NOVEL AND EXCEPTIONAL TECHNOLOGY AND RESEARCH ADVISORY COMMITTEE

Minutes of Meeting

August 29, 2023

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
August 29, 2023

MEMBERS IN ATTENDANCE
Cinnamon Bloss, Ph.D. (Chair)
Suzanne Bakken, Ph.D., RN, FAAN, FACMI, FIAHSI
Karen Caindec
James Collins, Ph.D.
Gigi Kwik Gronvall, Ph.D.
Insoo Hyun, Ph.D.
Sachin Kheterpal, M.D., M.B.A.
Alan I. Leshner, Ph.D.
Pilar N. Ossorio, Ph.D., J.D.
Kenneth Oye, Ph.D.
Sarah M. Richardson, Ph.D.
Margaret F. Riley, J.D.
Kevin O. Saunders, Ph.D.
Leigh Turner, Ph.D.
Letisha R. Wyatt, 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; Lawrence A. Tabak, D.D.S., Ph.D., NIH Acting Director; and Lyric Jorgenson, Ph.D., Acting NIH Associate Director for Science Policy and Acting Director of the NIH Office of Science Policy

Dr. Bloss called the virtual meeting to order at 2:00 p.m. ET and welcomed NExTRAC members, members of the NExTRAC Data Science and Emerging Technology Working Group (WG), and members of the public attending the meeting remotely. A recording of the meeting is available online.

Dr. Bloss reviewed the role of the NExTRAC, which is to advise the NIH Director on matters related to the conduct and oversight of research involving emerging technologies and biomedical science. NExTRAC is also a public forum for discussing scientific, safety, and ethical issues associated with emerging biotechnologies.

Dr. Bloss then introduced Dr. Tabak, who reminded the attendees that emerging technologies, such as digital health devices, high-throughput omics, neural recordings, and artificial intelligence (AI), hold immense potential for helping understand and improve human health, but with that immense potential come unique ethical issues regarding consent, privacy, and respect for individuals. NExTRAC has contributed valuable time and diverse expertise and experience in assisting NIH as it navigates the challenges of balancing emerging technologies' risks and benefits.

Dr. Tabak noted that NExTRAC has developed a framework that incorporates public deliberations on the implications of emerging biotechnologies. The committee has grappled with responsible stewardship of gene drive technologies that have potential applications in fighting vector-borne illnesses such as malaria. He noted that NIH recently issued a proposal to update the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules*, partly in response to these recommendations. Now, there is great potential with the use of data from smartwatches and social media, AI and machine learning, and new approaches to combining datasets to inform biomedical research. However, it is essential to consider the implications of these emerging types of data science, both for research participants and for the general public.

Dr. Tabak then introduced Dr. Jorgenson, who reviewed the charge to NExTRAC on Data Science and Emerging Technology and provided some context for the presentation of the WG's report. NIH is committed to ensuring that emerging biotechnologies and novel approaches to combining data proceed responsibly, safely, and ethically. In June 2021, NIH asked NExTRAC to define and characterize the types of research questions that require increased granularity and aggregation of data about individuals that are likely to be addressed through emerging technologies. To address these topics, NExTRAC was asked to consult with research participants, patient groups, ethicists, privacy experts, data scientists, technology developers, and public health officials to learn how people view the use of their health data in biomedical research. These conversations engaged about 160 people from diverse communities across the U.S.

The WG on Data Science and Emerging Technology has developed a draft report of its findings and recommendations based on the community conversations and discussions with experts across the field. This meeting of the full committee is meant to serve as a public session to discuss the draft report. After discussion, NExTRAC will vote on whether to accept the report and endorse the WG's recommendations to NIH.

Dr. Jorgenson expressed her gratitude to the WG for its efforts, as well as to the people across the country who participated in the discussions about data uses.

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.

Dr. Tucker also announced that the meeting was open to the public and was being videocast and recorded.

ACKNOWLEDGMENT OF DEPARTING AND NEW NExTRAC MEMBERS
Cinnamon Bloss, Ph.D., NExTRAC Chair

Dr. Bloss acknowledged the recent passing of NExTRAC member Angela C. Birnbaum, M.P.H., Director of the Office of Biosafety and Director of Containment Operations and Quality Assurance at Tulane University. The Committee greatly appreciates her expert contributions to the scientific enterprise and her passion for working with NExTRAC.

