Novel and Exceptional Technology and Research Advisory Committee

A DRAFT Report of the Engaging the Public as Partners in Clinical Research (ENGAGE) Working Group

September 2025

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ENGAGE Vision and Goal for Clinical Research Engagement at NIH

GOAL: for people and communities to influence the agenda and direction of, as well as have meaningful input into, research that is relevant and impactful to them

VISION: a future where clinical research engagement is standard practice, promoting responsiveness to community needs, accountability, and transparency while helping turn discoveries into improved health

Clinical research engagement has emerged as a critical component of the modern-day research landscape because it improves research efficiency, builds public trust, increases study relevance, and supports broader results dissemination. Clinical research engagement occurs when people, groups of individuals, communities, and/or organizations partner with researchers to plan, design, and conduct research so that the research and its outcomes are meaningful, actionable, or support understanding of disease for those who could benefit from the research.

The National Institutes of Health (NIH) does not have a unified vision and framework for including patient and community voices in the design and conduct of its clinical research. Building on previous efforts by the Novel and Exceptional Technology and Research Advisory Committee's (NExTRAC) Data Science and Emerging Technology in Biomedical Research Working Group, the NIH recognized the need for a cohesive engagement framework for its clinical research.[1]

Therefore, in August 2023, the NIH charged the NExTRAC with establishing the Engaging the Public as Partners in Clinical Research (ENGAGE) Working Group (WG) to:

- Develop a framework for including public voices in the design and planning of NIH-funded clinical research[2]
- Convene public consultations with patient partners, caretakers, community representatives, research participants, patient advocacy organizations, clinical researchers, local health providers, and others to inform recommendations
- Provide recommendations on how different engagement methods may be used in clinical research

Clinical Research Engagement: Benefits and Challenges

Clinical research engagement provides value to researchers, research organizations, and most importantly, to the people who are affected by the research. Clinical research engagement increases efficiency through higher recruitment rates and improved participant retention, improves study feasibility through identification of logistical problems during the design phase, increases the relevance of study outcomes, helps make the results of research more meaningful for patients, clinicians, and others who could benefit from the research, and builds trust by involving community members in study design, addressing one of the NIH Director's priorities.

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[1] The ENGAGE WG defines clinical research as medical research that involves people and is designed to learn more about disease, health, and how to improve health, including studies across the research continuum and those utilizing different designs and data types.

[2] The ENGAGE WG elected to use the phrase 'clinical research engagement' throughout the report to describe the concept of including public voices in the design and planning of NIH-funded clinical research.

Despite the identified benefits of clinical research engagement, there remain numerous challenges that hinder its broad and scalable implementation. Financial constraints, inflexible timelines, lack of training opportunities, and limited organizational support can make it difficult for researchers and their community partners to undertake meaningful engagement.

Public Input and What We Learned

The NIH Office of Science Policy supported the WG's effort by soliciting public input using a Request for Information (RFI), a virtual listening session, and a series of six in-person Community Conversations held in communities across the United States. Insights from all three sources of input identified five key themes:

- **Centering Communities in the Research Process –** research should start with understanding community health priorities and lived realities, and involve community members early in the process
- **Relying on Trusted Voices to Build Relationships –** trusted community voices provide a bridge between researchers and the communities they wish to partner with
- **Implementing Engagement Strategies with Purpose –** researchers must follow through on promises, build reciprocal relationships with communities, and return results in meaningful ways
- **Investing in Building Sustainable Capacity for Engagement –** the NIH and academic organizations should invest in making engagement standard practice and building enduring partnerships with communities
- **Offering Compensation and Incentives for Engagement –** community members and organizations who partner with researchers should be offered fair and equitable compensation

Figure 1. Framework for Clinical Research Engagement

Framework for Clinical Research Engagement

The *Framework for Clinical Research Engagement* (Figure 1) was informed by public input and refined to create a roadmap for clinical research engagement. The *Framework* is organized around the clinical research lifecycle, recognizes that community health needs should influence research priorities, and that integrating communities in the process builds trust and increases study relevance. The *Framework* includes four key partners – community, researchers, organizations, and funders. Community refers to a group of people who share a common bond or interest. Researchers refer to individuals who have training or experience in designing and conducting health research. Organizations refer to both research-focused organizations that employ researchers to carry out clinical research and community-based organizations that are embedded in specific communities. Funders are entities that provide financial resources to researchers or organizations to conduct clinical research.

Researchers must adequately prepare for engagement before implementing the *Framework* by:

- Establishing bi-directional research-community partnerships

- Offering and agreeing on community partner compensation, identifying available funding, and planning for resource allocation
- Developing baseline expectations for research-community processes and study oversight
- Educating and training community partners and researchers.

The WG developed an engagement objective and associated action steps for each stage of the clinical research lifecycle (Table 1). The most important consideration in using the *Framework* is ensuring that community perspectives and expertise are integrated into the study design, execution, interpretation and dissemination.

Table 1. The *Framework for Clinical Research Engagement's* Objectives and Action Steps

Stage of Research Lifecycle	Engagement Objective	Action Steps
STAGE 1 **Identify Health Needs**	Articulate the community's health needs and why those needs are important to improving health	• Ongoing and consistent collection and assessment of community health needs by researchers and communities • Develop understanding of the importance of the community health need(s)
STAGE 2 **Set the Research Question**	Undertake a shared priority-setting process to match community needs with evidence gaps to create the study's research question(s)	• Execute a shared priority-setting process that includes both researcher and community participation • Clarify evidence gaps and possibilities for research • Craft the research question(s) and identify potential funding opportunities
STAGE 3 **Plan the Research**	Co-design a research study aimed at answering the selected research question(s)	• Reach agreement on community and researcher roles, responsibilities, and decision-making processes • Deliver study- or role-specific training to prepare community partners and researchers for collaborative design • Incorporate community expertise into study design to improve quality and feasibility
STAGE 4 **Carry Out the Research**	Conduct the clinical research study to gather scientific evidence	• Monitor study progress to ensure community-centeredness and fulfillment of responsibilities • Implement community-informed study modifications to address obstacles • Co-interpret study results with input from both community partners and researchers
STAGE 5 **Share the Findings**	Collaboratively return research results to study participants, community of focus, scientific audiences, and the broader public	• Co-design tailored plans for returning results to participants, community(ies), scientists, and the public • Co-create the dissemination products • Co-communicate dissemination products through multiple channels

Recommendations to the NIH to Standardize Meaningful Clinical Research Engagement in NIH-Funded Clinical Research

The ENGAGE WG created four bold recommendations to the NIH that will meaningfully address known barriers to engagement and standardize the inclusion of the *Framework* in NIH-funded clinical research (Figure 2).

