



April 24, 2023

NIH Office of Science Policy
National Institutes of Health
6705 Rockledge Dr #750
Bethesda, MD 20817

Re: NOT-OD-23-091, Request for Information on the NIH Plan to Enhance Public Access to the Results of NIH-Supported Research

Submitted electronically at: <https://osp.od.nih.gov/nih-plan-to-enhance-public-access-to-the-results-of-nih-supported-research>

Dear NIH Office of Science Policy,

The Alliance for Nursing Informatics (ANI) appreciates the opportunity to comment as nursing stakeholders on the NIH Plan to Enhance Public Access to the Results of NIH-Supported Research.

[The Alliance for Nursing Informatics](#) (ANI), co-sponsored by AMIA and HIMSS, advances nursing informatics leadership, practice, education, policy, and research through a unified voice of nursing informatics organizations. We transform health and healthcare through nursing informatics and innovation. ANI is a collaboration of organizations representing more than 25,000 nurse informaticists and bringing together 29 distinct nursing informatics groups globally. ANI crosses academia, practice, industry, and nursing specialty boundaries and collaborates with the more than 4 million nurses in practice today.

We fully support the goals of the NIH Plan to Enhance Public Access to the Results of NIH-Supported Research, aligning with the U.S. Government's directive for "Ensuring Free, Immediate, and Equitable Access to Federally Funded Research" and acknowledge the central role patients and the public play in health care and health research. Recognizing the importance of patient engagement in these initiatives to building the infrastructure for research dissemination and improving care delivery, it is equally important that the plan does not supersede patient privacy and autonomy. We provide the following recommendations for your consideration:

1. Steps for improving equity in access and accessibility of publications.

We applaud the NIH's aims to improve equity in access to publications by diverse communities of users. Our research shows that returning study findings to patients increases trust in the scientific process, especially for underrepresented groups.¹ Therefore, we propose that NIH

¹ Mangal S, Niño de Rivera S, Choi J, et al. Returning study results to research participants: Data access, format, and sharing preferences. *Int J Med Inform.* 2023;170:104955.

consider two important features of access and accessibility, namely: (1) findability and (2) comprehensibility.

Many members of the American public may be unfamiliar with scholarly resources and instead rely on mainstream media for their scientific news, which may contribute to misinformation and misinterpretation of findings.² To improve findability, NIH should consider partnering with mainstream platforms to drive readers to the source of information on the NIH's website (e.g., PubMed).

Disparities in consumer health literacy, literacy, and numeracy skills decrease comprehension of scientific abstracts.³ Lay interpretations of abstracts with published manuscripts on publicly accessible platforms (e.g., PubMed) are needed. For example, generative artificial intelligence and machine learning platforms could assist scientists in producing lay abstracts. Providing easy-to-read and interpretable abstracts will promote broader comprehension by the lay public and help reduce misinterpretations associated with scholarly publications.

2. **Early input on considerations to increase findability and transparency of research.**

ANI appreciates the NIH's [2023 Data Management & Sharing Policy](#) with the inclusion of justifiable reasons for limiting data sharing. However, in practice, our members note that grant management teams remain unclear on the precise interpretation of these guidelines and what constitutes a strong rationale for limiting data sharing.

Our concern focuses on the number of specific types of health data for which persistent identifiers (PIDs) and metadata would significantly compromise patient confidentiality. First, electronic health records (EHRs) used in research are easily re-identifiable,⁴ and the risk of re-identification is higher when external metadata are available.⁵ Attempts to fully de-identify EHR datasets (e.g., date removal) render the data meaningless for research purposes. Second, data from wearable devices, such as smartphones and smartwatches, are growing in use for health research to collect sensitive data, such as reproductive health, and granular, continuous data about individuals' locations and behaviors. The exposure of these data through public repositories represents risks for those participating in research for stigmatized conditions (e.g., mental health, sexually transmitted infections) and those that are subject to changing laws, for which the patient and/or their healthcare professionals may be criminally liable (e.g., limited reproductive rights).⁶ Third, transcripts from qualitative interviews can never be truly anonymized; even with the omission of names and other overtly identifying information,

