



NIH ENGAGE INITIATIVE UPDATE

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National Institutes
of Health

REMINDER

FOSTERING ENGAGEMENT, TRANSPARENCY, & TRUST IN CLINICAL RESEARCH

- **Aug 2023:** NIH charged the Novel and Exceptional Technologies Research Advisory Committee (NExTRAC) to develop a vision and framework for including public voices in the design and planning of NIH-funded clinical research (*to consult with ACD*)
- **Dec 2023:** ACD briefing on NEXTRAC working group plan of action
- **Jun 2024:** NIH launches ENGAGE Initiative to bring together external and internal efforts in promoting the public as essential and equal partners in the success of clinical research
- **Dec 2024:** Discussion with ACD on NExTRAC and NIH's progress, preliminary findings, and next steps



ENGAGE INITIATIVE

Develop a vision and framework for incorporating public voices in all phases and types of clinical research

NEXTRAC WORKING GROUP

ENGAGING THE PUBLIC AS PARTNERS IN CLINICAL RESEARCH



Suzanne Bakken
Columbia U



Christin Veasley
Chronic Pain
Research Alliance



Jessica Ancker
Vanderbilt U



María Aranda
U Southern California



Cinnamon Bloss,
UC, San Diego



Roberta Diaz Brinton
U Arizona



Karen Caindec
Southcentral Foundation



Kristin Carman
PCORI



Venus Ginés
Día de la Mujer Latina



Tiffany Haynes
U Arkansas for
Medical Sciences



Sally Hodder
West Virginia U



Lance Jasper Jones
Jasper House Warriors



Annie Kennedy
EveryLife Foundation
for Rare Diseases



Kent Key
Community Based Org.
Partners/Michigan State



Alexa Kimball
Harvard Medical Faculty
Physicians/Beth Israel



Esther Krofah
FasterCures



Doug Lindsay
The Lindsay Center
LLC/Doug Says LLC



Marjorie Mau
U Hawai'i at Mānoa



Kenneth Oye
Massachusetts Institute
of Technology



Somava Saha
Well-being and Equity
(WE) in the World



Judy Stecker
Hill+Knowlton
Strategies



Maria Trent
Johns Hopkins U



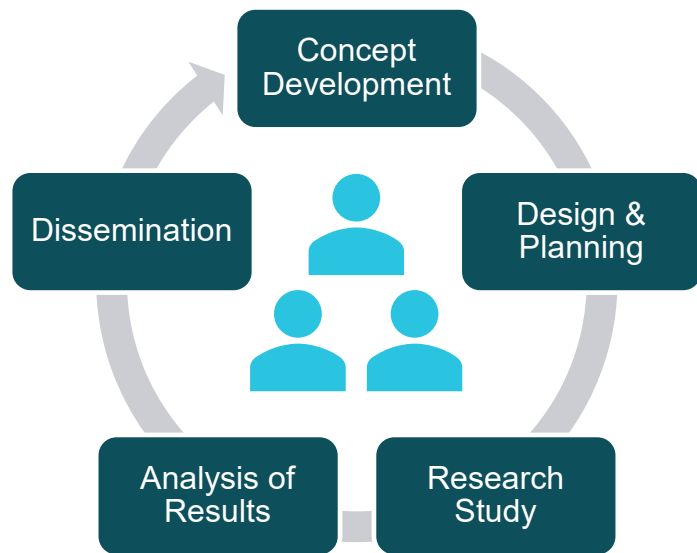
Michelle Sie Whitten
Global Down Syndrome
Foundation

ENGAGE Progress

- Draft definition for clinical research engagement & identify key players
- Develop draft framework graphic and content to serve as engagement roadmap
- Identify helpful resources and tools to support clinical research engagement

What is Clinical Research Engagement?

CLINICAL RESEARCH ENGAGEMENT: 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.