Figure 2. ENGAGE WG's Recommendations to the NIH to Standardize Meaningful Clinical Research Engagement in NIH-Funded Clinical Research

1 **NIH should require and support the integration of the *Framework for Clinical Research Engagement* into its funded clinical research by providing financial and training resources**

- **Strategy 1A:** Define for applicants the requirements for incorporating and budgeting for engagement into proposal development, study design, and study execution for NIH-funded clinical research studies
- **Strategy 1B:** Require and fund clinical research studies to return research results to participants, the community of focus, and the broader public using methods that make results accessible and meaningful, protect participant privacy, and prevent group harm
- **Strategy 1C:** Require that study leaders and community-facing personnel be trained in clinical research engagement best practices

2 **NIH should actively foster an environment in which bi-directional researcher-community partnerships are standard practice**

- **Strategy 2A:** Ensure that funding opportunities support the development and maintenance of researcher-community partnerships before, during, and after a clinical research study, including providing adequate funding for community organizations to execute engagement activities
- **Strategy 2B:** Create a comprehensive repository(ies) of clinical research engagement resources (e.g., trainings, best practices, templates) for both researchers and community partners
- **Strategy 2C:** Integrate into the peer review process an assessment of academic and other research organizations' engagement resources and practices (e.g., engagement cores)

3 **NIH should create a process to ensure robust community input on NIH initiatives from a broad range of community organizations and advocates**

- **Strategy 3A:** Establish a coordinated agency-wide approach for engagement activities, including technical support and resources, across the Institutes, Centers, and Offices
- **Strategy 3B:** Ensure NIH staff, NIH leaders, and peer reviewers are knowledgeable about the benefits of clinical research engagement, best practices, and methods for incorporating community input
- **Strategy 3C:** Require each Institute, Center, or Office that supports clinical research to integrate community input in their next (and all subsequent) strategic plans and initiatives

4 **NIH should invest in the continuous evolution and improvement of its clinical research engagement methods and processes**

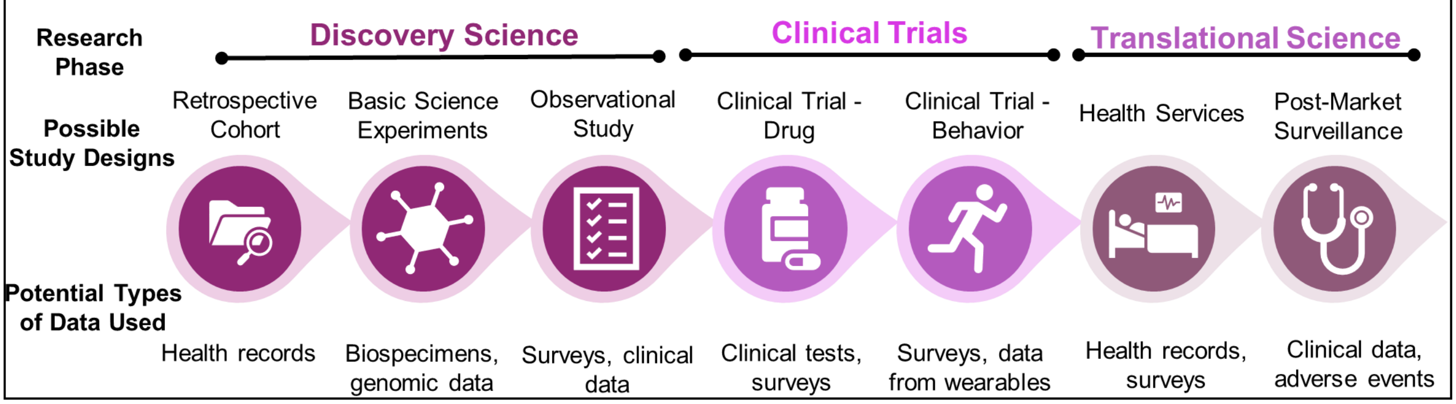
- **Strategy 4A:** Operationalize the *Framework for Clinical Research Engagement* and develop associated metrics to assess improvement in scientific research and community health
- **Strategy 4B:** Support researchers to monitor, assess, and report their engagement methods and progress on *Framework* metrics (from Strategy 4A) at annual reviews to inform future improvements
- **Strategy 4C:** Develop procedures to hold researchers accountable to engagement expectations and identify consequences for non-adherence
- **Strategy 4D:** Develop targeted funding opportunities to support larger-scale assessments of different clinical research engagement methods and their impact on *Framework* metrics (from Strategy 4A)

I. The ENGAGE Working Group and its Vision for Clinical Research Engagement at the NIH

Introduction to Clinical Research and Clinical Research Engagement

Clinical research is medical research that involves people and is designed to learn more about disease, health, and how to improve health. This definition includes studies conducted across the research continuum from discovery science to translational science, and studies that utilize different designs and data types (Figure 3).

Figure 3. A Visual Depiction of the ENGAGE Definition of Clinical Research



Clinical research engagement has emerged as a critical component of the modern-day research landscape because it improves research efficiency, enhances transparency, builds public trust, and increases the relevance of study outcomes. Clinical research engagement occurs when people, groups of individuals, communities, and/or organizations partner with researchers to plan, design, and conduct research so that the research and its outcomes are meaningful, actionable, or support understanding of disease for those who could benefit from the research. The goal is for people and communities to guide the direction of, and/or partner in, research that is relevant and impactful to them.