² Funk C, Gottfried J, Mitchell A. Science news and information today. Pew Research Center's Journalism Project. Published September 20, 2017. Accessed April 16, 2023. <https://www.pewresearch.org/journalism/2017/09/20/science-news-and-information-today/>

³ Prince LY, Schmidtko C, Beck JK, Hadden KB. An Assessment of Organizational Health Literacy Practices at an Academic Health Center. *Qual Manag Health Care*. 2018;27(2):93-97. doi:10.1371/journal.pone.0028071

⁴ El Emam K, Jonker E, Arbuckle L, Malin B. A systematic review of re-identification attacks on health data. *PLoS One*. 2011;6(12):e28071. <https://doi.org/10.1371/journal.pone.0028071>

⁵ Xia W, Liu Y, Wan Z, et al. Enabling realistic health data re-identification risk assessment through adversarial modeling. *J Am Med Inform Assoc*. 2021;28(4):744-752. doi:10.1093/jamia/ocaa327

⁶ Dong Z, Wang L, Xie H, Xu G, Wang H. Privacy Analysis of Period Tracking Mobile Apps in the Post-Roe v. Wade Era. In: *Proceedings of the 37th IEEE/ACM International Conference on Automated Software Engineering*. ASE '22. Association for Computing Machinery; 2023:1-6. <https://doi.org/10.1145/3551349.3561343>

qualitative research is inherently personal and involves sharing personal experiences and perspectives.⁷

The evidence demonstrates participant trust in research can erode when participants have limited control over how and with whom their personal health data is shared.¹ Exposure of these data types and other sensitive data not explicitly mentioned through public repositories may inadvertently discourage patients from participating in medical research. Patients may also hesitate to seek care at academic medical centers where their medical records may be used for research. In particular, this may deter participation among racial and ethnic minority groups whose trust in medical research may already be limited.⁸

Additionally, data-sharing policies are much stricter in Canada, the European Union, and many other countries globally where U.S. researchers conduct NIH-funded research.⁹ These differences across countries complicate matters for researchers and grant administrator teams attempting to comply with differing and sometimes competing data-sharing policies between the U.S. and other countries.

Therefore, while PIDs combined with metadata can promote transparency, increased scientific integrity, and public trust in research, we suggest increased guidance and clarity on specific justifications for limiting data sharing and to address researchers' uncertainty about the appropriateness of particular research contexts that justify withholding.

Thank you for the opportunity to comment on the NIH Plan to Enhance Public Access to the Results of NIH-Supported Research.

Sincerely,



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ANI Co-chair



Nancy Beale, Ph.D., RN-BC
ANI Co-chair

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⁷ Saunders B, Kitzinger J, Kitzinger C. Anonymising interview data: challenges and compromise in practice. *Qual Res.* [2015;15\(5\):616-632. https://doi.org/10.1177/1468794114550439](#)

⁸ Milani SA, Swain M, Otufowora A, Cottler LB, Striley CW. Willingness to Participate in Health Research Among Community-Dwelling Middle-Aged and Older Adults: Does Race/Ethnicity Matter? *J Racial Ethn Health Disparities.* 2021;8(3):773-782. [https://doi.org/10.1007/s40615-020-00839-y](#)

⁹ Rehm HL, Page AJH, Smith L, Adams JB, Alterovitz G, Babb LJ, Barkley MP, Baudis M, Beauvais MJS, Beck T, Beckmann JS, Beltran S, Bernick D, Bernier A, Bonfield JK, Boughtwood TF, Bourque G, Bowers SR, Brookes, AJ . . . & Birney E. GA4GH: International policies and standards for data sharing across genomic research and healthcare. *Cell Genom.* 2021 Nov 10;1(2):100029. doi:[10.1016/j.xgen.2021.100029](#)

innovation. ANI is a collaboration of organizations representing more than 25,000 nurse informaticists and bringing together 29 distinct nursing informatics groups globally. ANI crosses academia, practice, industry, and nursing specialty boundaries and collaborates with the more than 4 million nurses in practice today. [Contact ANI.](#)