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

Minutes of Meeting

June 17, 2024

**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
June 17, 2024**

MEMBERS IN ATTENDANCE

Cinnamon Bloss, Ph.D. (Chair)
Suzanne Bakken, Ph.D., RN, FAAN, FACMI, FIAHSI
Shawneequa Callier, J.D.
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.
Kenneth Oye, Ph.D.
Sarah M. Richardson, Ph.D.
Margaret F. Riley, J.D.
Kevin O. Saunders, Ph.D.
Letisha R. Wyatt, Ph.D.

INCOMING/ AD HOC MEMBERS IN ATTENDANCE

Antonio T. Baines, 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 Lyric Jorgenson, Ph.D., NIH Associate Director for Science Policy and Director of the NIH Office of Science Policy

Dr. Bloss called the virtual meeting to order at 11:30 a.m. ET and welcomed NExTRAC members, members of the NExTRAC Engaging the Public as Partners in Clinical Research Working Group (ENGAGE 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 a federal advisory committee that provides recommendations to the NIH Director and a public forum for the discussion of the scientific, safety, and ethical issues associated with emerging biotechnologies.

Dr. Bloss then introduced Dr. Jorgenson, who emphasized NIH's commitment to engaging the public as partners on issues surrounding clinical research, specifically on designing research that boosts health outcomes that are important for all. Participation in clinical trials is often considered the primary opportunity where the public can engage in research, but NIH recognizes a need to expand engagement across all stages of clinical research.

In August 2023, NIH charged the NExTRAC to establish the ENGAGE 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 charge notes that 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 considering the potential opportunities and challenges across varying levels of engagement activities.

As part of this charge, the WG will 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. These public consultations will be used to provide recommendations to explore how different engagement methods can be used effectively to encourage public participation in research, such as the optimal timing for meaningful activities and approaches that are equitable and inclusive. During this meeting of the full committee, the ENGAGE WG will provide an update on their progress to date, followed by an update on NIH's internal activities to prepare for the potential NExTRAC recommendations.

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.

ACKNOWLEDGEMENT OF NEW NExTRAC MEMBER

Dr. Cinnamon Bloss, Ph.D., NExTRAC Chair

Dr. Bloss welcomed Antonio Baines, Ph.D., who joined the NExTRAC meeting in an ad hoc capacity as he awaits final onboarding onto the committee.

UPDATE FROM THE WORKING GROUP ON ENGAGING THE PUBLIC AS PARTNERS IN CLINICAL RESEARCH

Suzanne Bakken, PhD, RN, FAAN, FACMI, FIAHSI and Christin Veasley, ENGAGE WG Co-Chairs

Dr. Bakken opened by acknowledging that a critical part of the WG's charge is establishing a toolkit for public engagement that is useful for a variety of audiences such as researchers, participants, and the public. She then acknowledged the 24 members of the ENGAGE WG who have met a total of 19 times since October 2023. From October 2023 to January 2024 the WG has focused on Phase I of their efforts – planning and mapping of next steps and development of draft products. Next, the WG identified three focus topic areas during Phase II of their work. After consulting the public during Phases III-IV, the draft products will be updated before being delivered to the NExTRAC by summer 2025.

Ms. Veasley then introduced the WG's draft definition of Clinical Research Engagement, defined as “involvement that varies by level and type depending on research and community needs, with individuals, groups of people, communities, and/or organizations across the various stages of clinical research so that the research and its outcomes are meaningful and actionable to relevant partners”. The various stages of clinical research include, but are not limited to, concept development, design and planning, the research study, analysis of results, and dissemination of findings. Relevant partners in this process include patient partners, caretakers, local health providers, clinical researchers, advocacy groups, research participants, the community, and more. Ms. Veasley emphasized that this was a draft definition and that the WG would be receiving public input before finalizing it for consideration by the NExTRAC.

Ms. Veasley then highlighted the draft Vision and Goals, which are intended to reflect what the world will be like in 5-10 years if the ENGAGE WG is successful. The draft

vision states that “engagement in clinical research is a standard practice to promote responsiveness to community needs, accountability, and transparency while helping turn discoveries into improved health of people.” The draft goal of the WG is that “people and communities have a say in the agenda and direction of research that is relevant and impactful to them.”

The WG has also identified four cross-cutting themes of importance, including:

- Leveraging emerging technologies such as artificial intelligence/machine-learning (AI/ML)
- Building partnerships that are driven by patients and community members and reframing the paradigm to focus on trustworthiness, accountability, and empowerment of partners
- Promoting access and transparency throughout the research process
- Advancing justice and equity through balancing local, regional, and global needs and perspectives using a decolonized approach.