Dr. Bloss thanked outgoing NExTRAC members: Zach N. Adelman, Ph.D.; Kathleen Boris-Lawrie, Ph.D.; Freda C. Lewis-Hall, M.D., DFAPA; Matthew Porteus, M.D., Ph.D.; and Leigh Turner, Ph.D. Dr. Bloss welcomed the four new members of the committee: Suzanne Bakken, Ph.D., R.N., FAAN, FACMI, FIAHSI; Karen Caindec; Sachin Kheterpal, M.D., M.B.A; and Sarah M. Richardson, Ph.D. Drs. Bakken and Kheterpal have already been deeply involved in the Data Science and Emerging Technology WG.

PRESENTATION OF THE DRAFT REPORT OF THE WG ON DATA SCIENCE AND EMERGING TECHNOLOGY

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

Dr. Kheterpal acknowledged the efforts of the WG members and their perspectives that contributed to the draft report; he also thanked Dr. Ossorio for her capable guidance as cochair. In addition to the cochairs, the WG included NExTRAC members Dr. Bakken; Dr. Bloss; Alan I. Leshner, Ph.D.; and Margaret F. Riley, J.D. as well as ad hoc members Lorraine M. Albritton, Ph.D; Husseini K. Manji, M.D., FRCPC; and Debra J.H. Mathews, Ph.D., M.A.

Dr. Kheterpal presented the WG's charge:

- 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, electronic health record 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., AI, cloud computing)
- For the questions and technologies defined above, consult with stakeholders to discuss and assess the technologies' value and the 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 at the individual level, through the community, or within broader expectations for public health advancement

Dr. Kheterpal summarized key portions of the draft report. In Phase 1, the WG focused on developing research questions that experts think will be of most relevance to NIH over the next 5 to 10 years. Phase 1 laid a foundation for Phase 2, which focused on engagement of stakeholders' perceptions on the social and ethical issues raised by such research, how stakeholders weigh the inherent risks and benefits, and how they make other value trade-offs. Dr. Kheterpal also noted that the WG did not thoroughly consider generative AI (e.g., large language models such as ChatGPT), which had yet to emerge for broad public use and awareness during Phase 1.

Dr. Kheterpal explained that the product of Phase 1 comprised a list of types of biomedical research questions involving new types of data, new types of analysis, and data linkage and aggregation. The questions included the following:

- How are personal health data collected from outside of the traditional health system (e.g., wearables, apps, social media) used to study health-related questions and predict health risks?
- How can other consumer and lifestyle data from non–health-specific sources (e.g., sensors in the home, credit card and consumer rewards data) be used to study health-related questions and predict health risks?
- What is the role of computer-based technologies (e.g., AI, machine learning, automated image analysis) in advancing health decision making?
- How can new methods for integrating data while maintaining the security of private information (e.g., privacy-preserving record linkage) be used for precision medicine and public health?
- How should the research context (e.g., clinical, public health) and participants' consent status affect data linkage and aggregation?

The findings from Phase 1 were as follows:

- Emerging technologies to capture, store, and analyze personal health data (e.g., wearables, apps, AI) offer rich resources for research. However, responsibly realizing their full benefits will require more policy and ethics work.
- Emerging methods to harmonize and aggregate data from different studies and across the world show great promise for precision medicine and public health. Still, refinements are needed to limit variation that can reduce significance, accuracy of results, and generalizability of conclusions.

Dr. Kheterpal said that WG deliberation and discussions with subject matter experts (SMEs) led to the topics for public engagement during Phase 2. For this phase, NIH hosted community conversations in-person across a wide geographic range of the U.S. and via several webinars to garner reactions to the research questions and learn about community members' views of the risks and benefits of research using personal health data. In general, respondents' support for personal data use and analysis depended on who was receiving the data (e.g., for-profit entities versus academia), whether those recipients were considered trustworthy, and whether there would be significant return in terms of health benefits to the individual or community. Community members expressed concern about how little they know about how their data are used and how little control they seem to have over those uses. In general, community members wanted greater transparency about uses of their data and reassurances that the benefits would offset the potential risks. Return of results and return of value were key concepts that emerged during the community discussions.

The second phase culminated in an NIH- hosted workshop, Using Public Engagement to Inform the Use of Data in Biomedical Research, during which several WG members and other stakeholders—including ethicists, scholars, developers, and researchers—reflected on the observations from the community conversations and discussed central themes. Attendees discussed the potential value of data from emerging technologies, as well as potential implications for individuals, groups, and society. This event was videocast live and open to the public.

Dr. Kheterpal thanked all who contributed to the very engaging and informative sessions, particularly the many community members who provided candid assessments of the potential risks and benefits of data use in medical research. He acknowledged the support that Palladian Partners and Pyxis Partners provided in organizing, summarizing, and facilitating the meetings, as well as the SMEs who contributed key insights.

