

Stephanie Weiner  
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1401 Constitution Ave. N.W., Washington, D.C. 20230

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**Re: NTIA-2024-0004 [Docket No. 241204-0309]**  
Request for Comment: Ethical Guidelines for Research Using Pervasive Data  
<https://www.regulations.gov/document/NTIA-2024-0004-0001>

*Submitted electronically via Regulations.gov*

Dear Chief Counsel Weiner,

The Multi-Regional Clinical Trials Center of Brigham and Women's Hospital and Harvard (“MRCT Center”) appreciates the opportunity to comment on the National Telecommunications and Information Administration (“NTIA”) potential writing of “Ethical Guidelines for Research Using Pervasive Data” published at [Fed. Reg. On December 11, 2024](#), by the Department of Commerce. With the increasing ubiquity of data collection, storage, and use, this writing is timely.

The MRCT Center is a research and policy center that seeks to improve the ethics, conduct, oversight, and regulatory environment of international, multi-site clinical trials. Founded in 2009, it functions as an independent convener to engage diverse stakeholders from industry, academia, patients and patient advocacy groups, non-profit organizations, and global regulatory agencies. The MRCT Center focuses on pre-competitive issues, to identify challenges and to deliver ethical, actionable, and practical solutions for the global clinical trial enterprise. The responsibility for the content of this document rests with the leadership of the MRCT Center, not with its collaborators nor with the institutions with which its authors are affiliated.<sup>1</sup>

While our focus is on clinical research and use of data in health-related contexts, we are commenting here on the use and misuse of data generally. Below are recommendations to enhance the ethical challenges for the implementation of the proposed writing.

### *Recommendations*

We commend the NTIA’s first step in addressing the widespread issue of how independent third-party researchers can work with pervasive data while meeting the ethical expectations of research and protecting individuals' privacy and other rights. Since there is an inability to retreat on the data that exists publicly, there must be greater protections for the data of individuals and

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<sup>1</sup>Brigham and Women’s Hospital, Mass General Brigham, Harvard Medical School, and Harvard University.

communities, and consequences for its misuse, as the greatest risk in this context is to the data subjects.

The Genetic Information Nondiscrimination Act (“GINA”) is seemingly limited in its protections. To mitigate this gap in legislation and construct reliable safeguards, expanded legislative measures, including the extension of its protections beyond employment and limited insurance provisions, are critically important to prevent misuse not only of genetic information but also personal data.

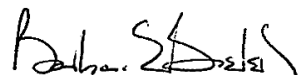
Mandating disclosure of data sources and methodologies in addition to funding entities can help establish mechanisms for accountability. Transparency and accountability are the cornerstone of an ethical foundation that should be utilized as such. Similarly, this includes ethical oversight. Implementing continuous ethical oversight, including post-research evaluations to assess long-term impacts on participants and communities can add to how ethical standards are maintained beyond initial approval.

As public trust in science erodes, it is pressing that this writing recognizes the impact on public confidence in data protections. Compliance with robust legal and governance standards, such as those promulgated by the General Data Protection Regulation (“GDPR”) should be considered for upholding public confidence in research.

Because of the significant implications for privacy legislation, participant protections, and the equitable application of emerging technologies, there must be civil and criminal consequences for the misuse of data. Appropriate use should be clearly defined. Definitions should be periodically reviewed to ensure the appropriate interpretation of inevitable data and data use changes. Given the rapidity with which data is being accumulated and used, and the unpredictability of innovation in data science, any ethical framework should be periodically revisited and revised with broad input from researchers and data scientists, and, importantly, civil society.

By integrating these recommendations, NTIA can strengthen its ethical guidelines to better navigate the complexities of pervasive data research, ensuring they are conducted responsibly.

Respectfully submitted,



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On behalf of Sarah A White, MPH, Julia S Etkin, BA, and the MRCT Center