Clinical Research Engagement at the NIH

NIH does not have a unified vision and framework for including patient and community engagement in the design and conduct of its funded clinical research. Some of the individual Institutes, Centers, and Offices that comprise the NIH have developed innovative engagement practices tailored to their missions, including:

- The NIH Pragmatic Trials Collaboratory developed comprehensive information and resources for clinical research engagement.[3]

Clinical Research Engagement

Occurs when people, groups of individuals, communities, and/or organizations partner with researchers to plan, design, and conduct research so that the research and its outcomes are meaningful, actionable, or support understanding of disease for those who could benefit from the research

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[3] Fraser J, Moloney R, Tambor E, et al. Building partnerships and teams to ensure a successful trial. Updated October 3, 2022. Accessed on September 8, 2025. https://rethinkingclinicaltrials.org/chapters/engaging-stakeholders/engaging-stakeholders-and-building-partnerships-to-ensure-a-successful-trial/

- National Cancer Institute-designated cancer center grants include community engagement as a core element.[4]
- The Rare Diseases Clinical Research Network works directly with patient advocates through the Coalition of Patient Advocacy Groups to inform clinical research studies.[5]
- Clinical and Translational Science Awards include community engagement cores.[6]

Despite these examples, most clinical research engagement efforts remain decentralized and inconsistently implemented across the NIH. It is time for the NIH to create a cohesive approach and mandate the integration of clinical research engagement across all NIH Institutes, Centers, and Offices, and in all NIH-funded clinical research. Clinical research engagement directly addresses the NIH Director's concern in the declining public trust in clinical research.[7] By partnering with the American people to design and execute clinical research studies, as well as disseminate findings, researchers increase the likelihood that their studies are relevant to those who could benefit, are feasible and efficient to implement, are disseminated to broader audiences, and result in the improved health of the American people.

The ENGAGE Working Group

Building off the efforts of the NIH's Novel and Exceptional Technology and Research Advisory Committee (NExTRAC)'s Data Science and Emerging Technology in Biomedical Research Working Group,[8] the NIH charged the NExTRAC with establishing the Engaging the Public as Partners in Clinical Research (ENGAGE) Working Group (WG) in August 2023. The WG was responsible for developing a unified vision and framework for including patient and community engagement in the design and conduct of NIH-funded clinical research and dissemination of study findings. Specifically, the ENGAGE WG was charged to[9]:

- Develop a framework for including public voices in the design and planning of NIH-funded clinical research[10] that outlines engagement approaches appropriate for the breadth of study designs, assesses the opportunities and challenges of varying levels of engagement activities, and assesses the impact and value of engagement on patients, communities, and research quality
- Consult the NIH Advisory Committee to the Director and convene public consultations with patient partners, caretakers, community representatives, research participants, patient advocacy organizations, clinical researchers, local health providers, and others to inform recommendations

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[4] 73 NCI-Designated Cancer Centers. National Cancer Institute Office of Cancer Centers. Updated March 2025. Accessed on September 8, 2025 at: https://cancercenters.cancer.gov/

[5] About the Coalition of Patient Advocacy Groups (CPAG). Rare Diseases Clinical Research Network. Accessed on September 8, 2025 at: https://www.rarediseasesnetwork.org/patient-advocacy-groups/cpag

[6] Clinical and Translational Science Awards (CTSA) Program. National Center for Advancing Translational Sciences. Updated on July 18, 2025. Accessed on September 8, 2025 at: https://ncats.nih.gov/research/research-activities/ctsa

[7] Kennedy B, Tyson A. *Americans' Trust in Scientists, Positive Views of Science Continue to Decline.* Pew Research Center; 2023. Access on September 8, 2025 from: https://www.pewresearch.org/wp-content/uploads/sites/20/2023/11/PS_2023.11.14_trust-in-scientists_REPORT.pdf

[8] Novel and Exceptional Technology and Research Advisory Committee: Data Science and Emerging Technology in Biomedical Research Report. Updated September 2023. Accessed on September 8, 2025 at: https://osp.od.nih.gov/policies/novel-and-exceptional-technology-and-research-advisory-committee-nextrac#tab5/

[9] The full charge of the ENGAGE WG can be found on the NIH Office of Science Policy website: https://osp.od.nih.gov/policies/novel-and-exceptional-technology-and-research-advisory-committee-nextrac#tab5/. Accessed on August 29, 2025.

[10] The ENGAGE WG elected to use the phrase 'clinical research engagement' throughout the report to describe the concept of including public voices in the design and planning of NIH-funded clinical research.

- Provide recommendations on how different engagement methods may be used in clinical research (particularly for research employing novel technologies), optimal timing for meaningful engagement, and approaches for making engagement equitable and inclusive

To ensure all critical expertise was included within the ENGAGE WG, the four NExTRAC members serving on the WG were complemented with 17 additional experts representing patient advocates, community members, clinicians, researchers, and non-profit organization leaders. The WG undertook a structured, multi-step process, including the development of a theory of action (Appendix A),[11] to identify opportunities for NIH to improve clinical research engagement. It created a vision and goal for clinical research engagement at NIH, developed a framework for clinical research engagement to be used in NIH-funded clinical research, and crafted recommendations for the NIH to build an environment where meaningful engagement in clinical research becomes the norm and not the exception.

The ENGAGE Vision and Long-Term Goal

In creating the ENGAGE WG, the NIH emphasized its commitment to engaging the public as partners in the design and planning of clinical research, as well as dissemination of study findings. The ENGAGE WG built on this commitment to create the following goal and vision for clinical research engagement in NIH-supported clinical research:

- **Goal**: for people and communities to influence the agenda and direction of, as well as have meaningful input into, research that is relevant and impactful to them
- **Vision:** a future where clinical research engagement is standard practice, promoting responsiveness to community needs, accountability, and transparency while helping turn discoveries into improved health

In the remaining sections of this report, the WG provides a detailed description of the *Framework for Clinical Research Engagement* (Section IV), their recommendations to the NIH (Section V) to make this vision a reality, an overview of the scientific literature on the benefits of clinical research engagement and its challenges (Section II), and a summary of the public input that influenced their deliverables (Section III).

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[11] A theory of action is a logical chain of reasoning that explains how change will lead to improved practices.

II. Clinical Research Engagement: Benefits and Challenges

Clinical research engagement provides value to researchers, organizations, and most importantly, to the people who are affected by research. Growing evidence shows that when scientists incorporate engagement strategies, research relevance, trust, study feasibility, and results dissemination improve (Figure 4).

