have on us in the near future. We need to think about what AI to create, how to use it, what risks AI can pose, how we can prepare for and control these risks, and how this might inform future policy. This workshop will explore the ethical and practical considerations for the use of AI in research involving humans.

## AGENDA

Time	Sessions
	<b>Opening</b>
9:45 a.m.–10:00 a.m.	<b>Welcome from OHRP</b>
<b>Session 1</b>	<b>Exploring the Ethics and Governance Principles for Human Research with AI</b>
10:00 a.m.–11:20 a.m.	<b>Moderator:</b> Jessica Vitak, Ph.D. <i>Full Professor, College of Information, University of Maryland</i>  <b>1. Defining AI</b> Speaker: Kevin McKee, A.B., <i>Staff Research Scientist, Google DeepMind</i>  <b>2. How Is AI Currently Used in Research Involving Human Subjects?</b> Speaker: Craig Lipset, <i>Co-Chair, Decentralized Trials &amp; Research Alliance</i>  <b>3. How to Create a Responsible and Responsive Research Program for AI</b> Speaker: Reid Blackman, Ph.D., <i>Founder and CEO, Virtue Consultants</i>  <b>4. Governance Across the AI Spectrum: Key Considerations from Data to Deployment</b> Speaker: Stephanie Batalis, Ph.D. <i>Research Fellow, Center for Security and Emerging Technology, Georgetown University</i>  <b>5. Creating a Trustworthy Health AI Ecosystem – Establishing Best Practices Based on Principles of Equity, Fairness, Safety, Transparency, and Reliability from the Outset</b>  Speaker: Michael Pencina, Ph.D., <i>Chief Data Scientist, Duke Health, Vice Dean for Data Science, Director of Duke AI Health Professor of Biostatistics &amp; Bioinformatics, Duke University School of Medicine</i>
11:20 a.m.–12:00 p.m.	<b>Panel Discussion</b>
12:00 p.m.–1:00 p.m.	<b>Lunch</b>

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<b>Session 2</b>	<b>Examining the Challenges of Applying the Belmont Principles and the Common Rule to Research Involving AI</b>
<b>1:00 p.m. – 1:50 p.m.</b>	<p><b>Moderator:</b> Eric Mah, Ed.D., M.H.S., <i>Associate Dean, Clinical and Translational Research, University of California, San Diego</i></p> <ol style="list-style-type: none"> <li><b>Key Regulatory Terms and AI Tools in Human Subjects Research (HSR)</b> Speaker: Iris Jenkins, Ph.D., <i>Director of Research Integrity and Consultation, Virginia Tech</i></li> <li><b>How Does the Use of AI in Research Test the Notions of Personal Privacy and Identifiability of Data or Biospecimens?</b> Speaker: Benjamin C. Silverman, M.D., <i>Senior IRB Chair, Human Research Affairs, Mass General Brigham; Director of Ethics, McLean Institute for Technology in Psychiatry, McLean Hospital; Instructor in Psychiatry and Faculty Member in the Center for Bioethics, Harvard Medical School, Mass General Brigham/McLean Hospital/Harvard Medical School</i></li> <li><b>Disclosing the Role and Use of AI in HSR</b> Speaker: Sara Gerke, Dipl.-Jur. Univ., <i>Associate Professor of Law and Richard W. &amp; Marie L. Corman Scholar, University of Illinois Urbana-Champaign College of Law</i></li> </ol>
<b>1:50 p.m. – 2:30 p.m.</b>	<b>Panel Discussion</b>
<b>2:30 p.m. – 2:45 p.m.</b>	<b>Break</b>
<b>Session 3</b>	<b>Exploring the Challenges with Maintaining Public Trust and Aligning AI with Human Values</b>
<b>2:45 p.m. – 3:35 p.m.</b>	<p><b>Moderator:</b> Jeffery Smith, M.P.P., <i>Deputy Director, Certification &amp; Testing Division, Office of the National Coordinator for Health IT, U.S. Department of Health and Human Services</i></p> <ol style="list-style-type: none"> <li><b>Data Privacy Isn't as Important as You Think</b> Speaker: Reid Blackman, Ph.D., <i>Founder and CEO, Virtue Consultants</i></li> <li><b>AI and Values: Alignment, Privacy, and Autonomy</b> Speaker: Karina Vold, Ph.D., <i>Assistant Professor, Institute for the History and Philosophy of Science and Technology, University of Toronto</i></li> <li><b>The Role of AI in Biomedical and Health Research - A Research Participant's Perspective</b> Speaker: Hugo Campos, <i>Participant Ambassador, NIH All of Us Research Program</i></li> </ol>
<b>3:35 p.m. – 4:15 p.m.</b>	<b>Panel Discussion</b>
<b>4:15 p.m.</b>	<b>Closing</b>