Dr. Ossorio spoke about some points to consider for investigators as they are engaging with participants in biomedical research using their personal data. The approach, which is outlined in the report, consists of four stages, and also applies to secondary uses of data.

Stage 1: Designing the study. Researchers should assess benefits and risks, assure protections, use familiar technology, explain health relevance, and disclose potential for profit.

Stage 2: Recruiting participants. Researchers should understand how the study is relevant to participants, assess protections, clarify their methods and processes, and obtain informed consent with full transparency about data use.

Stage 3: Conducting the research. Researchers should maintain and update security and privacy practices, offer appropriate compensation to offset the burden of participation, and renew consent as needed.

Stage 4: Disseminating results. Researchers should communicate with the communities on what was done with their contributed data and the impact of the research in terms of actionable change or new studies.

Researchers planning secondary uses of the data should maintain and update security and privacy practices while being transparent about data uses. Sharing and discussing findings of secondary uses with communities is also important. Dr. Ossorio observed that in the community conversations, the WG did not always receive robust feedback on secondary uses, perhaps because people do not consider such uses when envisioning research processes using their data. There is more work to be done in thinking about how the values and concepts articulated during the community conversations would apply to secondary research.

Dr. Ossorio highlighted the three main themes of the WG's recommendations to NIH: trustworthiness and transparency in research, as well as respect for participants and communities; issues with informed consent for control of data sharing and linkage; and return of value on participation in research, data sharing, and linkage. The recommendations are as follows:

1. NIH should catalogue, evaluate, and, as appropriate, coordinate efforts among current initiatives addressing public engagement and ethical and technical issues in data science.
2. When NIH invests in public engagement, especially around emerging technologies, the agency should be prepared to update processes and infrastructure and to revise its programs and policies in accordance with public expectations and social justice principles or to clearly explain to the public why the agency may not change its course.
3. In consultation with other federal agencies as appropriate, NIH should align its policies on data and research governance with widely held public values.

4. NIH should help establish long-term relationships between members of the public and research communities to facilitate sustained public engagement on evolving issues regarding the use, analysis, management, and reuse of personal health data in biomedical research.
5. NIH should encourage investigators to prospectively address bioethical considerations in emerging areas of data science that are particularly important to participant communities, as reflected in public engagement, in their research programs and proposals.
6. In consultation with other federal agencies as appropriate, NIH should develop and disseminate best practices on informing participant communities about how their personal health data are being managed, reused, and linked to other data, especially when these best practices extend beyond regulatory requirements.
7. NIH should leverage prior research and support further public engagement to inform best practices for return of results from biomedical research that uses emerging data science and to determine implementation infrastructure needs.
8. NIH should support exploration of methods for providing benefits and return of value beyond returning research results to participants and their communities, when appropriate and as consistent with current regulations.

Dr. Ossorio underscored the importance of obtaining additional input from NExTRAC on recommendations 2 and 3 in particular, because of an apparent misalignment between some members of the public's expectations and some NIH policies and programs on the use and analysis of personal health data for biomedical research. Regarding recommendation 6, Dr. Ossorio observed that participants in the community meetings frequently mentioned that they did not know what was being done with their data. They do not understand data linkage or why researchers would want to link data, nor do they understand the risks involved in data linkage. The WG suggested developing an array of tools to help people better understand data use and linkage. NIH may be in a position to provide guidance to address this gap.

Dr. Ossorio further noted that people are generally not focused on long-range benefits, but they are interested in receiving immediate benefits, including return of research results and other forms of return of value. More than 20 years' worth of NIH-funded studies on return of research results has yielded a substantial body of knowledge on this subject. What is needed is capacity building within communities, as well as educational resources on data science and creative messaging about the benefits of taking part in research. Furthermore, financial remuneration should go beyond compensation for time and inconvenience.

Dr. Bloss said that a great deal of public input is reflected in the report, but no public comments were received through formal channels in advance of this meeting, so there was no public comment period during the meeting.

Dr. Bloss encouraged NExTRAC members to discuss the draft report and suggest amendments with an eye toward finalizing it. She noted that, if appropriate, the NExTRAC could vote to accept the report with the understanding that any agreed-upon changes will be implemented.

GENERAL DISCUSSION

Dr. Albritton said that the WG consulted a number of SMEs and wanted to credit them in an appendix to the report. Dr. Ossorio said that all the SMEs have consented to having their names and professional titles published, so they will be acknowledged in the report. When NExTRAC votes on whether to accept the report, the members should bear in mind that the report will include this acknowledgement.