Some Benefits of Clinical Research Engagement

- Aligns study design to **community needs** to improve study relevance and community health
- Builds **trust** by involving community members in design
- Improves study **feasibility** by identifying logistical problems during study design
- Increases **efficiency** through higher recruitment rates and improved participant retention

Figure 4. Summary of Some Benefits of Clinical Research Engagement

Benefits for Communities, Patients, and the Broader Public

When research is shaped with communities, patients, and the broader public, it becomes more accessible, relevant, and impactful. Engagement at the design and conduct stages helps ensure that study interventions are culturally appropriate, practically feasible, and aligned with patients' real-world preferences, values, and needs.[12,13] It also increases community knowledge of clinical research. Engaging the public and communities is central to the successful dissemination, adoption, and implementation of effective study interventions.[14,15] For example, Cyril et al. found that studies with engagement components resulted in improved health behaviors, outcomes, and knowledge, as well as participation in health screening programs.[16] Ultimately, engagement fosters the development of solutions that can inform best practices, guide policy decisions, and support resource allocation.

Benefits for Researchers

Engaging with members of the public and communities is critical for building trust between researchers and participants, community partners, and the broader public. Trust is a foundational factor that influences the effectiveness of research by impacting participant recruitment and retention, as well as the public's acceptance

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[12] Cunningham-Erves J, Mayo-Gamble T, Vaughan Y, et al. Engagement of community stakeholders to develop a framework to guide research dissemination to communities. *Health Expect.* 2020;23(4):958-968. doi: 10.1111/hex.13076

[13] Forsythe LP, Carman KL, Szydlowski V, et al. Patient engagement in research: Early findings from the Patient-Centered Outcomes Research Institute. *Health Aff.* 2019;38(3):359-367. doi: 10.1377/hlthaff.2018.05067

[14] Cohn E., McCloskey DJ, Berman L, et al., eds. Principles of Community Engagement. 3rd ed. Centers for Disease Control and Prevention; 2025.

[15] Domecq JP, Prutsky G, Elraiyah T, et al. Patient engagement in research. A systematic review. *BMC Health Serv Res.* 2014;14:89. doi: 10.1186/1472-6963-14-89.

[16] Cyril S, Smith BJ, Possamai-Inesedy A, Renzaho AMN. Exploring the role of community engagement in improving the health of disadvantaged populations: A systematic review. *Glob Health Action.* 2015;8:29842. doi: 10.3402/gha.v8.29842

and utilization of study findings.[17,18] Mistrust can emerge when communities are not part of the process. Engagement activities allow communities to provide critical information on their needs and priorities, and researchers, in turn, use this understanding to refine the purpose and scope of research. Additionally, individuals are more likely to participate in a research study if people from their communities are involved in study planning and design.[19] Engagement can also enhance the relevance and adoption of the tested health interventions.[20]

Clinical research engagement also helps researchers improve their study designs by adding practical insights, avoiding unrealistic burdens on study participants, and making the research more feasible in real-world settings. Community members often point out logistical problems that researchers might miss, leading to study designs that are both scientifically strong and easier to carry out. For example, clinical research engagement strategies have improved studies through study schedule adjustments, better data collection tools, clarifications on patient-facing materials, recommendations for recruitment strategies, input on new study measures, and updates to user interfaces of technology components.[21,22,23,24]

Benefits for Research Efficiency and Investment

Recruitment delays, participant attrition, mistrust, and other obstacles are major drivers of clinical research study inefficiency and increased costs. Clinical research engagement improves the efficiency of research while delivering a strong return on investment for funders, institutions, and the public. Studies of patient-centered initiatives and other engagement strategies have shown that when researchers incorporate engagement, studies have higher recruitment and retention rates, improving both trial quality and speed.[25,26] Engagement improves recruitment and retention by fostering trust, tailoring messaging, and creating a more responsive study experience.

Through improvements in study design and efficiency, clinical research engagement delivers a strong return on investment. For example, Levitan and colleagues found that incorporating just one engagement activity in a pre-phase 3 trial increased the study's expected net present value by $75 million, a 750-fold return on a

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[17] Blom JMC, Rivi V, Tascedda F, Pani L. Building trust in clinical research: A systems approach to ethical engagement and sustainable outcomes. *Front Pharmacol.* 2025;16:1570899. doi: 10.3389/fphar.2025.1570899

[18] Maurer ME, Hilliard-Boone T, Frazier K, Forsythe L, Mosbacher R, Carman KL. Examining how study teams manage different viewpoints and priorities in patient-centered outcomes research: Results of an embedded multiple case study. *Health Expect.* 2023;26(4):1606-1617. doi: 10.1111/hex.13765

[19] Cargo M, Mercer SL. The value and challenges of participatory research: Strengthening its practice. *Annu Rev Public Health.* 2008;29:325-350. doi: 10.1146/annurev.publhealth.29.091307.083824

[20] Jull J, Giles A, Graham ID. Community-based participatory research and integrated knowledge translation: Advancing the co-creation of knowledge. *Implement Sci.* 2017;12:150. doi: 10.1186/s13012-017-0696-3

[21] Andersen A, Benger J, Getz K. Using patient advisory boards to solicit input into clinical trial design and execution. *Clin Ther.* 2019;41(8):1408-1413. doi:10.1016/j.clinthera.2019.06.006

[22] Manafo E. Petermann L. Mason-Lai P, Vandall-Walker V. Patient engagement in Canada: A scoping review of the 'how' and 'what' of patient engagement in health research. *Health Res Policy Syst.* 2018;16(1):5. doi: 10.1186/s12961-018-0282-4

[23] Mann C, Chilcott S, Plumb K, Brooks E, Man MS. Reporting and appraising the context, process and impact of PPI on contributors, researchers and the trial during a randomised controlled trial – the 3D study. *Res Involv Engagem.* 2018;4:15. doi: 10.1186/s40900-018-0098-y

[24] Maurer M, Mangrum R, Hilliard-Boone T, et al. Understanding the influence and impact of stakeholder engagement in patient-centered outcomes research: A qualitative study. *J Gen Intern Med.* 2022;37(Suppl 1):6-13. doi: 10.1007/s11606-021-07104-w

[25] Stergiopoulos D, Michaels DL, Kunz BL, Getz KA. Measuring the impact of patient engagement and patient centricity in clinical research and development. *Ther Innov Regul Sci.* 2020;54(1):103-116. doi: 10.1007/s43441-019-00034-0

[26] Crocker JC, Ricci-Cabello I, Parker A, et al. Impact of patient and public involvement on enrolment and retention in clinical trials: Systematic review and meta-analysis. *BMJ.* 2018;363:k4738. doi: 10.1136/bmj.k4738

$100,000 investment.[27] Engagement leads to this significant return on investment because it helps avoid costly pitfalls, such as delayed recruitment and reduced retention, and aids researchers in selecting relevant outcomes, among other important factors.[15]

Known Challenges to Clinical Research Engagement

Despite the benefits of clinical research engagement and its growing support, there remain numerous challenges that hinder its broad and scalable incorporation into clinical research.

