
**NOVEL AND EXCEPTIONAL TECHNOLOGY AND RESEARCH ADVISORY
COMMITTEE**

Minutes of Meeting

July 14, 2022

**U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service
National Institutes of Health**

**U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
NATIONAL INSTITUTES OF HEALTH (NIH)
NOVEL AND EXCEPTIONAL TECHNOLOGY AND RESEARCH ADVISORY
COMMITTEE (NExTRAC)**

Minutes of Meeting

July 14, 2022

MEMBERS IN ATTENDANCE

Cinnamon Bloss, Ph.D. (Chair)
Zach N. Adelman, Ph.D.
Lorraine M. Albritton, Ph.D.
Kathleen Boris-Lawrie, Ph.D.
Gigi Kwik Gronvall, Ph.D.
Benhur Lee, M.D.
Alan I. Leshner, Ph.D.
Pilar N. Ossorio, Ph.D., J.D.
Kenneth Oye, Ph.D.
Matthew Porteus, M.D., Ph.D.
Margaret F. Riley, J.D.
Leigh Turner, Ph.D.

INCOMING/AD HOC MEMBERS IN ATTENDANCE

Angela C. Birnbaum, M.P.H.
Shawneequa Callier, J.D.
Insoo Hyun, Ph.D.
Kevin O. Saunders, Ph.D.

NExTRAC is a federal advisory committee that provides recommendations to the NIH Director and serves as a public forum for the discussion of the scientific, safety, and ethical issues associated with emerging biotechnologies. NExTRAC proceedings, reports, and links to meeting videocasts are posted on the [Office of Science Policy website](#) to enhance their accessibility to the scientific and lay public.

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WELCOME AND REMINDER OF CHARGE

Cinnamon Bloss, Ph.D., NExTRAC Chair, and Jessica Tucker, Ph.D., NExTRAC Executive Secretary

Dr. Bloss called the virtual meeting to order at 1:00 p.m. ET and welcomed NExTRAC members, Data Science and Emerging Technology Working Group (WG) members, and members of the public to the meeting. A recording of this meeting is [available online](#). Dr. Tucker welcomed Dr. Bloss as the new Chair of the NExTRAC.

Dr. Tucker reviewed the role of NExTRAC, which is to provide advice to the NIH Director on matters related to the conduct and oversight of research involving emerging technologies and biomedical science. The committee provides guidance on the scientific, safety, ethical, and social issues associated with areas of emerging biotechnology research. In June 2021, then NIH Principal Deputy Director Lawrence A. Tabak, D.D.S., Ph.D. announced that the NIH would create a WG within the NExTRAC to understand how emerging technologies may enable the combination and use of human datasets, particularly from disparate sources, in an effort to anticipate potential benefits and risks for research participants, families, populations, and society. The Data Science and Emerging Technology WG was charged with the following:

1. Define and characterize the types of research questions that require increasing granularity and aggregation of data about individuals that are likely to be addressed through emerging technologies, considering:
 - Goals of such research studies and how they advance the NIH mission
 - Emerging technologies that may generate potentially sensitive datasets
 - Data types generated and their sources (e.g., digital health devices, EHR platforms) with an emphasis on exploring new data types or unique sources
 - Data science platforms and tools that facilitate data access, combination, and analysis (e.g., artificial intelligence, cloud computing)
2. For those questions and technologies defined above, consult with stakeholders to discuss and assess the value of and potential implications for individuals, groups, and society, considering:
 - Attitudes and perspectives about sharing participant data to advance biomedical research, specifically through the lens of balancing research risk (e.g., privacy, autonomy) with research deliverables
 - How these perspectives may evolve depending on the context of who is to benefit or assume risk, whether it be at the individual level, through the community, or broader society's expectations for public health advancement

Dr. Tucker stated that at the current meeting, attendees would discuss an update and progress report from the Data Science and Emerging Technology WG. Feedback from attendees will be taken into account as the WG continues to address the charge. Dr. Bloss noted that the Data Science and Emerging Technology WG is composed of both NExTRAC members and several ad hoc subject matter experts (SMEs).

CONFLICT OF INTEREST DISCLOSURES

Jessica Tucker, Ph.D., NExTRAC Executive Secretary

Dr. Tucker reminded committee members about the rules of conduct that apply to them as Special Government Employees, read the conflict-of-interest statement into the record, and indicated that related questions could be addressed to the Committee Management Office.