Dr. Bakken then introduced the three focus topic areas: developing a theory of action/ theory of change; reviewing existing frameworks and developing the ENGAGE framework; and identifying, collecting, and recommending a resource toolbox. Each focus topic area meeting is open to all WG members, although ENGAGE WG members each selected a primary topic area.

The Theory of Change is a model of the early stages of internal ENGAGE work, which helps the WG map out what is achievable in the short-term and governs internal processes. The Theory of Change can take different formats, such as a logic model, to help identify achievable goals in the short-term, using the tools currently available.

The Theory of Action is a visual of the late stages of ENGAGE work and implementation and highlights ways to act on and communicate recommendations to the larger public. The Theory of Action focuses on capacity-building for long-term goals, as well as identifying gaps and responsible agents. If ENGAGE is unable to reach all individuals or critical communities, the Theory of Action aims to understand why these individuals are inaccessible and provide reasoning for their exclusion.

The draft of Theory of Action integrates the various aspects covered by the focus topic areas. The schematic starts with Theory of Change providing a framework that then feeds into the social drivers of engagement. These drivers can either influence infrastructure development or toolkits for engagement optimization, which are critical resources that are needed to support the intended outcomes of engagement such as trustworthiness, accountability, partnership, and agency. This is intended to be an iterative process that begins again with each cycle. The Theory of Action/Change focus topic area will be iterating on this draft theory of action in coordination with the other focus topic areas.

Dr. Bakken then introduced the ENGAGE Framework focus topic area, led by Kent Key, PhD, MPH and Esther Krofah, MPP. The broad goals of the focus topic area include targeting a broad audience, not just individual researchers; actionable domains that are

clearly defined and provide methods for evaluation and accountability; a complementary maturity model to ensure partners are in the same place when engagement happens; and supporting each framework domain with case studies and examples.

Ms. Veasley explained the Draft Guiding Principles of the Framework topic. These guiding principles have been revised with input from the entire members WG. The principles include:

1. Effective and equitable research design requires bi-directional engagement among everyone involved in the research enterprise, including individuals, communities, grassroots/ community/ faith-based organizations, institutions, funders, and policy makers.
2. Engagement is not one-size-fits-all, and opportunities for tailoring and growth need to be integrated throughout the research endeavor.
3. Engagement efforts must understand the context of existing societal values and work to shift these values to be more equitable and inclusive.
4. Engagement requires investment in resources and infrastructure that reduce barriers, are culturally-tailored to the needs of diverse communities, and allow for long-term, sustainable efforts.
5. While people and communities have the right to either agree or decline to engage with researchers and the research process, it is still the obligation of researchers to equitably include the communities affected by the research in all stages of the process.
6. Tokenistic engagement (defined as including people for the purpose of “checking a box”) that is only a symbolic attempt at including the community’s voice rather than developing a meaningful and equitable partnership cannot be tolerated.
7. The goal of engagement is to improve research accountability, bring agency to community voices in the research process, and restore, rebuild, and advance trust between scientists and the public.
8. Equitable health outcomes result from engagement efforts that consistently and equitably partner with people, communities, grassroots/community/faith-based organizations, and institutions involved in clinical research.
9. Engagement strengthens the research enterprise and improves the quality of research by refining the questions being studied, expanding the analysis of the data generated, and sharpening the focus on outcomes that are most relevant and useful to the people who will use them.

The final focus topic area is Identifying, Collecting, and Recommending a Resource Toolbox, led by Jessica Ancker, PhD, MPH, FACMI. This focus topic area has identified four main goals which include: developing a framework outlining the types of tools and resources that could be used to support engagement in clinical research; identifying and collecting existing tools and resources in this domain; identifying recommended new tools and resources for NIH to develop as well as existing tools and resources that should be updated; and identifying potential barriers, at multiple levels, to using these tools to their greatest potential.

To meet these goals, the focus topic area established several domains to help identify, tag, and filter potential resources. Working on a landscape analysis, the WG will assess which resources are already available to the public and sort them into the seven domains: resource user, intended audience, when (research stage), how (engagement method), novel technology, resource format, and resource type. For each of these domains, the group has created options to sort available resources and are now stress testing using a variety of samples.

Ms. Veasley then stated that ENGAGE is currently in the first phase of public outreach at this time. The ENGAGE WG believes that public engagement should happen early and often throughout the clinical research process, and therefore public engagement needs to be an active part of the ENGAGE WG process. To that end, the NIH has launched the ENGAGE website (PartnersInResearch.nih.gov). The website features a video from the NIH Director about the effort, the vision and charge, several FAQs about clinical research engagement, and more. NExTRAC members were encouraged to explore the website for more information.

