INFORMING THE USE OF PERSONAL DATA IN BIOMEDICAL RESEARCH

MAXIMIZING THE IMPACT OF PUBLIC ENGAGEMENT IN POLICY DEVELOPMENT

Summary of Public Webcast and Closed Conversations with Invited Community Members

Public Webcast (November 13, 2023; 3:00 – 3:30pm ET, Webcast)

Welcome: Lyric Jorgenson, PhD – Acting Associate Director for Science Policy, NIH

Dr. Lyric Jorgenson welcomed the audience and introduced the topic of the webinar. She described how NIH helps ensure that public engagement is at the foundation of NIH-supported research. She also outlined how the Office of Science Policy (OSP) works with the Novel and Exceptional Technology and Research Advisory Committee (NExTRAC), an advisory committee to the NIH Director, to include the public in discussions about the future of biomedical research.

Overview of NExTRAC Report and Community Conversations: Cinnamon Bloss, PhD – Professor, University of California, San Diego; Chair, NExTRAC

Dr. Bloss introduced the NExTRAC and their role as an advisory committee to the NIH Director. She emphasized that the Committee centers public engagement when providing guidance to NIH on the use of emerging technology and methods in biomedical research. Dr. Bloss described the Committee's approach, findings, and recommendations in the Data Science and Emerging Technology in Biomedical Research Report, emphasizing three main points for NIH:
1. Engage more with communities and research participants throughout the research lifecycle.
2. Enhance the informed consent process and find ways to notify participants of how their data may be used.
3. Integrate bioethics in the research process, return results responsibly, and develop evidence for other ways to return value.

Dr. Bloss noted that community conversations across the US provided critical information to the NExTRAC as the committee developed this report. Dr. Bloss expressed her gratitude to the NExTRAC, the facilitators and staff that managed the community conversations, and the community members for their candor and generous participation.

Next Steps for NIH: Jessica Tucker, PhD – Acting Deputy Director, Office of Science Policy, NIH

Dr. Tucker discussed how NIH is addressing the NExTRAC's findings and recommendations from the Data Science and Emerging Technology in Biomedical Research Report. She emphasized NIH's commitment to public engagement, highlighting the NIH's new charge to the NExTRAC to develop a vision and framework for including public voices in the design and planning of NIH-funded clinical research. She described how NIH and the research community would benefit from a framework for engagement activities and described further efforts that share the value of clinical research with patients, communities, and the broader public.

Dr. Tucker also outlined NIH's efforts to responsibly return research results to individuals. Dr. Tucker noted that more work is needed to define responsible return of different types of results and to define what "return of value" might mean to different communities and described some of NIH's and OSP's current efforts in this space.

Dr. Tucker concluded by delineating the lessons that OSP has learned about community engagement in this partnership with the NExTRAC. She thanked those who facilitated community conversations and indicated that there will be further efforts to establish and sustain relationships with communities across the US to inform OSP's policy development.

<u>*Closed Conversation with Invited Community Members*</u>

Immediately following the webinar, NIH OSP hosted closed conversations with invited community members who had previously participated in community conversations that occurred from November 2022 to February 2023. Pyxis Partners' facilitators hosted four small breakout discussions (each with ~4 community members) that covered the topics below. Community members' shared individual perspectives and summaries were derived from notes captured by science writers present for each of the events. Quotes from participants and other potentially identifying information have been removed to protect participant privacy.

Topic 1: **Whether participant contributions are faithfully reflected in the report findings and recommendations.**

- Participants generally agreed that the report reflected feedback from convenings.
- In particular, participants were glad to see points made about the importance of consent, returning benefits to communities, and transparency in how data are collected and used in research.

Topic 2: **The process of including community feedback into policy and research and potential for improvement.**

- Some participants shared that their groups and communities are often overlooked and they were happy to have been included; they felt that their voices were heard.
- Many supported the diversity of communities that were included and thought the structure of the meetings encouraged people to speak their minds.
- There was strong support for the facilitators and their management of conversation, including the format of using case studies and a combination of small and large group conversations.
- Several noted robust engagement at the community conversations and felt the potential for real impact. Some indicated that financial compensation was appropriate for the events.
- A few participants suggested that OSP provide handouts of information for later reference.
- Some participants appreciated that identities were protected as this enabled honest discussion.
- Different opinions were noted on in-person vs. virtual events. Some suggested that in person events facilitated conversation, while others thought that virtual events could be more inclusive.