ACKNOWLEDGMENT OF DEPARTING AND NEW NExTRAC MEMBERS

Cinnamon Bloss, Ph.D., NExTRAC Chair

Dr. Bloss acknowledged five NExTRAC members who will soon be completing their terms of service: Zach Adelman, Ph.D.; Lorraine Albritton, Ph.D.; Kathleen Boris-Lawrie, Ph.D.; Benhur Lee, M.D.; and Matthew Porteus, M.D., Ph.D. Dr. Bloss also welcomed four incoming NExTRAC members joining the meeting in an ad hoc capacity: Angela Birnbaum, M.P.H.; Shawneequa Callier, J.D.; Insoo Hyun, Ph.D.; and Kevin Saunders, Ph.D. Dr. Bloss expressed her gratitude for the time and effort that the outgoing members gave to the NExTRAC and indicated that the roster of NExTRAC members and additional meeting materials, including written public comments, can be found on the NIH [Office of Science Policy website](#).

UPDATE FROM THE WORKING GROUP ON DATA SCIENCE AND EMERGING TECHNOLOGY

Pilar N. Ossorio, Ph.D., J.D., and Sachin Kheterpal, M.D., M.B.A., Data Science and Emerging Technology WG Co-Chairs

Dr. Kheterpal and Dr. Ossorio presented an update of the Data Science and Emerging Technology WG's activities thus far and the plans to meet Phase 2 of the charge.

In Phase 1, the WG has focused on understanding the key research questions reflected in its charge. To this end, the WG has drafted a [progress update](#) that lists the key types of draft research questions identified by the WG through their deliberations, literature reviews, and discussions with SMEs. The WG identified these types of questions as the most relevant to the NIH over the next 5 to 10 years and indicated they may require the NIH to develop new policies to address these topics. In Phase 2, the WG will analyze stakeholders' perceptions of the social and ethical issues raised by such research questions, how stakeholders weigh the inherent risks and benefits, and how they make other value trade-offs.

The WG began its activities in the Fall of 2021. Over the past several months, the WG has been developing a draft list of types of research questions, drawing from discussions with SMEs in WG meetings. The WG has also been planning for stakeholder engagements as part of Phase 2, which will occur in the Fall and Winter of 2022. After the engagement events are held, the WG will compile a report based on the input collected, and this draft report will be presented to the NExTRAC in the Summer of 2023.

In identifying these types of research questions, the WG considered several themes and ethical, legal, and social implications. These include novelty, context, complexity, sensitivity, justice, access, reliability, unintended consequences, control, aggregation, identifiability, privacy, and confidentiality. These themes were used to help focus the efforts of the WG to identify specific topics; however, the WG acknowledges that there are many other research areas that they considered and many that they could have, which are not captured in this list.

The questions identified by the WG can be categorized into three topic areas:

- **Novel Data:** The WG found that many of the unique issues that require consideration in the next 5 to 10 years are from sources outside of the traditional healthcare system, such as wearable technology, social media, cell phone applications, home devices, and other consumer and lifestyle data.
- **Models and Algorithms:** A variety of novel artificial intelligence (AI) and machine learning techniques are being applied to the analysis of both traditional and non-traditional sources of health data. In the next 5 to 10 years, these approaches will become more common and will be further integrated into clinical care and biomedical research.
- **Integration:** Data linkage and aggregation of different datasets from multiple sources pose unique issues. There are many different datasets available to researchers, with many different types of data, but they have varying degrees of standardization and of identifiable information about individuals. In the next 5 to 10 years, combining this data will get easier, again raising a number of issues for the NIH to consider.

For each area, the WG has defined general types and examples of research questions that the NIH might encounter. There is some overlap in these three areas, but this categorization provides a helpful framework to think about emerging issues raised by data science. The WG is open to suggestions from the NExTRAC on revisions to the list of research questions compiled in Phase 1.

The goal of Phase 2 is to build upon information gathered in Phase 1 and to use the questions and themes developed in Phase 1 to stimulate dialogue and engage stakeholders on the underlying values and potential implications of these questions. It will be critical to reach stakeholders with diverse backgrounds and in different settings and to listen to voices that are not often heard.

The WG is tentatively planning four stakeholder engagement sessions over the Fall-Winter of 2022. The first three sessions will be designed to gather information from the general public, including potential clinical trial participants, patients, and caregivers. The fourth session will be designed to gather information from experts, including scientists, technology developers, and educators. The WG hopes to hold these engagements in a hybrid format to increase participation and accessibility, dependent on COVID-19 restrictions.

The first three engagement sessions will each take place in different geographical regions with unique participants, and will include the following elements:

- Introduction: Topics and types of questions presented at a high level.
- Facilitated small group discussions via case studies on informing health-related questions through:
 - Use of novel data from outside the traditional healthcare system
 - Use of models and algorithms
 - Data linkage and aggregation of disparate datasets from multiple sources
- Outcome: Synthesis of the themes from the discussions on stakeholder perspectives on the types of research questions and issues raised.