Dr. Bakken echoed Ms. Veasley's excitement about the ENGAGE website, as well as the current Request for Information (RFI), which is now open to the public. Although RFIs are not always the most accessible way to gather information, Dr. Bakken stressed that it is an important first step in engaging the public in research. The WG has also been discussing how to interact with constituencies in unique and innovative ways to ensure that the RFI is successful. The RFI includes 5 prompts:

1. **Strategies for researchers to best partner and work with people and communities.** For example, developing resources respectful of different cultures, facilitating open dialogues for decision-making, sharing results in a way that is valuable, etc.
2. **Ways for institutions performing research** (e.g., academic, medical centers, universities, health systems, primary care providers) **to support and incentivize active, bi-directional partnerships between researchers and people/communities.** Examples may include encouraging people/community members to establish shared decision-making on project milestones, prioritizing local community review of research questions and research proposals, specific research design factors, leveraging patient clinician relationships, etc.
3. **Approaches for research funders** (e.g., government agencies, non-profits, companies) **to incorporate partnerships between people, communities, and researchers into their programs and priorities.**
4. **Specific examples of things that may make people and communities more likely to want to engage with researchers and research institutions.** Examples may include emerging technologies that reduce the burden of research participation, opportunities, fair compensation, cultural competence training and/or culturally competent research models, etc.
5. **Specific examples of things that may make people and communities less likely to want to engage with researchers and research institutions.** Examples may include no/unfair compensation, participation opportunities only happening during typical work hours, lack of awareness of opportunities, etc.

The RFI will be accompanied by a [webinar and listening session](#) on July 17th, 2024. The next steps of the ENGAGE WG will focus on planning the public consultations outlined in the charge. The NExTRAC has experience with these public consultations as the NExTRAC WG on Data Science and Emerging Technologies had previously spoken with scientists and developers to discover topics pushing the frontier on data science and biomedical research, as well as held face-to-face and virtual interactions with more than 160 people to explore how pushing the frontiers in data science and biomedical research makes people feel about the use of their data.

Ms. Vealey then gave an overview of the goals for public outreach which include: respectfully communicating and engaging with the public early and often throughout the ENGAGE process; seeking diverse perspectives across the U.S. including, but not limited to, patient partners, caretakers, community representatives, research participants, patient advocacy organizations, clinical researchers, and local health providers; using mixed methods to gather input such as case studies, open-ended questions, and collecting stories.

Ms. Vealey closed out the presentation by inviting discussion from NExTRAC and ENGAGE WG members surrounding outreach initiatives and thanked the members of the WG for their tireless efforts, as well as the support from the NIH staff.

Dr. Bloss noted that 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 thanked the Co-Chairs were thanked for their presentation and asked them to moderate the general discussion.

GENERAL DISCUSSION

Alan Leshner, Ph.D., asked about the criteria for the resources in the toolbox, stating that there are thousands of materials publicly available regarding engagement. Dr. Leshner noted that the most important product will be the “how-tos” establishing what works in engagement via effective strategies.

Dr. Bakken answered that, at this time, the initial process is to perform the environmental scan and tag the information. Given the length of time and resources required, the focus topic area will likely focus on a series of toolbox recommendations rather than creating a full, searchable repository. She also stated that the WG is very interested in addressing the gaps in engagement resources that currently exist.

Dr. Ancker added that while making assessments of the quality of the materials is going to be important, finding and indexing materials is the focus topic area’s current priority. She agreed that a quality evaluation may be a critical next step.

Sachin Kheterpal, M.D., M.B.A., applauded the WG’s efforts and stated that learning from existing resources will be critical. He noted that rubrics and checklists are often helpful when partnering with patients in the grant-writing process, and recommended

doing an analysis of the current NIH-supported checklists to determine if they are sufficient. Dr. Kheterpal also mentioned that novel trials such as clustered-randomized trials opt-out patient consent and encouraged the WG to keep these nonclassical clinical trials in the scope of the WG's work.

Dr. Bakken noted that the WG is thinking carefully about research and data sources beyond clinical trials and beyond only engaging with research participants, as the WG wants to engage the broader community regarding all types of clinical research.

Ms. Veasley commented on Dr. Kheterpal's mention of rubrics and checklists, agreeing that they are important but noted that the WG is focused on providing resources for every stage of clinical engagement to help increase the engagement of all communities, regardless of where they are in the engagement process. The goal of the toolbox focus topic area is to provide a range of resources tailored to the broad range of engagement experiences.

