

Dated: September 21, 2023.

Lawrence A. Tabak,

Acting NIH Director, National Institutes of Health.

[FR Doc. 2023–21233 Filed 9–27–23; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Request for Information (RFI): Inviting Comments and Suggestions on Opportunities and Challenges for the Collection, Use, and Sharing of Real-World Data (RWD) Including Electronic Health Records, for National Institutes of Health (NIH) Supported Biomedical and Behavioral Research

AGENCY: National Institutes of Health, HHS.

ACTION: Request for information.

SUMMARY: The purpose of this National Institutes of Health (NIH) Request for Information (RFI) is to solicit public comments on the use of Real-World Data (RWD), including Electronic Health Records, for Biomedical and Behavioral Research.

DATES: The NIH RFI is open for public comment. To assure consideration, your response must be received by December 14, 2023, 11:59 p.m. (ET).

ADDRESSES: All comments must be submitted electronically on the submission website at <https://datascience.nih.gov/rfi-rwd>.

Responses must be received by 11:59:59 p.m. (ET) on December 14, 2023.

Responses to this RFI are voluntary and may be submitted anonymously. You may voluntarily include your name and contact information with your response. If you choose to provide NIH with this information, NIH will not share your name and contact information outside of NIH unless required by law.

Other than your name and contact information, please do not include any personally identifiable information or any information that you do not wish to make public. Proprietary, classified, confidential, or sensitive information should not be included in your response. The Government will use the information submitted in response to this RFI at its discretion. Other than your name and contact information, the Government reserves the right to use any submitted information on public websites, in reports, in summaries of the state of the science, in any possible resultant solicitation(s), grant(s), or

cooperative agreement(s), or in the development of future funding opportunity announcements. This RFI is for informational and planning purposes only and is not a solicitation for applications or an obligation on the part of the Government to provide support for any ideas identified in response to it. Please note that the Government will not pay for the preparation of any information submitted or for use of that information.

We look forward to your input and hope that you will share this RFI opportunity with your colleagues.

FOR FURTHER INFORMATION CONTACT:

Questions about this request for information should be directed to Dr. Susan Gregurick, 301–435–1923, RWD-rfi@od.nih.gov, National Institutes of Health, Office of Data Science Strategy, 9000 Rockville Pike, Bethesda, Maryland 20892.

SUPPLEMENTARY INFORMATION: The National Institutes of Health (NIH) is requesting public comment on the use of Real World Data (RWD) for NIH supported biomedical and behavioral research, including opportunities for leveraging the benefits of RWD and strategies for responsible use. NIH also seeks to better understand community perspectives on the potential value and constraints—including scientific, administrative, legal, business, and bioethical—for the greater use of RWD in NIH-sponsored biomedical and behavioral research. This request for information (RFI) is in accordance with 42 U.S.C. 281 as amended.

Background

Researchers are increasingly using data collected in real-world settings to augment traditional research studies, as well as develop more effective treatments and interventions for patients. These “real-world data (RWD)”, defined by the U.S. Food and Drug Administration, are data relating to patient health status and/or the delivery of health care routinely collected from a variety of sources. Examples of RWD include data derived from electronic health records, medical claims data, data from product or disease registries, and data gathered from other sources (such as digital health technologies) that can inform on health status. While these data hold tremendous promise for biomedical and behavioral research, they can be collected from a variety of sources through multiple mechanisms, creating challenges for researchers and questions for those whose data are being shared.

Importantly, NIH is committed to ensuring participant privacy and

autonomy are protected in all NIH-supported research. As NIH establishes health-related research data platforms that include access to RWD, NIH continues to prioritize maximizing data access while upholding participant preferences regarding the collection and use of their data. Most recently, through the Advisory Committee to the NIH Director, (<https://www.acd.od.nih.gov/index.html>), NIH staff met with stakeholders to better understand their perspectives on benefits and risks of combining and using human datasets, particularly from disparate sources (e.g., research and non-research settings) and how their data should be used in biomedical and behavioral research. NIH will continue working to incorporate these perspectives in its research studies to build trust and honor participant preferences. Input requested on this RFI will be used to inform NIH’s continuing development of guidance on the use of RWD for research and assist in the planning for appropriate mechanisms and programs for research with RWD.

Information Requested

NIH is requesting public comment on the use of RWD for NIH-supported biomedical and behavioral research, including opportunities for leveraging the benefits of RWD and strategies for its responsible use. NIH also seeks to better understand community perspectives on the potential value and constraints—including scientific, administrative, legal, business, and bioethical—for the increased use of RWD in biomedical and behavioral research.

Response to this RFI is voluntary and may be submitted anonymously. Respondents are free to address any or all topics listed below, as well as other relevant topics, for NIH’s consideration.

1. *Scientific value and quality considerations for collection, use, and sharing of RWD in biomedical and behavioral research.* NIH seeks broad input on how RWD is acquired and used in NIH-funded research, the demonstrated and anticipated value of RWD in research, and opportunities and challenges related to data standards and quality, representativeness, and potential biases for using RWD in research. Additionally, NIH is seeking information on:

(a) Biomedical and behavioral research questions that could be investigated using RWD, including novel unanticipated insights that have been enabled by using RWD in research.

