NATIONAL INSTITUTES OF HEALTH

FOSTERING ENGAGEMENT, TRANSPARENCY, & TRUST IN CLINICAL RESEARCH: NExTRAC UPDATE

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NEW NIH EFFORT

PUBLIC ENGAGEMENT IN CLINICAL RESEARCH

- NIH launching a new effort to develop a harmonized and implementable vision and framework for including public voices in the design, planning, and dissemination of NIH-funded clinical research
- Spearheaded by a working group of the NIH Director's Novel and Exceptional Technology and Research Advisory Committee (NExTRAC) with ties to the ACD
- Goal is to outline approaches appropriate for the breadth and diversity of NIH-funded clinical research studies and assess potential opportunities and challenges

NExTRAC WORKING GROUP

ENGAGING THE PUBLIC AS PARTNERS IN CLINICAL RESEARCH

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SOME CONTEXT

CLINICAL RESEARCH KEY FOR TURNING DISCOVERY INTO HEALTH

Viewpoint

April 28, 2023

Transforming Clinical Research to Meet Health Challenges

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The COVID-19 pandemic made "clinical trials" a household phrase, highlighting the critical value of clinical research in creating vaccines and treatments and demonstrating the need for large-scale, well-designed, and rapidly deployed clinical trials to address the public health emergency. As the largest public funder of clinical trials, the National Institutes of Health (NIH) launched a high-level effort to absorb the lessons of the pandemic and to assess and build on ongoing initiatives to improve efficiency, accountability, and transparency in clinical research.

- NIH is the steward of the Nation's largest public investment in clinical research (~$18B in FY22)
- Recent NIH Clinical Trial Stewardship Task Force made recommendations for improving meaningful engagement with patients to enhance health outcomes

SOME CONTEXT

MEANINGFUL ENGAGEMENT YIELDS BETTER OUTCOMES

THE NIH DIRECTOR

August 29, 2023

Recommendations on responsible stewardship of personal health data in clinical research

The NExTRAC recommendations emphasize the importance of engaging research participants and communities early and often throughout the research lifecycle on the use of personal health data, improving how researchers inform and gain consent from participants on the use and sharing of their health data, and ensuring that bioethics is integrated into research to inform the return of the value from these studies, including the research results, to participants and their communities.
- Acting NIH Director

SOME CONTEXT

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

HBCD
HEALthy Brain and Child Development
Babies · Brains · Bright Futures

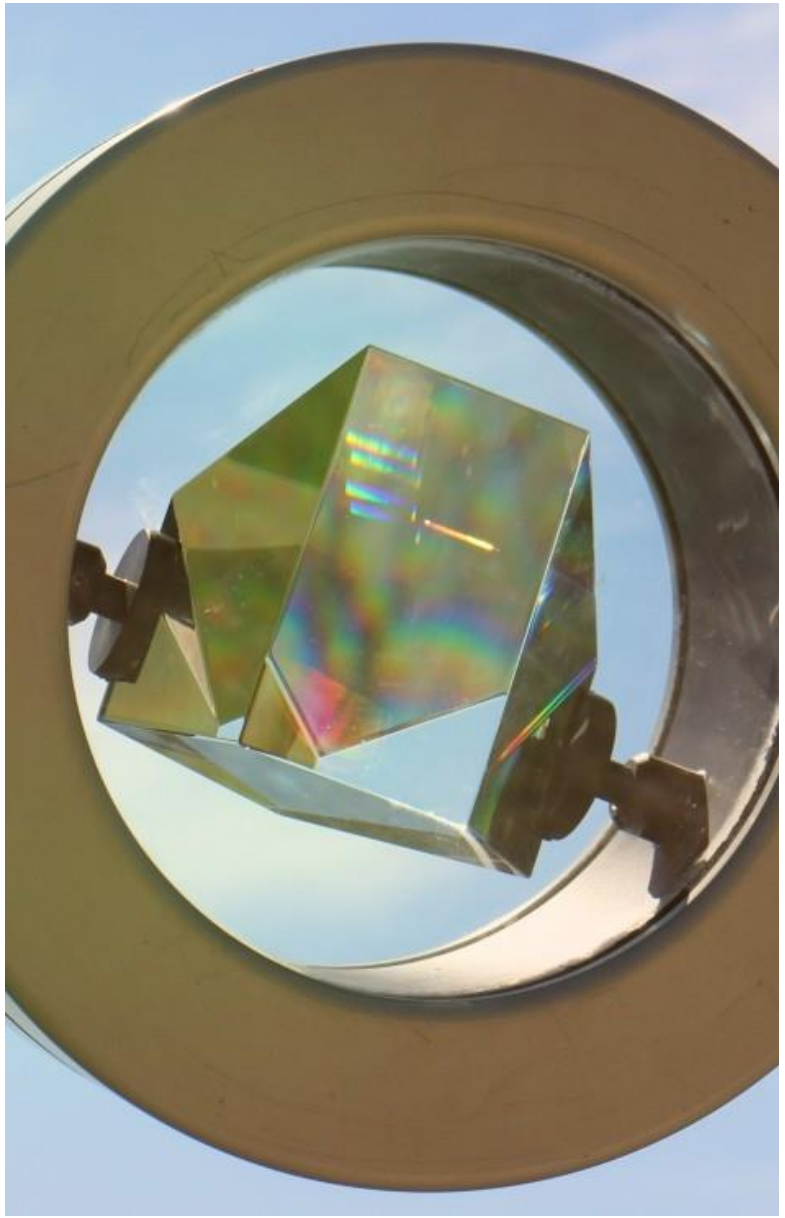
HEAL
NIH · Helping to End Addiction Long-term®

NIH Collaboratory
Health Care Systems Research Collaboratory

WHAT WE'VE LEARNED – IT'S COMPLICATED

- **Meaningful engagement requires:**
  - Resources – approach takes time, money, and infrastructure
  - Expertise – the public isn't homogenous; must recognize unique community perspectives, needs, and values
  - Commitment – setting expectations and holding to them; partnership on part of public and researchers

- **There will not be a one size fits all approach**
  - Different engagement methods may be dependent on the community, including research employing novel technologies, unknown data capabilities, and potentially sensitive datasets
  - Variability in the optimal timing for meaningful engagement across the design and conduct of a study, as well as dissemination to promote uptake/adoption
  - Real need for tailored approaches to ensure research is equitable and inclusive



VISION FOR DELIVERABLES

- **Unified vision for NIH engagement activities in clinical research**
- **“Toolkit” of options for researchers to incorporate engagement strategies in clinical research by defining:**
  - Opportunities and challenges of varying levels of engagement activities for different types of clinical research studies
  - Consideration of potential trade-offs in research investment (e.g., cost, time) and benefits for improved trust, participation, outcomes, research uptake, implementation of new interventions, etc.
  - 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

POTENTIAL OUTCOMES

FOR RESEARCHERS: A practical set of options for meaningful engagement that can be tailored to the objectives, design/scale of the study

FOR SCIENCE: Increased representation and understanding of factors affecting successful study design and completion

FOR PARTICIPANTS: A public vision and framework for how participants can contribute to the scientific enterprise

FOR THE PUBLIC: A roadmap for building understanding of and trust in NIH and scientific research

NEXT STEPS & ACD DISCUSSION

= Updates to ACD