



WORLD **PRIVACY** FORUM

Emerging Technologies, Human Subject Research, and the Common Rule: *High level overview of the 2023 OHRP Research Community Forum*

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Earlier this month, the World Privacy Forum (WPF) attended the [OHRP Research Community Forum](#) in Knoxville, TN. This was a joint conference presented by the [U.S. Department of Health and Human Services Office for Human Research Protections \(OHRP\)](#), [East Tennessee State University](#), [Oak Ridge Associated Universities](#), and the [University of Tennessee, Knoxville](#). Most of the attendees were Institutional Review Board (IRB) members and university and health facility research administrators; all are regular participants in the conduct or oversight of human subjects research. Through lively speaker presentations and interactive discussions addressing research case scenarios, conference participants contemplated how emerging technologies including Artificial Intelligence (AI) and evolving data forms such as biometrics and location data affect application of the [Common Rule in new environments](#).

The Common Rule for the protection of human research subjects applies to federally-funded entities and establishes federal standards, procedures, protections, and rights

for those who conduct or are subjects of research. Other countries have comparable research standards and privacy protections.

The Knoxville Forum speakers included Professor Renée Cummings, AI ethicist and Data Activist in Residence at the University of Virginia's School of Data Science; Yvonne Lau, director of OHRP's Division of Education and Development; Jacob Metcalf, Ph.D. and leader of the AI on the Ground Initiative at the Data and Society Research Institute; and Ivor Pritchard, senior advisor to the director of OHRP.

Together, they presented research concepts and analysis regarding research participant identity protections amid novel re-identification techniques, the shifting meaning of public data, secondary research use of genomic and biospecimen data, and the impact of the private sector on the research landscape. There is a lot of new ground to cover.

Some key sessions and topics included:

- Interactive workshops analyzing research case scenarios involving mobile apps, the use of open-source software, location and social media data, mental health chatbots, and other emerging technology factors affecting human subjects research,
- A discussion about balancing study recruitment goals with the need for meaningful informed consent when research involves complex data gathering systems and devices, and,
- A presentation entitled "Big Data Research" addressing the blurring distinctions between public and private data.

OHRP's recent work signals that these issues are top-of-mind in the research community and at the agency. The Knoxville forum follows work dating from October 2022, in which the HHS Secretary's Advisory Committee on Human Research Protections (SACHRP) addressed many of these same issues in its [*IRB Considerations on the Use of Artificial Intelligence in Human Subjects Research*](#).

It is too early to ascertain the dynamics of how the Common Rule will be interpreted amidst new technological shifts such as AI. Indeed, it is not yet known whether the rule will retain its place as a foundation for all human subject research protections, or if there will be new HHS guidance on AI that addresses the challenges of new technology. The SACHRP's recent work and educational conferences like the one held in Knoxville seek to define next steps to ensure the Common Rule protects individuals in current and future research environments.

Old issues familiar to WPF arise anew with changing technologies. For instance, in its sessions, OHRP staff suggested the agency may need to establish new criteria for evaluating the conditions of confidentiality provisions of shared private and public data. How to prevent re-identification of health data stripped of identifiers is a continuing issue under the federal HIPAA health privacy rules. AI and other technologies only put more pressure on policy makers to update existing rules.

The Knoxville conference outlined the contours of an important conversation regarding AI and human subjects research, but it will take time to fill the gaps in meaningful ways, and none of this will be easy.

Related World Privacy Forum Work regarding the Common rule and Human Subject Research:

- **WPF comments regarding Confidentiality of Substance Use Disorder Patient Records, 42 CFR Part 2, 45 CR Part 164. 2023:** ([PDF, 10 pages](#)) https://www.worldprivacyforum.org/wp-content/uploads/2023/01/WPF_Comments_HHS_Confidentiality_Substance_Use_Disorder_Patient_Records_26Jan2023_fs.pdf
- **Comments of the World Privacy Forum to the Secretary's Advisory Committee on Human Subject Research Protections regarding the SACHRP AI Framework:**

2022 (PDF, 7 pages) https://www.worldprivacyforum.org/wp-content/uploads/2022/08/WPF_Comments_SACGHS_AI_Frameowrk_July2022_fs.pdf

- **WPF Report: *Privacy, the Precision Medicine Initiative, & the All of Us Research Program: Will Any Legal Protections Apply?* By Robert Gellman and Pam Dixon Second Edition, March 2017 Revised, includes 21st Century Cures Act.** (PDF, 39 pages) http://www.worldprivacyforum.org/wp-content/uploads/2017/03/WPF_PrecisionMedicineInitiative_2nd_ed_March14_2017_fs.pdf
- **WPF Comments on Federal Proposal For Human Subject Research (Common Rule). 2016:** (PDF, 30 pages) http://www.worldprivacyforum.org/wp-content/uploads/2016/01/WPF_CommentsNPRM_CommonRule_Jan2016_fs.pdf
- **Comments of the World Privacy Forum to the Presidential Commission for the Study of Bioethical Issues. 2012:** (PDF, 5 pages) http://www.worldprivacyforum.org/wp-content/uploads/2012/05/WPF_Comments_PresidentialCommissionBioEthics_May152012_fs.pdf
- **WPF Comments on Proposed changes to the HIPAA Privacy Rule regarding Accounting of Disclosures under the Health Information Technology for Economic and Clinical Health Act. 2011:** (PDF, 20 pages) http://www.worldprivacyforum.org/wp-content/uploads/2011/08/WPF_HIPAA_August2011_fs.pdf
- **Comments of the World Privacy Forum regarding Request for Information Regarding Sections 101 Through 104 of the Genetic Information Nondiscrimination Act of 2008. 2008** (PDF, 11 pages) http://www.worldprivacyforum.org/wp-content/uploads/2008/12/WPF_GINA_Dec09_2008_fs.pdf

- **World Privacy Forum Comments regarding OHRP Human Subjects Protection, Training, and Education. 2008:** (PDF, 8 pages) http://www.worldprivacyforum.org/wp-content/uploads/2008/09/WPF_OHRP_09222008fs.pdf
- **Comments of the World Privacy Forum on the Draft Report on Policy Issues Associated with Undertaking a Large U.S. Population Cohort Project on Genetics, Environment, and Disease, prepared for the Office of the Secretary, Health and Human Services, Secretary's Advisory Committee on Genetics, Health, and Society; the National Institutes of Health; U.S. Public Health Service. 2006:** (PDF, 9 pages) http://www.worldprivacyforum.org/wp-content/uploads/2006/07/WPF_comments_HHS_SACGHSfs.pdf

Related documents and links:

- **OHRP Research Community Forum:** <https://www.orau.org/event/research-forum/index.html>
- **HHS Office of Human Research Protection:** <https://www.hhs.gov/ohrp/index.html>
- **HHS, Revised Common Rule:** <https://www.hhs.gov/ohrp/regulations-and-policy/regulations/finalized-revisions-common-rule/index.html>
- **IRB Considerations on the Use of Artificial Intelligence in Human Subjects Research:** <https://www.hhs.gov/ohrp/sachrp-committee/recommendations/irb-considerations-use-artificial-intelligence-human-subjects-research/index.html>
- **East Tennessee State University:** <https://www.etsu.edu/ehome/>
- **Oak Ridge Associated Universities:** <https://www.orau.org/>
- **University of Tennessee, Knoxville:** <https://www.utk.edu/>