(b) Barriers to using RWD in research, such as bias, underrepresentation of populations in data, and technical

issues of data harmonization and linkage.

2. *Using RWD as part of the scientific paradigm, including open science, scientific rigor and reproducibility, and team science.* NIH seeks broad input on the opportunities and challenges related to using RWD as part of the scientific process.

(a) Approaches or methods for using RWD in collaborative teams and ensuring reproducibility.

(b) How do researchers assess the validation and verification of RWD data that is used in research.

(c) Appropriate open science practices and use of the FAIR principles (<https://www.nature.com/articles/sdata201618>) for research using RWD and approaches for maximizing appropriate data sharing when expected by the NIH Policy for Data Management and Sharing (<https://sharing.nih.gov/data-management-and-sharing-policy>) or other policies.

3. *Administrative and logistical considerations for collecting, using, and sharing RWD for biomedical and behavioral research.* NIH seeks broad input on the opportunities and challenges related to the process of acquiring, using, and making RWD available for biomedical and behavioral research, including:

(a) Pros and cons of various approaches for obtaining RWD through algorithms, purchasing RWD through trusted parties, accessing RWD through secure enclaves, etc.

(b) Considerations regarding licensing, costs, third party involvement, and restrictions for data use and sharing.

(c) Availability/utility of emerging de-identification technologies and data storage/sharing considerations.

4. *Ethical considerations for using RWD for biomedical and behavioral research.* NIH seeks broad input on the opportunities and challenges related to potential bioethical issues regarding the collection, use, and sharing of RWD, including:

(a) Strategies for protecting participant privacy and autonomy.

(b) Potential re-identification risks for RWD, including the technical feasibility of re-identifying linked data and the possibility of anonymity for patients, research participants, and their families.

(c) Ethical implications of data as a "commodity", in terms of buying and selling personal health data.

This RFI is for planning purposes only and should not be construed as a solicitation for applications or proposals, or as an obligation in any way on the part of the United States Government. The Government will not pay for the preparation of any

information submitted or for the Government's use. Additionally, the Government cannot guarantee the confidentiality of the information provided.

Dated: September 21, 2023.

Tara A. Schwetz,

Acting Principal Deputy Director, National Institutes of Health.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Establishment of the Social and Community Influences on Health Integrated Review Group

Pursuant to the Federal Advisory Committee Act, as amended (5 U.S.C. 1001-1014), the Director, National Institutes of Health (NIH) announces the establishment of the Social and Community Influences on Health Integrated Review Group (IRG) as authorized by 42 U.S.C. 282(b)(16), section 402(b)(16) of the Public Health Service Act, as amended.

The Director, NIH, has determined that the Social and Community Influences on Health IRG is in the public interest in connection with the performance of duties imposed on NIH by law, and that these duties can best be performed through the advice and counsel of the committee.

The committee provides advice and recommendations on funding applications and proposals, including but not limited to, the scientific and technical merit of applications for grants-in-aid for research, research training, or research-related grants and cooperative agreements, or contract proposals relating to scientific areas relevant to social, interpersonal, community, and cultural influences on health, development, and well-being across the life span.

Inquiries may be directed to Claire Harris, Director, Office of Federal Advisory Committee Policy, Office of the Director, National Institutes of Health, 6701 Democracy Boulevard, Suite 1000, Bethesda, Maryland 20892 (Mail code 4875), Telephone (301) 496-2123, or Claire.Harris@nih.gov.

Dated: September 21, 2023.

Lawrence A. Tabak,

Acting NIH Director, National Institutes of Health.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Notice of Meeting

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the Board of Scientific Counselors, National Cancer Institute.

This meeting will be a hybrid meeting held in-person and virtually and will be open to the public as indicated below with attendance limited to space available. Individuals who plan to attend in-person or view the virtual meeting and need special assistance or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting. The open session can be accessed from the NIH Videocast at the following link: <http://videocast.nih.gov/>.

The meeting will be closed to the public as indicated below in accordance with the provisions set forth in sections 552b(c)(6), title 5 U.S.C., as amended for the review, discussion, and evaluation of individual intramural programs and projects conducted by the National Cancer Institute, including consideration of personnel qualifications and performance, and the competence of individual investigators, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Board of Scientific Counselors, National Cancer Institute.

Date: November 13, 2023.

Open: 10:00 a.m. to 10:30 a.m.

Agenda: Remarks from the NCI Director.

Closed: 10:30 a.m. to 4:00 p.m.

Agenda: Personnel qualifications and performance, and competence of individual investigators.

Name of Committee: Board of Scientific Counselors, National Cancer Institute.

Date: November 14, 2023.

Closed: 11:00 a.m. to 1:45 p.m.

Agenda: Personnel qualifications and performance, and competence of individual investigators.

Place: National Institute of Health, Building 31, C Wing, 6th Floor, Conference Room C, 9000 Rockville Pike, Bethesda, MD 20892 (Hybrid Meeting).

Contact Person: Brian E. Wojcik, Ph.D., Senior Review Administrator, Institute Review Office, Office of the Director, National Cancer Institute, National Institutes of Health, 9609 Medical Center Drive, Room 3W414, Rockville, MD 20850, 240-276-5660, wojcikb@mail.nih.gov.

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when