Lack of financial resources, inflexible funder and/or organizational timelines, and limited academic organization support (e.g., engagement efforts not included in promotion criteria) make it challenging for researchers to undertake meaningful engagement.[28] Additionally, sometimes organizations or funders set specific priorities that will dictate the focus of a funding application. These organizational priorities may differ from community priorities, and researchers may struggle to bridge this divide. Researchers may also believe community members lack the expertise needed to contribute meaningfully to research design.[12]

Many of these challenges arise from lack of training for both researchers and community partners. Researchers vary in their understanding of clinical research engagement and how to appropriately implement patient engagement methods.[29] Community members vary in their understanding of research, its design process, and how to make sense of research findings.[30] Addressing these challenges will enable researchers to incorporate meaningful engagement in their studies, ensuring that communities can be valued partners throughout the entirety of the research lifecycle.

Conclusion

Clinical research engagement increases study feasibility and relevance, enhances efficiency, builds community and public trust, and increases the likelihood of wider dissemination and adoption of study findings. It has a strong return on investment for funders, researchers, research organizations, and the American people. Despite its benefits, clinical research engagement remains challenging for many researchers due to lack of financial resources, organizational expectations to prioritize research outputs (e.g., journal publications, conference presentations) in promotion decisions, and limited training opportunities. The ENGAGE WG addresses these challenges by creating the *Framework for Clinical Research Engagement* and providing key recommendations to the NIH that will build an environment where meaningful clinical research engagement can become standard practice.

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III. Public Input and What We Learned

Methods for Gathering Public Input

NIH endeavored to gather broad and diverse public input – which was critical in informing the WG's efforts – through three strategies: a Request for Information (RFI), a virtual listening session, and six in-person structured dialogues called Community Conversations.

Request for Information (RFI)

The RFI was open for public written comment from June 12, 2024, to August 14, 2024. The RFI requested public input on the following:

- Strategies for how researchers can best partner and work with people and communities
- Ways for organizations performing research (e.g., universities, hospitals) to support and incentivize active, bi-directional partnerships between researchers and communities
- Approaches that research funders can utilize to incorporate partnerships between people/communities and researchers into their programs and priorities
- Specific examples of things that may make people and communities more (or less) likely to engage with researchers and research organizations

Individuals submitted their written comments through an online form on an NIH website. NIH received 61 comments.[31] Individuals who submitted comments were most commonly patients/patient advocates, investigators/researchers, and community advocates. The majority of individuals who responded (75%) frequently engaged with researchers.

Virtual Listening Session

The webinar and virtual listening session, held on July 17, 2024, allowed individuals to register in advance to share public comments with the NIH. The webinar began with presentations from representatives from the NIH and Center for Information and Study on Clinical Research Participation – a non-profit organization dedicated to engaging the public and patients as partners in the clinical research process – who discussed the significance of clinical research engagement. They highlighted the importance of transparency, trust-building, and equitable access to research. The session also addressed strategies to overcome research participation barriers, especially among populations underrepresented in NIH clinical research. Following the presentations, the event transitioned into a listening session. Ten individuals who previously registered – professors, representatives of advocacy organizations, and leaders of community-based organizations – then shared their perspectives and experiences related to clinical research engagement.

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[31] All written comments received through the RFI were compiled and can be found on the NIH Office of Science Policy website: https://osp.od.nih.gov/wp-content/uploads/2024/12/ENGAGE_Compiled-Public-Comments.pdf. Accessed on August 29, 2025.

Community Conversations

Between October 2024 and January 2025, the NIH held six in-person Community Conversations across the United States (Figure 5). Several factors were taken into consideration when selecting locations, including but not limited to, locations with communities underrepresented in clinical research, locations with high and low clinical research infrastructure, and geographical representation across the country.[32]

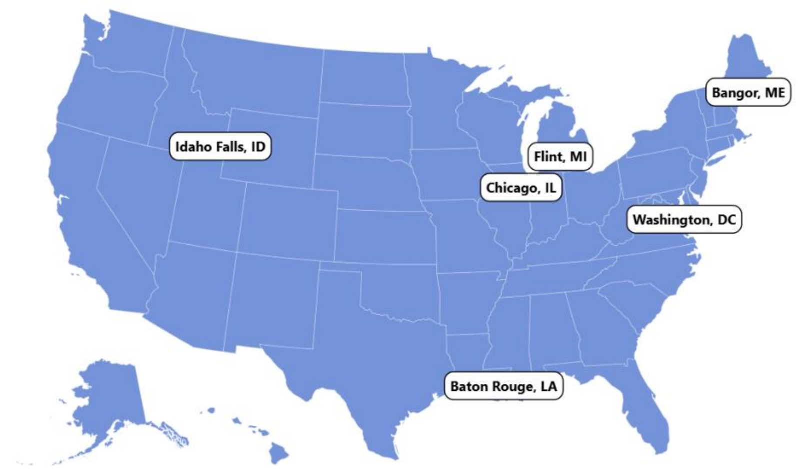

Figure 5. Locations of Six Community Conversations

The events had three aims:

- To gather feedback on how community input can be used to improve clinical research
- To discuss the content and design of a potential framework for clinical research engagement
- To provide a forum for open discussion about how communities can be partners in the research process.

Table 2. Location for Each Community Conversation, the Community Organization NIH Partnered With, and Total Number of Attendees

Location	Community Partner	Number of Attendees
Washington, DC	Community of Hope	29
Chicago, IL*	Pilsen Arts & Community House	27
Idaho Falls, ID	Eastern Idaho Community Action Partnership	22
Bangor, ME	Dignity First	28
Flint, MI	Community-Based Organization Partners AND Charles Stewart Mott Department of Public Health at Michigan State University	27
Baton Rouge, LA	Family & Youth Service Center	25

*The Chicago, IL event was held in Spanish

The NIH and ENGAGE WG worked with Pyxis Partners – a healthcare advocacy firm with expert facilitators and established relationships in communities across the United States – to design the meetings, identify and invite potential community partners, and moderate the sessions. A total of 158 individuals attended the community conversations (Table 2), ranging in age from 17 to over 75 years. Twenty-nine percent of the individuals were African American/Black, 22% were Hispanic/Latino, and 41% were White. They were also predominantly female (71%). Approximately 75% had at least some college or trade school education, and most (77%) frequently or somewhat frequently interacted with the healthcare system. The majority had never served as a community partner on a research study (85%) nor participated in a research study (69%).[32] The information gathered during the conversations was summarized and presented to the ENGAGE WG to inform their proceedings, discussions, and work products.