Kenneth Oye, Ph.D., referred to page 12 of the report, where there is a section on the use of models and algorithms. He cautioned that bias in algorithm development can affect populations differentially by race/ethnicity, gender or sexual identity, and other protected categories. He asked whether the WG discussed additional information on discrimination stemming from models and algorithms that is not presented in the report. From a legal standpoint, when discussing discrimination that can result from reliance on algorithms, there is a difference between effect and intent to discriminate; he asked whether there are concerns about medical practice and discrimination for AI and machine learning.

Ms. Riley noted that the law on intent and effect is a moving target, so offering an opinion on that topic would not be ideal for now, and that was not a focus of the WG. People were aware of effect and intent, and they were far less concerned about bad intent than they were about bad effect. Nevertheless, the WG did not look into the legal piece—how a court would view this issue about possible discrimination arising from use of algorithms. Dr. Ossorio agreed with Ms. Riley's summary, but with regard to tort law, there could be a risk of lawsuits based on allocation of care by institutions using algorithms, for example. In a tort context, the distinction between intent and effect does not matter as much as it does in the civil rights area. Dr. Ossorio said that some communities and SMEs raised concerns about algorithms' possible discriminatory effects or the possibility that their use could exacerbate inequalities.

Dr. Oye spoke about a small body of literature on models and algorithms in the context of medical decision making in diagnosis and treatment (e.g., indicators of eligibility for kidney transplant). Dr. Oye said that diagnostic and treatment criteria are likely to evolve in light of widespread use of machine learning, regardless of whether gender or race are explicit in models. He asked whether this topic came up in public discussions.

Dr. Bakken indicated that the main points that came up during community sessions were about the populations used in the datasets for training the models and how the training datasets would affect generalizability. People also cared a great deal about who communicated with them about the algorithm output, with most respondents saying they would want to learn about the results of an algorithm from a trusted provider, because of the opportunity for discussion and personal context. Dr. Ossorio agreed, saying that the topic of justice received limited coverage in the report because it was not a strong focus of the case studies used to facilitate the community conversations. During discussions with SMEs, the topic did come up.

Letisha R. Wyatt, Ph.D., asked whether any demographic information was collected about stakeholder groups, because it would be important to hear from diverse voices, and

whether that information could then be shared or added to the report. Dr. Kheterpal said that attendance was taken at the community meetings, but he was not aware of such information being collected. Dr. Bloss explained that there was a significant effort to achieve balance in representation by reaching out to a wide variety of areas and communities for convening the meetings. However, this effort was not considered generalizable research, so there was no focused effort to recruit participants representative of the US population.

Dr. Albritton explained that two virtual meetings were convened with American Indian and Alaska Native groups, and an in-person meeting was held in Jackson, Mississippi, on the campus of Jackson State University, a historically Black university. Participants were highly concerned about ensuring that their input was anonymous. Dr. Bakken added that for the session convened in Harlem, New York, all the participants were from that community, and the meeting in the Bronx, New York was conducted in Spanish. Dr. Ossorio said that age ranges varied from meeting to meeting, as did levels of familiarity with technology. Therefore, the group of community members were diverse along several different axes.

Ms. Caindec said that discrimination is a concern for communities, but AI and data aggregation and linkage are new topics, and communities do not know what questions they should be asking.

Regarding recommendation 6, Ms. Caindec remarked on the consenting process, which can be very complicated and is still evolving, especially for genetic samples. She suggested mentioning or linking to any available NIH best practices, as informing people about results starts with consent. Dr. Jorgenson agreed and noted that NIH has developed resources for best practices for informed consent, and will continue to do so, moving forward. Ms. Caindec suggested linking to the relevant best practices resource(s) or providing a footnote in the NExTRAC report.

In response, Dr. Ossorio said that the wording of recommendation 6 was kept broad in part because in many situations of data reuse, a person may have consented to have their data added to a repository as part of a wider consent (e.g., for sharing their hospital records). Those types of data are often used in research, although people may not remember that they consented to data sharing.

Dr. Jorgenson pointed out that NIH also has a supplemental resource for responsible management and sharing of American Indian/Alaska Native participant data, and Ms. Caindec noted that NIH's Tribal Research Office is an excellent resource.

Dr. Tabak noted that engaging with a Tribal Nation means working with a unique and sovereign nation. Some general approaches do apply, such as the requirement for a formal Tribal consultation. However, because those consultations are time-consuming for Tribal leaders, researchers must consider the best timing of such consultations. Another challenge involves individuals who have left the Tribal Nation to live away from Tribal lands. Tribal leaders may still consider those individuals part of the nation, but the

individuals may hold a different view; as U.S. citizens, they may want to participate as they choose.