Insoo Hyun, Ph.D., asked if the WG wants engagement in all types of trials knowing how many fail and voiced concerns about engagement-fatigue. Is the goal to encourage engagement on all trials or are there particular trials using, for example, novel technologies that the WG prioritizes? Dr. Hyun also questioned if there was a budget plan and inventory of the number of gaps in public engagement from the WG.

Dr. Bakken answered that the WG believes that engagement is not a one-size-fits-all approach, and engagement priorities will change depending on the state of the science, the questions being asked, and where engagement is most needed. Secondly, she noted that there are internal processes within the NIH that may need to be updated based on the final NExTRAC recommendations, and that NIH is already undertaking steps to be ready to receive potential recommendations regarding participant engagement.

Ms. Veasley added that perhaps community engagement would prevent high numbers of trials failing if the public was involved from the inception. She also emphasized that infrastructure goes hand-in-hand with the toolbox and the draft Theory of Action to ensure that resources developed will have the appropriate funding and infrastructure to be useful.

Kenneth Oye, Ph.D., stated that how data is assembled and put together is part of research and encouraged more conversations surrounding equity around data assembly and data protection and to not focus exclusively on clinical trials. Dr. Oye also added to Dr. Hyun's point that as demand for engagement in research increases, it may be difficult to avoid engagement-fatigue and maintain consistent engagement.

Dr. Bakken responded by noting that one of the draft principles is the right to not engage and emphasized the need for processes in place for people who wish to engage.

Shawneequa Callier, J.D., asked about the RFI and whether the WG has considered how to incentivize institutions to encourage community engagement and empowerment. Ms.

Callier underscored that while we often prioritize institutional ownership of data, there are likely cases where shared ownership with the community may be appropriate. Ms. Veasley stated that incentivization has been a consideration as it is difficult to insist researchers do engagement if the institution is not supportive.

Jonathan Jackson, Ph.D., added to Ms. Callier's point, stating that the WG is aware that the institutional level is one of the levers most in need of support in building engagement. The Theory of Change focus topic area specifies that initiatives should focus on both the community level as well as at the institution level, such as developing infrastructure and toolkits for institutions to engage the larger community. The WG is also considering several funding mechanisms designed to encourage institutional-level participation with the larger community. Furthermore, the WG is also focusing on principles of decolonizing research practices, such as encouraging robust research practices not just at large research institutions but also at smaller, local groups and institutions.

Dr. Key agreed with Dr. Jackson's points, pointing out that successful research is often tied to the researcher, such that if the researcher leaves the community the relationship with the community also degrades. Dr. Key highlighted that this WG is focused on building relationships beyond just the researcher and instead within the institution and the community so that relationships are maintained long-term.

Ms. Veasley added that the RFI questions are mainly geared toward the public, communities, and patient partners but it is critical to also target researchers, institutions, and funders of research about what resources they may need. Ms. Veasley encouraged the Committee to share suggestions of other important elements to include on future RFIs for institutions.

Dr. Oye stated that the WG has focused more on institutional incentives compared to community incentives. Dr. Oye noted that appropriate engagement with communities can improve the quality of research and stressed that the WG needs to focus on promoting self-interests of the public in research through incentives.

Ms. Krofah suggested that the WG should discuss the role of accountability in institutional incentives. Ms. Krofah clarified that there were two avenues of policy, small "p" policy and capital "P" policy. Small "p" policy focuses on the practical changes that are going to be incentivized differently within institutions. Most of these practice changes are governed at the higher level by capital "P" policy which focuses on what NIH needs to do to differently to direct incentives, for example having requirements for different forms of research regarding engaging with the public. Ms. Krofah stressed the need for accountability at all stages and in all forms of research participation, while recognizing that there will be different forms of accountability at different levels of engagement.

Doug Lindsay emphasized that, when considering incentivization, the WG will want to avoid giving communities a rooted interest in specific trial outcomes, for instance, the success of a cancer drug. He cautioned that ENGAGE doesn't want to motivate people

with incentives to such an extent to encourage bad science in which the public is deeply invested in the outcome of certain trials.

Ms. Veasley noted that NExTRAC members could share their recommendations and thoughts regarding prior community conversations with the Cochairs via email, to learn more what worked well and what could be improved.

Dr. Bloss thanked the Cochairs for giving an update on the WG's progress and noted that the Committee will now hear an update from NIH on internal efforts to advance clinical research engagement.