The engagement session for scholars, educators, and technology developers will be held last and will include the following elements:

- Introduction: Topics and types of questions presented at a high level.
- Summary of main themes from the first three engagement sessions.
- Panel discussions on informing health-related questions through:
 - Use of novel data from outside the traditional healthcare system
 - Use of models and algorithms
 - Data linkage and aggregation of disparate datasets from multiple sources
- Outcome: Synthesis of the themes from expert opinions on how different groups perceive different types of data use and the impact on themselves, their families, and their communities.

Dr. Ossorio welcomed members of the WG to add any additional thoughts on the WG deliberations to date and plans for the stakeholder engagements.

Suzanne Bakken, Ph.D., RN, FAAN, FACMI, a member of the WG, said that the WG had discussed whether engagement sessions should be conducted in both Spanish and English, and she asked NExTRAC members to provide input on this issue. Lorraine Albritton, Ph.D., a member of both the NExTRAC and the WG, suggested that during the fourth engagement session, the WG could gather information from experts on how to address laboratory safety.

GENERAL DISCUSSION

Dr. Ossorio opened the floor for NExTRAC's discussion on the WG's progress to date and plans for Phase 2.

Dr. Porteus asked how the WG plans to discuss with stakeholders how commercial genomic sequencing companies handle informed consent and whether their informed consent processes provide clear and accurate information about the many ways in which their customers' data can be used or sold. Dr. Ossorio responded that the WG has discussed data consent and agreed that people who use these services might not fully understand all the ways in which their data can be used. She said that the issue of providing consent for data use in research goes beyond consumer genomics companies and is applicable to all non-traditional sources of data for health research.

Kenneth Oye, Ph.D., observed that the WG has framed most questions based on classic concerns about risks and benefits of privacy, ethics, and informed consent. He asked whether the WG was considering issues beyond the scope of the informed consent framework or issues in which data use might have broader societal, security, health, or environmental implications. He also asked whether the WG was considering how other countries handle similar issues, as it is critical for the WG to think about how issues around data use can raise different concerns and have different implications for different communities. Dr. Kheterpal acknowledged that the WG has so far focused significantly on implications for an individual, and it is important for the WG to consider broader implications, such as the impact on communities or underserved populations. He noted that the WG has taken into consideration the fact that concerns about data use may vary in different communities. Dr. Ossorio requested that NExTRAC members send the WG any resources they might have on how data use concerns are handled in other countries.

Debra Mathews, Ph.D., a member of the WG, said that consumers are often unclear as to how information from genomic sequencing can affect their genetic or social family members, and noted this could also be the case for other types of data (such as social media). Dr. Ossorio said that the WG has discussed focusing on broader family, community, and societal implications of data use.

Dr. Bloss, NExTRAC Chair and member of the WG, said that there have been some conversations in the WG about the implications of social media data, and that it would be interesting to see what types of engagement literature exist on a person's broader social network.

Dr. Kheterpal indicated that the WG is more focused on sources of non-genetic data rather than genetic data, because many initiatives are already focused specifically on genetic data.

Ms. Callier asked whether the WG has considered the role of international companies and issues concerning data collection and sharing internationally. Dr. Kheterpal said that the WG would discuss these issues during the fourth stakeholder meeting.

Dr. Oye reminded the group that biases in results from machine learning and differences in suspicion and trust across various communities might amplify challenges in deriving accurate conclusions from research that uses data from traditional and non-traditional sources. He wondered whether focusing on the informed consent process will exacerbate underrepresentation among stakeholders who participate in these events.

Dr. Bakken said that the WG held extensive discussions on whether data integration, algorithms, and models should be considered under one broad group. The WG decided to separate out these aspects of data use for research to allow the group to highlight issues concerning bias with modeling, calibration, and similar processes. Using these classifications of potential areas of concern will help the WG's findings remain relevant in the future, when machine learning using multimodal datasets is likely to be the standard.

Dr. Ossorio noted that lack of representation and differences in how individuals from underrepresented groups are treated in the healthcare system create biases in data. Inclusion of individuals from different groups does not fully address the problem of representation due to implicit bias in the healthcare system. Different datasets may handle these biases in different ways. Dr. Oye responded that modes and varieties of discrimination are built into datasets, and it is encouraging that the WG is thinking deeply about issues related to bias. Dr. Bakken added that some researchers collect granular data on race and ethnicity but later have to aggregate these data for entry into NIH study enrollment tables, losing valuable details. Dr. Albritton indicated that the WG has extensively discussed the potential problems that might arise with combining data from various datasets, including disparities in methods of data collection and the equipment used by study staff.

Dr. Adelman asked about the extent to which the WG is selecting its audience (which could influence the responses received) and the lengths to which the WG is willing to go to recruit stakeholders from diverse backgrounds. He asked whether engagement sessions will be carried out in small or large groups. Dr. Kheterpal said that the WG plans to have small groups at each engagement session to facilitate in-depth discussions. He noted the WG also plans to hold engagement sessions in non-traditional locations to help engage with people who might not usually participate in such events. He asked that attendees who have experience with stakeholder engagement, especially during the COVID-19 pandemic, reach out to the WG. Dr. Oye responded that although meeting with stakeholders in their own communities can be challenging, doing so is most effective at reaching people who would not usually participate in such events.