Ms. Caindec referred to Figure 3 in the draft report and suggested that "Understand relevance of the study to participants" should be moved from stage 2 to stage 1—during early engagement with the community. She noted that both researchers and communities benefit from early engagement.

Insoo Hyun, Ph.D., asked about the extent to which industry decision makers were involved in Phase 1. Dr. Hyun pointed out that most of the onus for ethics and justice is placed on scientists and communities, not the companies that are fueling the pipeline of data. If industry decision makers were not consulted for some reason, that should be cited as a limitation of the report. Dr. Kheterpal said that the WG got some input from individuals from companies on data privacy issues. Some entrepreneurs who might be considered industry "disrupters" also provided input. There was a dialogue about privacy issues and user agreements that people must accept in order to use a tool, so they are contributing their data although they might otherwise be reluctant to do so.

Dr. Albritton noted that a report acknowledgement would list specific SMEs consulted during Phase 1 and that that list would provide more transparency for the public. She noted that at the expert workshop, academic stakeholders discussed that NIH's purview would limit the agency's influence on ethical and best practices in the private sector, but that the agency could lead by example.

Dr. Ossorio supported the idea of having a limitations section in the report. The WG intentionally focused on NIH and actions they could implement, and that would be worth mentioning as a limitation in scope.

Dr. Wyatt referred to recommendation 2, about increasing NIH engagement with the public, and said that is an excellent recommendation. However, she wanted to know whether the community conversations covered the regulatory aspects from the NIH side and the question of accountability when researchers are noncompliant (e.g., if they fail to obtain proper consent). Did the communities ask about accountability or restorative justice? Would communities have any influence on such policies or regulations? Debra J.H. Mathews, Ph.D., M.A., said that accountability at the point of failure was not a main focus; rather, the idea was to develop a proactive approach to prevent problems. Dr. Wyatt suggested adding something about downstream accountability to the report, because sometimes things do break down. She proposed adding a note about the critical importance of accountability. Even though it is not a focus of this report, accountability would be a good focus for future community engagement. Dr. Kheterpal suggested adding a note to the limitation section to explain that accountability was not a focus of discussion to date, but that it should continue to be explored.

Dr. Albritton asked whether limitations should be handled as footnotes or a separate section. Dr. Wyatt recommended developing a separate section, and Dr. Mathews suggested calling it "limitations and future directions" to highlight where future

engagement, research, and scholarly inquiry would be helpful. Dr. Ossorio pointed out that a large amount of data science research is done with data that are not readily identifiable, and the research is not human subjects research, so there would be no explicit policy or legal requirement that could be enforced. She noted that the report should acknowledge that additional work is needed to explore the implications of data science research potentially not being covered under the Common Rule (i.e., it is not human subjects research).

Dr. Oye recalled the differences between the former Recombinant DNA Advisory Committee (RAC) and NExTRAC. The RAC conducted project reviews, and researchers often directly and concretely identified issues. In contrast, the NExTRAC is considering issues that are constantly evolving with emerging technologies, and sometimes the specific applications are uncertain. Discussions of next steps and gaps should identify the need to collect information on problems as they emerge. Dr. Oye suggested alluding to this explicitly in the report, in part because NExTRAC is not the RAC. Dr. Kheterpal thanked Dr. Oye for the suggestion for a scoping activity.

Dr. Turner asked the WG how high-level the recommendations should be. He noted that some of the findings and recommendations in the report were vague, and reports like this could offer clearer, more direct guidance, such as a list of policies that need to be updated as soon as possible. Recommendations could include timelines and specify responsible parties to increase the chances that desired changes will be implemented in the next few years. Dr. Kheterpal responded that the suggested degree of specificity falls outside of the WG's charge. He stated that the focus of the WG's charge was more to consult with external parties, rather than an internal agency focus on specific recommended policy or programmatic changes. With this report, the WG has laid a foundation and identified a potential misalignment between public attitudes and some policies. Having both an external and internal focus would be challenging, and the WG focused on external, innovative engagement.

Dr. Bloss noted that the WG did discuss how concrete or aspirational the recommendations should be. She also pointed out that the charge did not ask for recommendations, but the WG chose to include them. She also noted that different charges NExTRAC has been given have spanned more specific and more general topics, and this charge was quite focused on the public engagement aspects of NExTRAC.

Dr. Jorgenson said that the WG's charge was unique on two levels: the focus on data science and how best to utilize public engagement to inform policy-making. Here, the NIH asked NExTRAC to think about how to use external input including community voices, needs, and perspectives in future policy-making.

Dr. Albritton noted that Dr. Wyatt had asked for demographic details of public engagement and suggested that Table 6 in the report could include some additional demograhic details to allow greater transparency. Dr. Jorgenson responded that it was important to respect the wishes of the individuals involved; because they did not agree to be identified in a government report, their demographic details were not included. Dr.