With input from the ENGAGE WG, the NIH created structured and interactive Community Conversations. Each three-hour event was open to the public and individuals who attended were compensated for their time. Information was gathered using various formats, including written responses on sticky notes, and large and

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[32] When NIH launched the series of Community Conversations in October 2024, they planned to conduct 10 in-person and two virtually. Six of these events were held as planned, and six scheduled for early 2025 were cancelled due to federal government communication and travel restrictions. Those planned in-person Conversations were supposed to occur in Los Angeles, CA; Honolulu, HI; Houston, TX; and Wichita, KS. The virtual conversations were supposed to be with leaders of academic organizations, researchers, and leaders of organizations serving American Indian and Alaska Native communities.

small group discussions. An illustrator attended each event and took live visual notes of the key points of the discussion (visual notes can be found in Appendix C).[33]

During the meetings, Pyxis staff first introduced the goals of the ENGAGE WG and walked the attendees through visual models of the clinical research lifecycle. Attendees provided input on the stages in the lifecycle stages where community and public input would be most valuable and where they'd most like to be involved. Attendees also reviewed a potential framework for clinical research engagement, offering feedback on its clarity, content, and relevance. The sessions concluded with discussion about building sustainable infrastructure (this included discussion of a potential toolbox of engagement resources during the final two events) and community-researcher partnerships, including how to support community engagement at every stage of the clinical research lifecycle and ensure that findings are returned to communities in accessible, meaningful ways.

Community Conversation attendees received a thank you email from the NIH staff following the event, and a second follow-up email a few months later briefly describing how their feedback influenced the evolution of the potential new framework for clinical research engagement. It also provided information on how they could stay up to date on NIH's efforts to improve clinical research engagement.

What We Learned

Pyxis and NIH staff reviewed recordings and written documents from all three information sources (RFI, virtual listening session, Community Conversations) and distilled the information into five themes.

Centering Communities in the Research Process

One of the most resounding takeaways was the importance of centering communities in the clinical research lifecycle. Feedback emphasized that the research process should start with researchers understanding lived realities and community health priorities, rather than research priorities being driven mostly or solely by the agendas of funders and/or research organizations. This includes the importance of partnering with communities early in the process so that researchers understand what matters most to the community before studies are designed. Further, collaborations with communities and advocacy organizations should be frequent and continuous because they help to foster effective partnerships, integrate community input into the study design and conduct, and improve dissemination of the real-world impacts of research to the public.

Relying on Trusted Voices to Build Relationships

Discussions repeatedly emphasized the need for researchers to rely on trusted voices, such as local health workers, leaders, and embedded organizations, to overcome skepticism and distrust. These individuals and organizations serve as a bridge to community members who may be concerned about partnering with researchers due to past experiences, like working with a researcher only for them to abandon the community after the research study was over. These trusted voices can help researchers understand past problems and create communication approaches that will help begin to build and sustain trust with community members.

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[33] A written summary of each Conversation and other materials presented during each can be found on the ENGAGE website: https://partnersinresearch.nih.gov/community-conversations/

Implementing Engagement Strategies with Purpose

Individuals felt that engagement must not be a simple check-the-box action (i.e., “tokenism”), but rather a tailored approach that meets the needs and goals of community partners and researchers. Many called for a commitment from researchers to follow through on promises, build reciprocal relationships, and return research results to communities and the broader public in ways that are accessible and meaningful. However, individuals also indicated that community engagement is not just for individual researchers or studies. Funders and research organizations must also commit to pursuing bi-directional engagement as well. This allows communities to better understand the motivations of funders and research organizations, and for them to hear directly from the community on top health priorities.

Investing in Building Sustainable Capacity for Engagement

Feedback repeatedly highlighted the need for increased capacity to support sustainable engagement. Ideas included developing training for both researchers (e.g., engagement best practices) and community members (e.g., introduction to clinical research design and conduct), creating regular opportunities for community members to talk with researchers, and forming enduring partnerships between community organizations and research organizations. Many called upon the NIH and research organizations to invest in systems that will support engagement as a standard practice, not a one-off effort. Funders can enhance engagement by providing financial resources to support the infrastructure needed to build and sustain engagement and by requiring the inclusion of engagement plans in applications for funding.

Offering Compensation and Incentives for Engagement

To foster meaningful and sustained partnerships, funders and research organizations must ensure that fair compensation is offered to community members who contribute to the planning and conduct of clinical research studies, as well as dissemination of study findings. Many stressed that while monetary compensation is appropriate and appreciated, true engagement goes beyond payments – it includes recognition of time, expertise, and lived experience. Individuals also cited the importance of providing practical incentives like transportation, food, or caregiving assistance to ease the potential burdens of engagement.

Incorporation of Key Themes on the *Framework for Clinical Research Engagement*

The NIH and ENGAGE WG purposefully created a process to seek out public input early and often throughout its deliberations to ensure that the final deliverables represented the preferences and ideas of the broader public. The WG incorporated the five key themes described above in the *Framework for Clinical Research Engagement* in the following ways:

- **Centering Communities in the Research Process:** The WG included communities in every step of the *Framework.* In addition to starting the research lifecycle with identifying community health needs, the *Framework* outlines how researchers and community partners should work together from the earliest stages of the research co-design and planning process and continue partnering through to the dissemination of results and potentially in future clinical research studies (see pp. 20-24).
- **Relying on Trusted Voices to Build Relationships:** The WG appreciated the critical role trusted community leaders play in fostering meaningful community-research partnerships. To embed this into the *Framework,* they outlined ways for research organizations and researchers to partner with community-based organizations to identify and partner with these trusted voices, who can, when appropriate, help connect other individuals interested in partnering with researchers (see pp. 25-26).