Dr. Bloss said that in her experience with engagement, there is a trade-off between having in-depth discussions on a limited number of topics and having broader discussions on several topics but not addressing the details of each topic. It is important for the WG to consider which strategy would best help the NExTRAC provide valuable information to the NIH. Dr. Bloss added that the NExTRAC might be able to obtain additional comments from the public after the WG's report is drafted and posted for public comment. The NExTRAC is prioritizing stakeholder engagement, and the WG's efforts will help provide a roadmap for future engagement events on other topics.

Dr. Oye said that it is important to acknowledge the differences between the NExTRAC and the Recombinant DNA Advisory Committee (RAC). He said that with the RAC, project reviews would generate information. The NExTRAC does not have an individual project overview function, and it is not likely to generate a significant amount of specific information. The WG could review a subset of the applications or projects funded to flag those that raise interesting issues and challenge preconceived ideas. Dr. Ossorio responded that the WG has had NIH personnel from various NIH Institutes and Centers in attendance for some of its meetings and presentations. It might be helpful to hear whether these personnel know of or have funded any recent projects that might raise issues relevant to the NExTRAC.

Dr. Adelman said that using case studies or examples might make it easier for stakeholders to discuss tangible problems that affect their lives rather than abstract concepts.

Leigh Turner, Ph.D., raised points concerning the WG's choice of topics, focus, and boundaries. He said that it might be best for the WG to stick to a somewhat narrow range of focus to get important information out of stakeholder engagement events, and he noted the current scope seems appropriate. He said that in his experience with stakeholder engagement, some groups are easier to access than others. It might be helpful for the NExTRAC to hear more about the WG's practical plans to engage stakeholders from diverse backgrounds. He also asked whether stakeholder engagement could be considered as a research project that would require institutional review board (IRB) approval.

Dr. Hyun asked whether the WG will discuss issues concerning data from assisted reproductive technology, since this aspect of healthcare generates a lot of data. Dr. Kheterpal said that the WG will not include this area of research and plans to be clear to stakeholders about which topics are in and out of scope.

Dr. Kheterpal said that the WG could tap into or learn from community engagement resources from federally funded research studies, such as the *All of Us* Research Program. Dr. Ossorio said that the NIH is hiring a firm to support the WG's stakeholder engagement events. This support should help facilitate the process of hosting these events. She said that the WG could consider treating their planned stakeholder engagement as a research project. Dr. Tucker said that it would be helpful to build upon existing NIH engagement efforts and rely on NIH and NExTRAC experts for guidance. This is an area for which the NIH has strong expertise.

Dr. Bloss responded that the WG's stakeholder engagement efforts seem less a research project, as the scope of these events is specifically tailored to answering questions of interest to the NIH as opposed to generating generalizable knowledge. She said that because there is already a lot of data on similar issues, it may be best for the NExTRAC to focus on making recommendations to the NIH and not on an independent research project. Dr. Albritton agreed.

Dr. Kheterpal and Dr. Ossorio summarized that it sounds like there is support for the general direction of the WG's plans. They thanked NIH staff, NExTRAC members, and other attendees for their thought-provoking contributions.

ADJOURNMENT

Dr. Bloss thanked the participants for their contributions and the WG Co-Chairs for their leadership. She said that the WG will provide the NExTRAC with an update in 2023, after the stakeholder engagement events have taken place. Dr. Bloss adjourned the meeting at 2:25 p.m.

Date: October 12, 2022

Jessica M.
Tucker -S

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Jessica Tucker, Ph.D.
NExTRAC Executive Secretary

I hereby acknowledge that, to the best of my knowledge, the foregoing Minutes and the following Attachments are accurate and complete.

This Minutes document will be considered formally by NExTRAC; any corrections or notations will be incorporated into the Minutes.

Date: October 12, 2022

Cinnamon
Bloss

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Cinnamon Bloss, Ph.D.
Chair, Novel and Exceptional
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ACRONYMS AND ABBREVIATIONS

AI	artificial intelligence
IRB	institutional review board
NExTRAC	Novel and Exceptional Technology and Research Advisory Committee
RAC	Recombinant DNA Advisory Committee
SME	subject matter expert
WG	working group

**ATTACHMENT I: NOVEL AND EXCEPTIONAL TECHNOLOGY AND
RESEARCH ADVISORY COMMITTEE ROSTER**

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**ATTACHMENT II: DATA SCIENCE AND EMERGING TECHNOLOGY
WORKING GROUP ROSTER**

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