Topic 3: **Ways NIH can be responsive to participant views on how to responsibly use personal health data in biomedical research.**

- Many advocated that NIH ensure that research benefits communities.
- Several participants suggested that researchers collect data with the help of trusted community liaisons (e.g., religious centers, schools, community centers, and community health organizations).
- Many asserted that privacy assurances remain important for participation.
- Several participants emphasized that NIH needs to build trust-based relationships through consistent engagement with participants and by returning value to their communities.
- Many wanted to see how participants' recommendations would translate to change in practices.

Topic 4: **Ways NIH can communicate with participants, especially regarding the impact of community contributions on policy and research outcomes.**

- Many participants suggested ways to make information more accessible, including:
  - using plain language and translating research to health outcomes when possible.
  - using multi-media approaches, such as infographics and short informational videos.
  - providing information publicly at varying levels of expertise.
- Several community members suggested meeting communities where they are, including:
  - at high schools, colleges, through community organizations, and social media.
  - by working with community liaisons to contextualize issues for particular communities using tailored language and references.

Topic 5: **Potential opportunities for communities to provide ongoing feedback.**

- Participants suggested utilizing technology to reach audiences broadly. Specific ideas included:

- o offering feedback forms and short surveys.
  - o disseminating information through listservs, including with professional organizations.
  - o offering virtual meetings for accessibility.
- Some participants suggested developing relationships with community liaisons in person and through continued conversation, by, for example:
  - o engaging with representatives from relevant communities and organizations at conferences and proactively inviting them to discussions and sessions.
  - o engaging with multiple individuals within organizations to bolster connections.

Topic 6: **Measuring impact of efforts to engage communities and the principles of successful community engagement.**

- Participants had many suggestions that generally fell into three categories:
  - o track whether people participate in multiple events, whether new people attend in addition to previous participants, and whether attendance increases at events over time.
  - o define successful inclusive practices by identifying whether people from underrepresented groups are willing to participate and how often they contribute to discussions.
  - o delineate how engagement leads to changes in practices and policies.

Topic 7: **New ways in which participant data are being used or analyzed for research that participants may be interested in discussing in the future.**

- Many participants wanted to further understand how data, AI, and linkage might alter clinical decision making and preventative health care beyond current norms, including:
  - o use of AI in the clinic and for making diagnoses.
  - o bringing healthcare and health research to people through telehealth and mobile health data collection –for mental health, social determinants of health, gene–environment interaction, and food systems.
- Some suggested a disease focus (e.g., cancer) while others supported a technology focus (e.g., whole genome sequencing).

Topic 8: **Interest in engaging further with NIH OSP or other NIH Institutes, Offices, or Centers and what factors might motivate further engagement.**

- Most participants signaled enthusiasm for OSP's work and willingness to participate further in OSP events. Some were interested in learning about other NIH efforts and the people managing them prior to committing.
- A few participants emphasized relationship building with consistent touchpoints. Touchpoints should emphasize how community feedback is reflected in reports and translated into change in policy and practice.
- Many participants affirmed that monetary compensation would be critical to continued participation. Additionally, a few noted that co-authorship on publications could show true partnership and could help some participants professionally.

Reference materials to learn more about this project:

1. [Novel and Exceptional Technology and Research Advisory Committee (NExTRAC) Data Science and Emerging Technology in Biomedical Research Report](#)
   - For a report overview including findings and recommendations to NIH, see the executive summary on p1-3.
   - For a summary of the case studies discussed, see Appendix 1 on p35-40.

2. Video recordings of NIH and NExTRAC meetings associated with this effort:
   - [Novel and Exceptional Technology and Research Advisory Committee Meeting](#) (6/25/2021)
   - [Novel and Exceptional Technology and Research Advisory Committee Meeting](#) (7/14/2022)
   - [NIH Workshop: Using Public Engagement to Inform the Use of Data in Biomedical Research](#) (2/27/2023)
   - [Novel and Exceptional Technology and Research Advisory Committee Meeting](#) (8/29/2023)
   - [NIH Meeting: Maximizing the Impact of Public Engagement in Policy Development: Informing the Use of Personal Data in Biomedical Research](#) (11/13/2023)