Various Stages of Clinical Research



Relevant Partners

Building Long-Term Partnerships

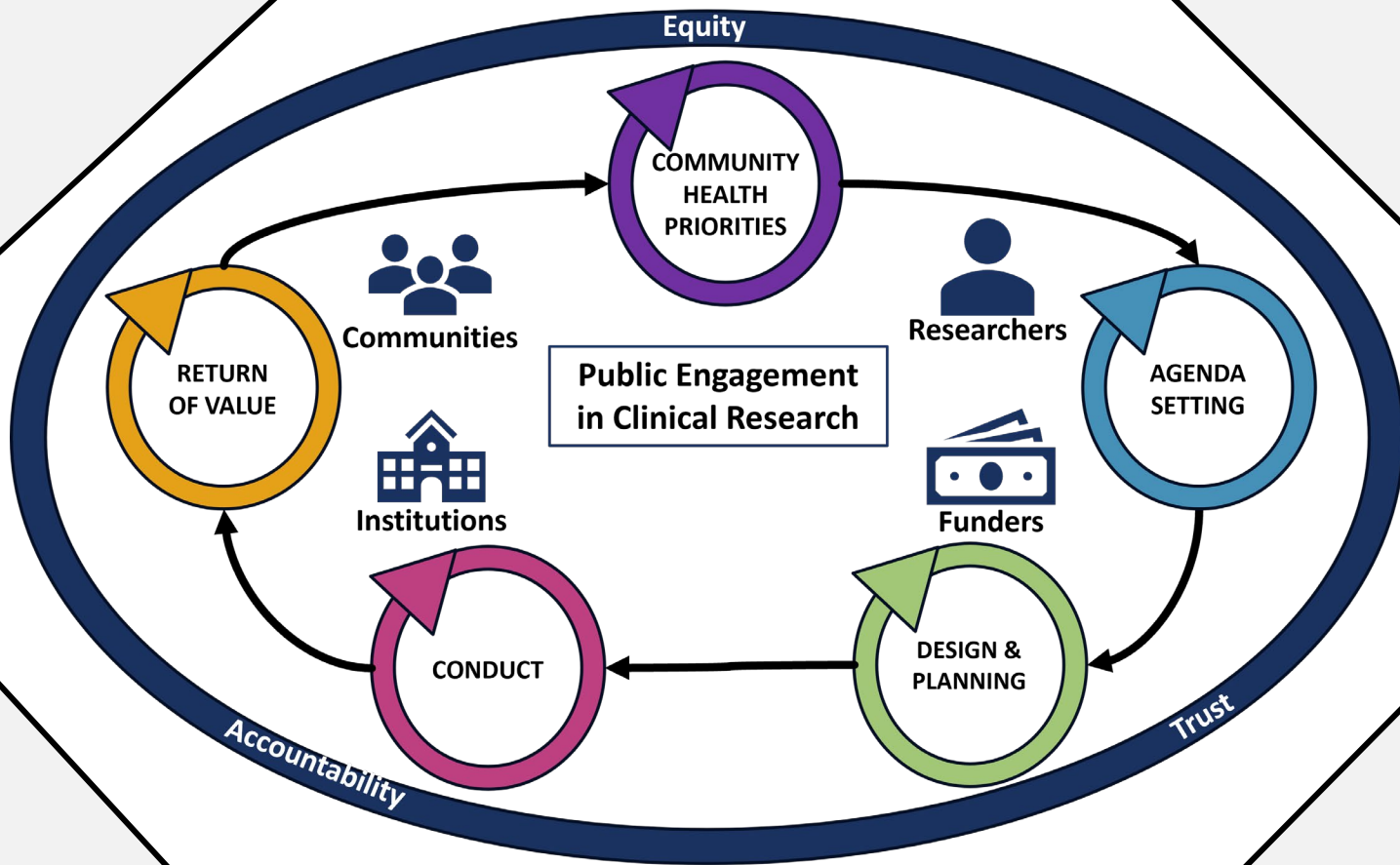
Mitigating Social Determinants of Health

Community Knowledge and Lived Experience

Community Infrastructure

Organizational Knowledge

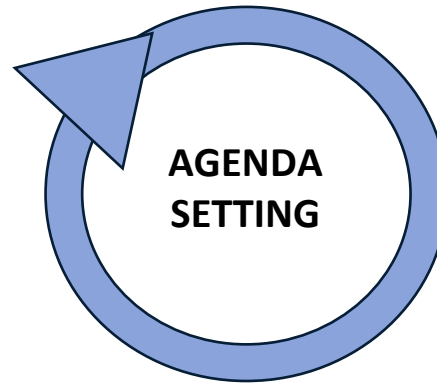
Organizational Infrastructure



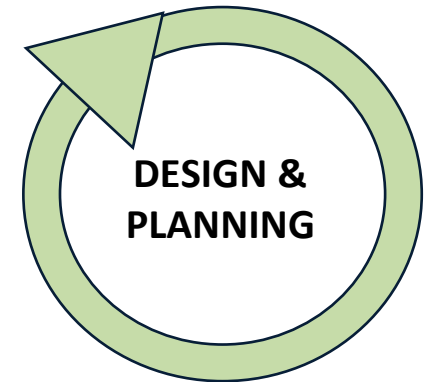
Draft Objectives



Research question or research study is informed and driven by community health needs and priorities.



Shared, equitable priority setting process where community needs are matched to the research questions.



Ensure that the research question or research study is co-designed with community members.