- **Implementing Engagement Strategies with Purpose:** The WG created a final *Framework* that provides clear objectives and action steps for researchers and communities to promote genuine engagement and avoid tokenism. They highlighted the critical importance of accountability for all partners and the role that funders and research organizations play in creating an environment where meaningful engagement becomes standard practice (see pp. 20-24).
- **Investing in Building Sustainable Capacity for Engagement:** The WG developed guidance on how researchers should prepare for engagement, including the training needed before undertaking engagement. The WG also provided suggestions for how research organizations can create internal capacity, like Community Advisory Boards, to sustain community partnerships[34] (see pp. 25-28).
- **Offering Compensation and Incentives for Engagement:** The WG summarized key considerations for identifying fair and equitable compensation for community partners, as well as potential alternative incentives that are not monetary in nature (e.g., access to university libraries, caregiving assistance, food) for those who are not able (or do not want) to accept monetary compensation (see pp. 26-27).

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[34] Additional capacity building and infrastructure needs are detailed in the recommendations to the NIH.

IV. Framework for Clinical Research Engagement

Introduction

The ENGAGE WG undertook a multi-step process to develop the *Framework for Clinical Research Engagement,* including the examination of existing engagement frameworks and creation of goals and principles to guide its development (Appendix C). The NIH then hosted six in-person Community Conversations (see Section III) to gather public input, which was shared with the WG to inform further *Framework* revisions.

The resulting *Framework for Clinical Research Engagement* is a roadmap of concrete steps that researchers, individuals, organizations, funders, and others can use to employ meaningful clinical research engagement.[35] The concrete steps create a standardized approach to engagement across study designs, research questions, and community partnerships. It places communities at the center and supports bi-directional engagement throughout the research process. Incorporating and standardizing meaningful clinical research engagement in all NIH-funded clinical research will aid in rebuilding public trust, improving research efficiency, increasing study feasibility, and turning discoveries into improved health.

Figure 6. Framework for Clinical Research Engagement

The *Framework for Clinical Research Engagement*

The *Framework for Clinical Research Engagement* (Figure 6) includes four key partners – community, researchers, organizations, and funders – and five stages of the research lifecycle: (1) identify health needs, (2) set the research question, (3) plan the research, (4) carry out the research, and (5) share the findings. For each stage of the research lifecycle, the *Framework* outlines an engagement objective and action steps.

The *Framework* is informed by three core values: trust, accountability, and equity. Trust is built and strengthened when researchers consistently show up, communicate transparently, and follow through on commitments – even when it's inconvenient. Trust also grows when community partners see how their input shapes the research, from design to dissemination. Being accountable to community partners means honoring their time, expertise, and contributions. It involves defining roles and responsibilities at the outset, co-developing timelines and deliverables, and regularly checking in to ensure that commitments are met. Finally, clinical research engagement should support the participation of all partners. This requires researchers and community partners to share decision-making and credit, ensure fair compensation for community partners, and provide training or capacity-building support.

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[35] Clinical research engagement occurs when people, groups of individuals, communities, and/or organizations partner with researchers to plan, design, and conduct research so that the research and its outcomes are meaningful, actionable, or support understanding of disease for those who could benefit from the research.

The Key Partners in Engagement

The *Framework* depicts four key partners in engagement – community, researchers, organizations, and funders – each of whom is heavily involved in and impacted by clinical research. In some circumstances, additional engagement partners may be included, such as payers, policymakers, and clinicians. It is important to define who the key partners are for each research study because each will contribute in different ways, and methods should be tailored to the topic being studied and the partners' preferences. When research is conducted in partnership among all shareholders, studies are more scientifically sound, relevant, impactful, and aligned with the priorities of those they aim to serve.

Examples of Community Partners

- Patients
- Caregivers
- Clinicians
- Community health workers
- Peer mentors
- Advocacy or community leaders

Community

Community refers to a group of people who share a common bond or interest. This connection could be geography (e.g., rural county), a demographic characteristic (e.g., age), having a specific health condition (e.g., kidney disease), holding a certain role (e.g., caregiver), or others.

Examples of Researchers

- Professors
- Clinicians
- Fellows
- Graduate students
- Undergraduate students
- Research assistants

Researchers

Researchers are those who have training and experience in designing and conducting health research. They develop study questions, ensure research protocols are followed, analyze data, and share results.

Examples of Organizations

- Universities
- Hospitals
- Churches
- Non-profit organizations
- Advocacy groups
- Recreation centers

Organizations

Organizations refers to research-focused organizations and community-based organizations. Research organizations employ researchers to carry out clinical research. Community-based organizations are embedded in specific communities and understand the community's unique needs, such as professional organizations, non-profit organizations, or advocacy groups.

Examples of Funders

- Federal research agencies (e.g., NIH)
- Non-profit organizations
- Biotechnology & pharmaceutical companies
- Healthcare systems

Funders

Funders are entities that provide financial resources to researchers or organizations to carry out clinical research. Funders are often government agencies, such as the NIH, but they can also be non-profit organizations or private companies.

Description of *Framework* Stages, Engagement Objectives, and Action Steps

The *Framework* presents a new standard for NIH and its funded researchers to integrate research-community partnerships into clinical research. Every stage includes an engagement objective and is supported by two to three action steps. The *Framework* provides a detailed description on how to identify community needs, create impactful research questions, design feasible research studies, and share the research results with the community and the broader public.

STAGE

1

IDENTIFY HEALTH NEEDS

Engagement Objective: Articulate the community's health needs and why those needs are important to improving health

Clinical research should be grounded in community health needs to ensure its outcomes are relevant and beneficial to the people it's intended to serve. Therefore, the first stage of the *Framework* is to 'Identify Health Needs.' The purpose of this stage is to identify and collect information on health needs directly from the community(ies) to ensure their perspectives and preferences are understood and prioritized. Specifically, successful accomplishment of this objective requires two actions:

- Ongoing and consistent collection and assessment of community health needs by researchers and communities
- Develop understanding of the importance of the community health need(s)

Ongoing and Consistent Collection and Assessment of Community Health Needs by Researchers and Communities

Possible Ways Key Partners Contribute to Stage 1

Community partners use their experiences to discuss why health needs are important

Researchers interact with community partners to understand health needs

Organizations provide community connections, resources, and expertise

The consistent collection and assessment of community health needs is an ongoing effort to understand the most pressing health needs of the community. The approach can be flexible and evolve over time. Individual community members, community-based organizations, individual researchers, and/or research organizations can initiate and/or sustain these regular assessments or utilize existing data and information, as appropriate. Regardless of who initiates and sustains these efforts, it is important that they incorporate a bi-directional relationship between community members and researchers/research organizations. Further, the collection approach should be tailored to the unique needs of the community of focus. This ensures that community needs are regularly communicated to research teams to support early brainstorming efforts, and that community members have a consistent venue for sharing emerging health needs.