UPDATE ON NIH CLINICAL RESEARCH ENGAGEMENT EFFORTS

Joni Rutter, Ph.D., Director of the National Center for Advancing Translational Sciences and Lyric Jorgenson, Ph.D., NIH Associate Director for Science Policy and Director of the NIH Office of Science Policy

Dr. Jorgenson announced that the NIH launched a program on June 6th, 2024, to pilot work at a national primary care research network called the Communities Advancing Research Equity for Health™ (CARE for Health™), which will provide \$30 million in funding over the next two fiscal years. This program seeks to improve access to clinical research to inform and improve care, especially for historically underrepresented communities. CARE for Health focuses primarily on new prevention approaches that are meaningful to these populations in particular.

Dr. Jorgenson then provided an update on the complementary activities of the internal-NIH WG, the Clinical Research Engagement and Activities Team (CREATE). CREATE's goal is to provide a landing pad for the eventual NExTRAC recommendations in summer 2025, informed by engagement efforts of NIH and NIH-funded researchers.

Dr. Rutter stated that CREATE is charged with improving meaningful public engagement in clinical research. CREATE is expected to provide a collaborative forum to share best practices, develop an NIH-wide Community of Practice to form meaningful public engagement, support the ENGAGE WG with data or information needs, identify resource and infrastructure needs to address NExTRAC recommendations, and serve as stewards for public engagement across NIH to relay updates on current and future directions for public engagement.

CREATE is composed of individuals from across NIH, and members were nominated based on their experiences leading patient and community-centered research programs and initiatives across NIH. The CREATE workplan is broken into two phases: Phase I focuses on creating an external handbook of case studies of engagement while Phase II focuses on building institutional knowledge of best practices of engagement with the long-term goal to advise on the potential future implementation of the NExTRAC recommendations resulting from the ENGAGE WG.

During Phase I, CREATE's goal is to highlight strategies currently used to engage communities, recognizing that engagement is not a one-size-fits-all approach. The handbook created as part of Phase I will have case studies intended for patients, caregivers, patient advocacy groups, communities, and researchers. This resource is meant to be a living document that changes as new resources become available. The first 5 case studies are now [live](#).

The external handbook is intended to have case studies covering the three audience groups (patients and caretakers, communities, and researchers) across five different engagement objectives:

1. Collaborative decision-making – patients, community members, and research teams working together to make decisions and design research.
2. Equitable engagement – enabling patients and community members with diverse viewpoints and experiences to partner with research teams.
3. Methods of engagement – practical ways to include the ideas and opinions of patients and community members in research.
4. Sustainable engagement and capacity building – ensuring research partnerships have the resources and support to continue long-term.
5. Return of research value – making sure that research and its results are useful to patients and communities.

The case studies are therefore meant to cover a range of engagement-related initiatives and may, for example, have materials to help patients partner with researchers in the treatment-development processes, models for integrating patients into oversight programs, strategies for creating institutional capacity, etc.

Dr. Rutter highlighted the [ENGAGE website](#) with the available case studies, stating that in the future viewers will be able to sort case studies by engagement objective. When a case study is clicked on, it opens to its own page that has a high-level summary, a description of how the study applies to the different stages of the research process, the audiences who would benefit from the example, key takeaways and examples of the study in process, and links to relevant resources such as toolkits or webinar recordings. Finally, Dr. Rutter noted that CREATE welcomes any questions and feedback on the case studies from the NExTRAC.

WRAP-UP AND ADJOURNMENT

Dr. Bloss thanked Dr. Jorgenson and Dr. Rutter for their presentation, Dr. Bakken and Ms. Veasley for their leadership of the ENGAGE WG, and all members of ENGAGE for their work to date. She further thanked everyone who attended the meeting and all members of the public tuning in via videocast. Dr. Bloss adjourned the meeting at 12:59 p.m. ET.

Date: _____

Jessica M.
Tucker -S

Digitally signed by Jessica
M. Tucker -S
Date: 2024.09.18
11:24:13 -04'00'

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: _____

Bloss,
Cinnamon

Digitally signed by Bloss,
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09:41:13 -07'00'

Cinnamon Bloss, Ph.D.
NExTRAC Chair

ACRONYMS AND ABBREVIATIONS

ACD	NIH Advisory Committee to the Director
AI	artificial intelligence
CREATe	NIH Clinical Research Engagement and Advisory Team
ENGAGE WG	Working Group on Engaging the Public as Partners in Clinical Research
ML	machine learning
NExTRAC	Novel and Exceptional Technology and Research Advisory Committee
NIH	National Institutes of Health
RFI	Request for Information
WG	working group

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

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ATTACHMENT II: WORKING GROUP ON ENGAGING THE PUBLIC AS PARTNERS IN CLINICAL RESEARCH ROSTER

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