Building out a toolbox and tagging system



- Patients or advocacy groups
- Community
- Researcher
- Institution
- Funder

Resource User



- Patients or advocacy groups
- Community
- Researcher
- Institution
- Funder

Intended Audience



- Determine community health priorities
- Define the research question
- Design & plan the research
- Conduct research
- Return Results & Value

When



- Electronic health records
- Real world data
- Novel intervention
- AI/ML
- Patient-generated data

Novel or Emerging Tech



- Flow chart
- Guidelines
- Manuscript
- Sample
- Template
- Training
- Repository
- Case Study
- Glossary

Resource Type

SEEKING PUBLIC INPUT EARLY AND OFTEN

CHARGE: Convene public consultations to provide individual perspectives on:

- Different engagement methods
- Optimal timing
- Approaches for ensuring equity and inclusivity

PLAN: Seek public input through multiple channels:

- Request for Information (RFI)
- Virtual listening session
- 12 community conversations



Request for Information & Listening Session

1

Strategies for researchers to best partner and work with people & communities

2

Ways for institutions to support partnerships between researchers & communities

3

Approaches for funders to incorporate partnerships between people & researchers

4

Things that make people more likely to engage with researchers

5

Things that make people less likely to engage with researchers



KEY THEMES ACROSS ALL RESPONDENTS



**Incorporating patient
and community input
into research**



**Requiring incentives
and compensation
for engagement**



**Lack of resources
and infrastructure
are key barriers**



Washington, DC



Chicago, IL



Idaho Falls, ID



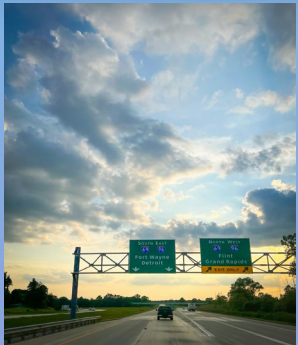
Bangor, ME



AI/AN Advocacy
Organizations

COMMUNITY CONVERSATION PLAN

Flint, MI



Baton Rouge, LA



Wichita, KS



Los Angeles, CA



Honolulu, HI



Houston, TX



Research
Community



Approach to Each Conversation

Pre-Conversation



Partner with community org



Facilitation guide



Questionnaire

During Conversation

~25 attendees



Live Illustrator



Post-Conversation



Thank you email



Reports



Updating website

Community Conversation

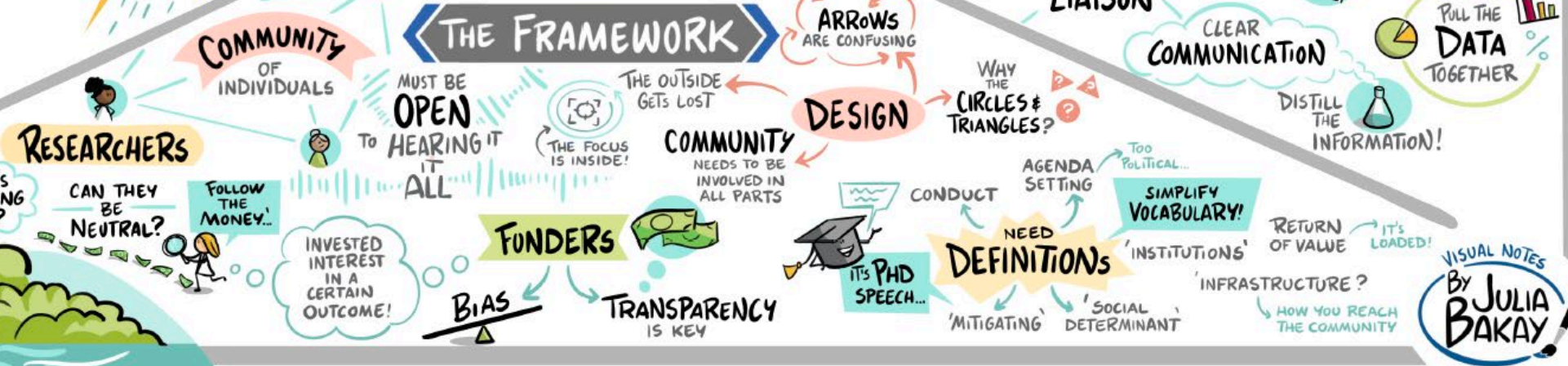
COMMUNITY INPUT



COMMUNITY PARTNERSHIPS



THE FRAMEWORK



VISUAL NOTES
By JULIA BAKAY!