Wyatt agreed about the importance of honoring agreements with members of the communities and noted that, in the future, there are approaches to collect this data and maintain privacy.

Dr. Bloss summarized four potential edits to the report:

1. An acknowledgment section listing all the SMEs who contributed to the report will be added.
2. Regarding recommendation 6, a link to NIH resources on best practices around informed consent will be added.
3. For Figure 3, which depicts the different stages of research projects using personal health data, the item "Understand relevance of the study to participants" will be moved to from stage 2 to stage 1.
4. A section on limitations/future directions will be added to the report and will include a mention about the scope being focused on NIH and the limited degree to which the NExTRAC discussed mechanisms of researcher accountability in the context of recommendation 2.

Dr. Kheterpal expressed his support for the four amendments to the report. Dr. Bloss called for a vote. Dr. Leshner moved to approve the WG's report with the four amendments outlined above.

Ms. Caindec seconded the motion. Dr. Tucker called the roll.

Vote: NExTRAC members that were present voted unanimously to approve the draft document with the edits described.

CHARGE TO NExTRAC: ENGAGING THE PUBLIC AS PARTNERS IN CLINICAL RESEARCH
Lawrence A. Tabak, D.D.S., Ph.D., Acting Director, NIH

Dr. Tabak began by acknowledging that NIH is the steward of the Nation's largest public investment in clinical research, investing nearly $18 billion in fiscal year 2022. Clinical trials are often the most visible part of NIH's investment in clinical research as they reflect the point at which the public is most directly engaged; however, NIH recognizes a need to expand engagement throughout clinical research more broadly.

NIH employs a broad spectrum of approaches to advance clinical research discoveries, such as harnessing emerging digital health technologies, integrating real-world data through electronic health records, piloting innovative clinical trial designs, and more. At the heart of this enterprise are the dedicated patients and communities who partner with researchers in hopes of turning discoveries into improved health. While emerging technologies can make clinical research more accessible to potential participants, the recent COVID-19 pandemic has clearly illustrated that more can be done to promote the inclusive environment needed to truly advance health outcomes for all.

Additionally, the NExTRAC's latest work and the recent community conversations held in support of NExTRAC's deliberations reinforced the necessity of trust and transparency

for building effective research partnerships with participants and the public. To turn these conversations into action, NIH is furthering its commitment to engaging patients and communities as partners in the planning and conduct of clinical research that is important to them, as well as the dissemination of study findings. Through this approach, NIH can strengthen bi-directional engagement in clinical research, foster transparency and trust, and create outcomes that provide value to the people NIH aims to serve. However, NIH recognizes that meaningful engagement requires resources, such as time, planning, and infrastructure, as well as a commitment to setting expectations and holding to them as part of a partnership between researchers and the public. Building trust in the scientific method and in the researchers themselves along the entire spectrum of research can affect the validity of the science and the ultimate success of the study.

To address these issues, Dr. Tabak charged the NExTRAC to establish the ENGAGE Working Group (WG) to develop a vision and framework for including public voices in the design and planning of NIH-funded clinical research, as well as widespread dissemination of study findings. The public should be defined broadly, including people with and without specific health conditions as well as their communities. This framework should outline approaches appropriate for the breadth and diversity of NIH-funded clinical research studies and assess the potential:

- Opportunities and challenges of varying levels of engagement activities for different types of clinical research studies, considering potential trade-offs in research investment (e.g., cost, time) and benefits for improved trust, participation, outcomes, research uptake, implementation of new interventions, etc.; and
- Impact and value of engagement with patients, communities, and the broader public on clinical research, including on the quality and significance of research, relevance of the findings to diverse communities, methods of building trust to improve adoption of evidence-based practices, as well as other relevant considerations deemed appropriate by the WG.

In addressing this charge, the WG shall consult with the NIH Advisory Committee to the Director (ACD) and convene public consultations including, but not limited to, patient partners, caretakers, community representatives, research participants, patient advocacy organizations, clinical researchers, and local health providers, to provide recommendations regarding:

- How different engagement methods may be used for clinical research in general, as well as research employing novel technologies, unknown data capabilities, and potentially sensitive datasets;
- Optimal timing for meaningful engagement activities across the spectrum of the design and planning of the clinical research study, as well as dissemination of study findings so that evidence-based practices are adopted in the community; and
- Approaches for public engagement in NIH clinical research to be equitable and inclusive.

