



NEW CHARGE TO THE NExTRAC

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August 29, 2023

BACKGROUND

IMPETUS

- 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
- COVID-19 demonstrated that to be effective in translating research discoveries into improved health outcomes, it is key to prioritize engagement and build trust early, often, and along the way
- Previous *Community Conversations* reinforced the necessity of trust and transparency in engagement for building effective research partnerships with patients, communities, and the broader public

OVERARCHING GOALS

- Engage members of the public as partners in the design and planning of clinical research that is important to them to improve science and health outcomes
- Strengthen bi-directional engagement in clinical research, foster transparency and trust, and create outcomes that provide value to the people NIH aims to serve

NExTRAC CHARGE

ENGAGING THE PUBLIC AS PARTNERS IN CLINICAL RESEARCH

The NExTRAC is charged with establishing the ENGAGE Working Group 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 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 and assess the potential:

- Opportunities and challenges of varying levels of engagement activities for different types of clinical research studies, considering potential trade-offs in research investment (e.g., cost, time) and benefits for improved trust, participation, outcomes, research uptake, implementation of new interventions, etc.; and
- 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, as well as other relevant considerations deemed appropriate by the Working Group.

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In addressing this charge, the Working Group shall 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, to provide recommendations regarding:

- How different engagement methods may be used for clinical research in general, as well as research employing novel technologies, unknown data capabilities, and potentially sensitive datasets;
- Optimal timing for meaningful engagement activities across the spectrum of the design and planning of the clinical research study, as well as dissemination of study findings so that evidence-based practices are adopted in the community; and
- Approaches for public engagement in NIH clinical research to be equitable and inclusive.

NExTRAC CHARGE VISION

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 vision and framework for how members of the public can contribute to the scientific enterprise

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

NExTRAC CHARGE TIMELINE

