

Setting the Stage: What is Engagement in Clinical Research?

Suzanne Bakken & Christin Veasley





What is the National Institutes of Health (NIH)

- ▶ **NIH** is the nation's medical research agency, which funds research across the U.S. to make important discoveries that improve health and save lives
- ▶ **NIH** invested nearly \$18 billion in clinical research in 2022 - the largest amount in the U.S.

What is Clinical Research?

- **Clinical research** is medical research that involves people to learn more about disease and improve health



Stages of Clinical Research

What is Research Engagement?

- **Research engagement** is when individuals, such as patients, groups of people, communities, and/or organizations partner with researchers to plan, design, and/or conduct research



Relevant Partners

Improving Public Engagement in Clinical Research

- ▶ Patients, communities, and other members of the public are essential partners to the success of research
- ▶ Engagement should be tailored to the needs and experiences of people and communities, and that they should guide the direction of research that is impactful to them
- ▶ To accomplish this, NIH has launched an effort to develop a vision and framework for incorporating public voices in all phases and types of clinical research



Engaging the Public as Partners in Clinical Research: Meet the Working Group

- ▶ NIH has asked a group of patients, advocates, researchers, clinicians, and non-profit representatives to develop a vision and framework for including public voices in the design and planning of NIH-funded clinical research



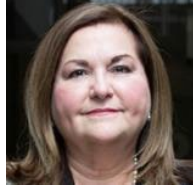
Suzanne Bakken
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(Co-Chair)
Patient Advocate



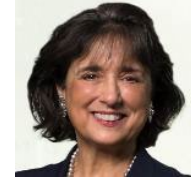
Jessica Ancker
Researcher



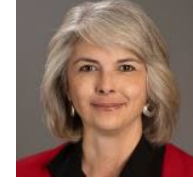
María Aranda
Researcher



Cinnamon Bloss,
Researcher



Roberta Diaz Brinton
Researcher



Karen Caindec
Non-Profit



Kristin Carman
Non-Profit



Venus Ginés
Patient Advocate



Tiffany Haynes
Researcher



Sally Hodder
Researcher



Jonathan Jackson
Researcher



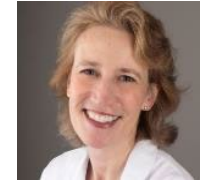
Lance Jasper Jones
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Annie Kennedy
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Kent Key
Researcher



Alexa Kimball
Clinician



Esther Krofah
Non-Profit



Doug Lindsay
Patient Advocate



Marjorie Mau
Researcher



Kenneth Oye
Researcher



Somava Saha
Clinician, Non-Profit



Judy Stecker
Patient Advocate



Maria Trent
Clinician, Researcher



Michelle Sie Whitten
Patient Advocate

Draft Vision & Goal

- ▶ **Vision:** 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.
- ▶ **Goal:** People and communities have a say in the agenda and direction of research that is relevant and impactful to them.





NIH ENGAGE

An Initiative to Increase Public Engagement in Clinical Research

Welcome

NIH is seeking information to assist the agency in developing additional engagement strategies that ensure public voices are meaningfully incorporated in NIH supported clinical research – and we want to hear from **YOU!**

- NIH recently released a **request for information** on strategies to maximize public engagement, see [here](#) for more information on how to submit a response.
- Save the date: NIH will be hosting an [information webinar](#) on July 17th, which will also include significant time for public feedback. More details on the webinar will be provided shortly.
- To learn more about the goals of ENGAGE, check out this [Under the Poliscope blog](#) authored by Lyric Jorgenson and the ENGAGE Co-Chairs, Suzanne Bakken and Christin Veasley.

PartnersInResearch.nih.gov



Multiple Opportunities for Input

- ▶ Currently open:
 - Verbal comments during today's session
 - Written comments (see next slide)
- ▶ Coming soon:
 - Community conversations across the U.S. (*anticipated Fall-Winter 2024-2025*)
 - Additional public NIH meetings
 - NIH always welcomes written comments: email to SciencePolicy@od.nih.gov
- ▶ Final report & recommendations: Summer 2025

We Want to Hear from You!

Request for Information: Strategies for Maximizing Public Engagement in NIH Supported Clinical Research

NIH is seeking information to assist the agency in developing additional engagement strategies that ensure public voices are meaningfully incorporated in NIH supported clinical research studies.

NIH is the nation's biomedical research agency, which funds research across the U.S. to make important discoveries that improve health and save lives. To accomplish this goal, NIH supports the conduct of [clinical research](#) to learn more about disease and improve health.

Patients, communities, and members of the public are essential partners to the success of clinical research. However, meaningfully engaging people and communities is not a one-size-fits-all approach. NIH believes that engagement should be tailored to the needs and experiences of people and communities, and that they should guide the direction of research that is impactful to them. This engagement should be done on an ongoing basis so that members of the public can become active leaders in all stages of the research process.

This request for information (RFI) is part of a larger NIH effort to develop a vision and framework for incorporating public voices in all phases and types of clinical research. To accomplish this, NIH asked the Novel and Exceptional Technology and Research Advisory Committee ([NExTRAC](#)) to form the ENGAGE Working Group. This Working Group includes patients, advocates, researchers, clinicians, non-profit representatives, and more.

For the purposes of this RFI, NIH is specifically seeking input about engaging the public throughout all stages of clinical research and not focused solely on recruitment or participation in clinical research and trials. The responses NIH receives to this request will help inform the development of the NExTRAC's recommendations on incorporating public perspectives in clinical research.

Learn more:



<https://bit.ly/3RMfZm2>

Written comments due August 14th!