Dr. Tabak noted that the goal of this effort is to have a deliverable that has meaning to many different people and roles throughout the biomedical research enterprise. For

researchers, NIH envisions a practical set of options for meaningful engagement that can be tailored to the objectives, design, and scale of the study. This effort seeks to improve science more broadly, through increased representation and understanding of factors affecting successful study design and completion. The deliverable will also be a public vision and framework for how patient partners can contribute to the scientific enterprise, as well as a roadmap on how to build public understanding of and trust in NIH and scientific research.

Dr. Tabak stated that this effort will take place over the next two years, with the WG delivering their findings to the NExTRAC around the summer of 2025. During this two-year period, the WG will meet to discuss and develop the framework, then engage with the community as laid out in the charge.

Finally, Dr. Tabak announced the two cochairs of the ENGAGE WG: NExTRAC member Dr. Bakken and patient advocate Ms. Christin Veasley. Dr. Bakken is the Alumni Professor of the School of Nursing and a Professor of Biomedical Informatics at the Vagelos College of Physicians and Surgeons within Columbia University, She has extensive experience with patient engagement in research, specifically promoting health and reducing health disparities in underserved populations through application of innovative informatics methods. Ms. Veasley is the cofounder of the Chronic Pain Research Alliance and holds advisory positions for numerous critical pain initiatives within federal agencies, such as the NIH, CDC and FDA; academic pain research studies; and various collaborative alliances and public-private partnerships working to promote pain research, treatment and education. She has been a passionate advocate at the Congressional and federal agency levels for bringing about public awareness of the profound impact of chronic pain, the urgent need for an increased federal research investment to address this public health crisis and the long-overlooked value of including patient perspectives in all aspects of the research continuum.

Dr. Jorgenson then noted that many of the central themes of this new charge build upon the work and recommendations of the Data Science and Emerging Technology WG, including the rigorous study of the engagement process, promoting trust in research, and respect for individual and community privacy. She stated that the ENGAGE WG will include patients, patient advocates, clinicians, engagement experts, academicians, and members of the NExTRAC. She invited NExTRAC members interested in joining the WG to contact Dr. Tucker.

Dr. Bakken said she is very excited about helping to lead this effort and looks forward to carrying out the work over the next couple of years.

Dr. Ossorio suggested that the ENGAGE WG also consult with state public health agencies and child welfare agencies. These organizations can be useful in helping researchers understand methods for engaging with their specific communities.

Dr. Oye said he was encouraged by the emphasis on health disparities. He asked if engagement related to global health disparities outside of the U.S. are included in the

scope of the ENGAGE WG. Dr. Tabak responded that NIH's interests extend beyond U.S. borders and recommended that the ENGAGE WG should not limit its work to domestic health disparities.

WRAP-UP AND ADJOURNMENT

Dr. Bloss thanked the Data Science and Emerging Technology WG for delivering its report, noting that the charge was issued two years ago. She also acknowledged the WG cochairs, staff liaisons, and partnering organizations Palladian Partners and Pyxis Partners, all of whom contributed to this effort. In addition, Dr. Bloss thanked Kendra Nervik, M.S., a graduate student at the University of Wisconsin, for providing analytic support and helping develop the themes presented in the WG's report.

In closing, Dr. Bloss thanked the members for their insights and acknowledged viewers who attended the meeting virtually. Dr. Bloss adjourned the meeting at 4:10 p.m.

Date: 11/22/23

Jessica M. Tucker -S

Digitally signed by Jessica M. Tucker -S
Date: 2023.11.22 16:33:40 -05'00'

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 _ 12/4/23

Bloss, Cinnamon

Digitally signed by Bloss, Cinnamon
Date: 2023.12.04 14:21:04 -08'00'

Cinnamon Bloss, Ph.D.
NExTRAC Chair

ACRONYMS AND ABBREVIATIONS

ACD	NIH Advisory Committee to the Director
AI	artificial intelligence
NExTRAC	Novel and Exceptional Technology and Research Advisory Committee
NIH	National Institutes of Health
RAC	Recombinant DNA Advisory Committee
SME	subject matter expert
WG	working group

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

Chair

BLOSS, Cinnamon, Ph.D.
Professor
Herbert Wertheim School of Public Health and Human Longevity Science
University of California, San Diego
La Jolla, CA 92093

Members

BAKKEN, Suzanne, Ph.D., R.N., FAAN, FACMI, FIAHSI
Alumni Professor of the School of Nursing
Professor of Biomedical Informatics
Vagelos College of Physicians and Surgeons
Columbia University
New York, NY 10032

CAINDEC, Karen
Chairperson
Board of Directors
Southcentral Foundation
Anchorage, AK 99508