CREATING A RUNWAY TO IMPLEMENTATION

REMINDER

NIH HAS VAST EXPERTISE TO BUILD UPON



All of Us
RESEARCH PROGRAM

CTSA Clinical & Translational
Science Awards Program

NIH NATIONAL CANCER INSTITUTE
Division of Cancer Control
& Population Sciences

NCI Cancer Centers' Case Studies on
Community Outreach
and Engagement

ADORE

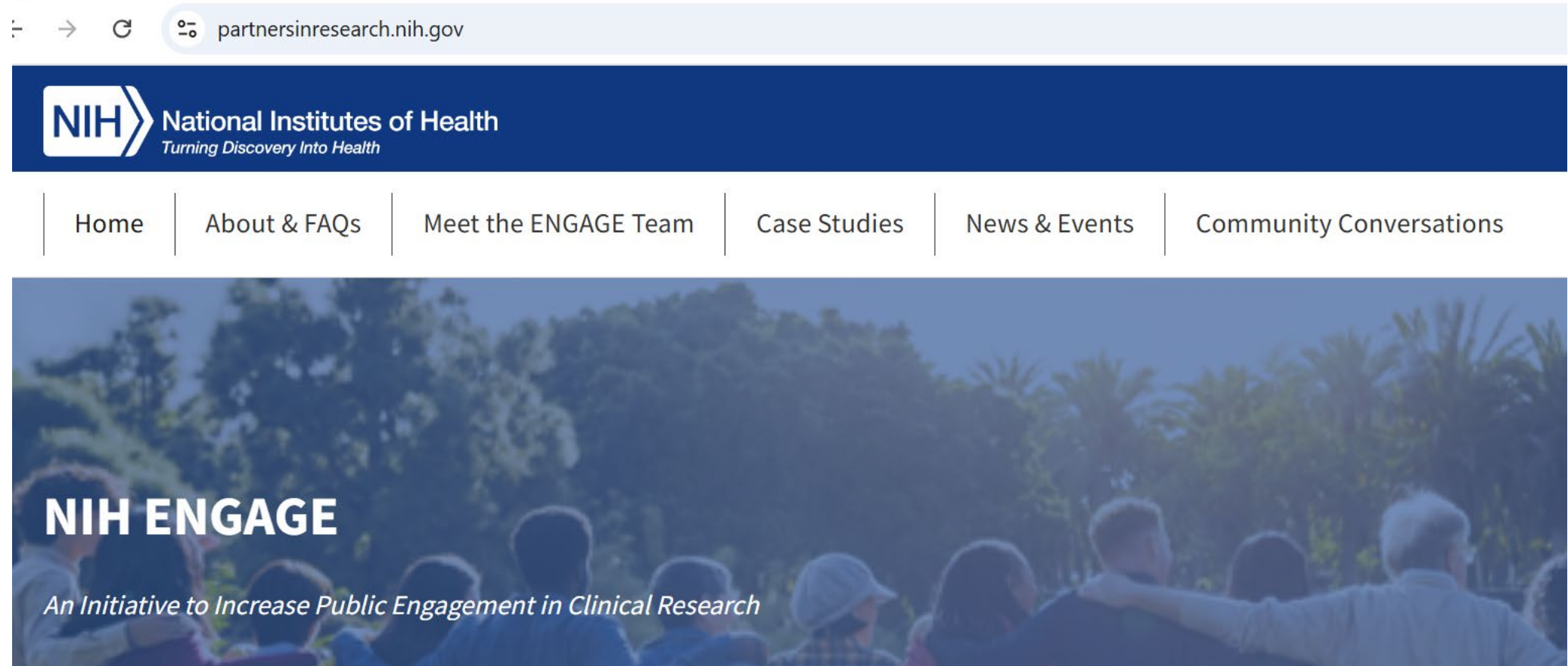


HEALTHY Brain and Child Development
Babies • Brains • Bright Futures



 **NIH Collaboratory**
Health Care Systems Research Collaboratory

NIH “Central Door”



Case Studies

Community Convenings with Faith-Based and Community Partners

Community Convenings are in-person conversations between community members and researchers. They are held at churches or other faith institutions, and the conversation is led by a faith leader...

[Learn More](#)

NINDS Nonprofit Forum: Progress Through Partnership

The Nonprofit Forum happens once a year and brings together diverse voices in the neurological disorder community. The Nonprofit Forum is attended by people with lived experience of neurological disorders, leaders of nonprofit organizations...

[Learn More](#)

Community Partnerships to Advance Science for Society (ComPASS)

The ComPASS program aims to empower community organizations to take ownership over their own health challenges and solutions. ComPASS is an innovative model that directly funds community organizations rather than...

Building Research for Academic and Community Equity (BRACE) Toolkit

The BRACE Toolkit is a set of materials to help community organizations and researchers build equitable partnerships. The toolkit provides information for both community organizations and researchers on...

NIH PROGRESS – TANGIBLE STRATEGIES

NEXT STEPS & ACD DISCUSSION



★ = Updates to ACD

BUILDING TRUST FOR THE FUTURE

- Science and technology can advance quickly
- Ethical and societal norms continuously evolve
- How can policymakers engage appropriately to
 - Responsibly advance science
 - Build trust
 - Improve health?
- **ENGAGE EARLY, OFTEN, AND ALONG THE WAY!**