CALLIER, Shawneequa, J.D.
Associate Professor of Clinical Research and Leadership
School of Medicine and Health Sciences
George Washington University
Special Volunteer, National Human Genome Research Institute
Washington, DC 20037

COLLINS, James, Ph.D.
Virginia M. Ullman Professor of Natural History and the Environment
Faculty Group Leader of Global Change Biology Faculty Group, School of Life Sciences
Professor, Center for Evolution and Medicine Affiliated Faculty
Lincoln Center Affiliated Faculty, Lincoln Center Applied Ethics
Arizona State University
Tempe, AZ 85287

GRONVALL, Gigi Kwik, Ph.D.
Associate Professor
Department of Environmental Health and Engineering
Johns Hopkins Bloomberg School of Public Health
Baltimore, MD 21202

HYUN, Insoo, Ph.D.
Director
Center for Life Sciences and Public Learning
Museum of Science
Boston, MA 02114

KHETERPAL, Sachin, M.D., M.B.A.
Associate Dean for Research Information Technology
Professor of Anesthesiology
University of Michigan Medical School
Ann Arbor, MI 48109

LESHNER, Alan I., Ph.D.
Chief Executive Officer, Emeritus
American Association for the Advancement of Science
Potomac, MD 20854

OSSORIO, Pilar N., Ph.D., J.D.
Professor of Law and Bioethics
University of Wisconsin
Madison, WI 53706
Investigator and Ethics Program Lead
Morgridge Institute for Research
Madison, WI 53715

OYE, Kenneth, Ph.D.
Professor, Political Science and Data, Systems and Society
Director, Program on Emerging Technologies
Center for International Studies
Massachusetts Institute of Technology
Cambridge, MA 02139

RICHARDSON, Sarah M., Ph.D.
Chief Executive Officer
MicroByre, Inc.
Berkeley, CA 94710

RILEY, Margaret F., J.D.
Professor,
School of Law
Professor of Public Health Science,
School of Medicine
Professor of Public Policy,
Batten School of Leadership and Public Policy
University of Virginia
Charlottesville, VA 22903

SAUNDERS, Kevin O., Ph.D.
Associate Professor
Department of Surgery
Duke University School of Medicine
Durham, NC 27710

TURNER, Leigh, Ph.D.
Professor, Health, Society & Behavior
Program in Public Health
University of California, Irvine
Irvine, CA 92697

WYATT, Letisha R., Ph.D.
Associate Professor of Neurology,
School of Medicine
Director of Diversity in Research,
OHSU Research & Innovation
Oregon Health & Science University
Portland, Oregon 97239

ATTACHMENT II: DATA SCIENCE AND EMERGING TECHNOLOGY WORKING GROUP ROSTER

Co-chairs

KHETERPAL, Sachin, M.D., M.B.A.
Associate Dean for Research Information Technology
Professor of Anesthesiology
University of Michigan Medical School
Ann Arbor, MI 48109

OSSORIO, Pilar N., Ph.D., J.D.
Professor of Law and Bioethics
University of Wisconsin
Madison, WI 53706
Investigator and Ethics Program Lead
Morgridge Institute for Research
Madison, WI 53715

Members

ALBRITTON, Lorraine M., Ph.D.*
Professor Emeritus
Department of Microbiology, Immunology, and Biochemistry
College of Medicine
The University of Tennessee Health Science Center
Memphis, TN 38163

BAKKEN, Suzanne, Ph.D., RN, FAAN, FACMI, FIAHSI
Alumni Professor of the School of Nursing
Professor of Biomedical Informatics
Vagelos College of Physicians & Surgeons
Columbia University
New York, NY 10032

BLOSS, Cinnamon, Ph.D.
Professor
Herbert Wertheim School of Public Health and Human Longevity Science
University of California, San Diego
La Jolla, CA 92093

LESHNER, Alan I., Ph.D.
Chief Executive Officer, Emeritus
American Association for the Advancement of Science
Potomac, MD 20854

MANJI, Husseini K., M.D., FRCPC*
Visiting Professor,
Oxford University
Co-Chair,
UK Mental Health Mission
Past Global Therapeutic Head for Neuroscience
Janssen Research & Development
Oxford, England

MATHEWS, Debra J.H., Ph.D., M.A.*
Associate Director for Research and Programs
Berman Institute of Bioethics
Associate Professor, Genetic Medicine
Johns Hopkins University
Baltimore MD 21205

RILEY, Margaret F., J.D.
Professor,
School of Law
Professor of Public Health Science,
School of Medicine
Professor of Public Policy,
Batten School of Leadership and Public Policy
University of Virginia
Charlottesville, VA 22903

****Ad Hoc Members***