Develop Understanding of the Importance of the Community Health Needs(s)

Researchers and research organizations need to understand why specific health needs are important to community members. In this step, researchers and their teams connect directly with community members to understand why specific health needs are important and how studying them would improve the community's health. The goal of this step is to ensure researchers understand the nuanced and layered context that brought a particular health topic to the forefront of the community's priorities. It allows researchers to hear more about individuals' experiences, and to begin to gather more detailed information to help craft research questions with high impact and significance. The information gathered in this step complements researchers' understanding of the gaps in scientific knowledge (described in Stage 2), and both perspectives should inform decisions about the research study.

STAGE

2

SET THE RESEARCH QUESTION

Engagement Objective: Undertake a shared priority-setting process to match community needs with evidence gaps to create the study's research question(s)

Once the community's health needs have been identified, researchers and community partners work together to define the scope of the study. This second stage of the *Framework* is called 'Set the Research Question.' The goal of this stage is to undertake a defined process to pair evidence gaps with community needs and craft an impactful research question(s). Successful accomplishment of this objective requires three actions:

- Execute a shared priority-setting process that includes both researcher and community participation
- Clarify evidence gaps and possibilities for research
- Craft the research question(s) and identify potential funding opportunities

Execute a Shared Priority-Setting Process that Includes Both Researcher and Community Participation

Once the research team has identified a longer list of community health needs, it's time to execute a priority-setting exercise to narrow multiple topics down to the most impactful topics. The priority-setting process should value the perspectives of both community partners and the research team and be tailored to the preferences of all involved. The priority-setting process can be a formal exercise that follows a specific set of rules for deliberation, or it can be an informal set of consecutive meetings between the research team and their community partners. It is essential that the selected process is agreed upon by all participants in advance.

Possible Ways Key Partners Contribute to Stage 2

Community partners provide insights on the most relevant topics to community health

Researchers identify the evidence gaps to address in the study

Organizations connect researchers with community partners for priority-setting

Funders create funding opportunities to answer specific research questions

Clarify Evidence Gaps and Possibilities for Research

Following priority-setting, researchers and community partners work together to identify related evidence gaps and areas where more research is needed. This effort can employ common methods such as systematic, scoping, or other types of reviews; qualitative studies; or retrospective chart reviews. It may also incorporate approaches that community-based organizations use to determine where to allocate resources, develop programming, or provide services. By undertaking this process collaboratively, researchers and community partners can better align the community's needs with evidence gaps.

Craft the Research Question(s) and Identify Potential Funding Opportunities

Next, researchers and community partners need to craft the research question(s) and identify the type of research that needs to be conducted to address the question(s). There should be a parallel effort to identify potential funding opportunities that align with the research type, topic, and question(s) being proposed. Sometimes funding opportunities are not available for the topic that the research-community partnership would like to examine. If this occurs, the group should decide as a collective unit how to proceed. By working on both tasks together, researchers and community partners can ensure alignment between the community's priorities, critical evidence gaps, and available funding opportunities.

STAGE

3

PLAN THE RESEARCH

Engagement Objective: Co-design a research study aimed at answering the selected research question(s)

The research team and their community partners next work together to design a clinical research study to answer the research question(s). This third stage of the *Framework* is called ‘Plan the Research.’ The goal of this stage is to co-design a feasible clinical research study by leveraging the expertise of both community partners and research teams. Successful accomplishment of this objective requires three actions:

- Reach agreement on community and researcher roles, responsibilities, and decision-making processes
- Deliver study- or role-specific training to prepare community partners and researchers for collaborative design
- Incorporate community expertise into study design to improve quality and feasibility

Possible Ways Key Partners Contribute to Stage 3

Community partners and **researchers** co-design a feasible research study to test the research question(s)

Organizations work together to create a multi-site study that can be implemented across locations

Funders work with research teams to design studies that meet specific funding objectives

Reach Agreement on Community and Researcher Roles, Responsibilities, and Decision-Making Processes

Before beginning co-design of the study, it is critical to outline the roles and responsibilities of community partners and research staff and to define decision-making procedures. This process should build on the decisions made when preparing for engagement (described below). It will also tailor agreed-upon processes and expectations to the social and cultural context of the community, the research topic, and respect the different expertise of each partner. Processes may vary but should ensure that all involved agree on how to work together. The agreement should also be documented, but the level of formality is flexible.

Deliver Study- or Role-Specific Training to Prepare Community Partners and Researchers for Collaborative Design

To complement training activities in the Preparing for Engagement phase (described below), the research team should ensure that any additional training, tailored to study-specific elements, is delivered before design and planning begins. Additionally, if community partners will interact with study participants (e.g., recruitment procedures), researchers should facilitate their participation in any required training (e.g., human subjects protections). Finally, researchers should complete any relevant training, like collaborative data analysis methods, appropriate for the study design.

Incorporate Community Expertise into Study Design to Improve Quality and Feasibility

Community input on study elements like recruitment approaches, method and frequency of data collection, and intervention methods, among many others, can assist researchers in designing a feasible study that aligns with the real-world experience of potential participants. Community partners also bring critical insights on which outcomes would be most relevant, helping to ensure the study results will be useful. The way community expertise is gleaned, how that expertise influences specific elements of the study design, and the timing of integration into the design process should be tailored to the specific community and research question(s) at hand.

STAGE

4

CARRY OUT THE RESEARCH

Engagement Objective: Conduct the clinical research study to gather scientific evidence

Once the research question has been selected and the study has been designed, the research team and their community partners execute their protocol and conduct the study. This fourth stage of the *Framework* is called 'Carry Out the Research.' The goal of this stage is to carry out the study by enrolling participants, collecting data, and analyzing the results. Successful accomplishment of this objective requires three actions:

- Monitor study progress to ensure community-centeredness and fulfillment of responsibilities
- Implement community-informed study modifications to address obstacles
- Co-interpret study results with input from both community partners and researchers

Monitor Study Progress to Ensure Community-Centeredness and Fulfillment of Responsibilities

Research teams and community partners should monitor the study throughout its execution to ensure it remains community-centered and respects cultural norms. Although the integration of culturally appropriate methods occurs in the design stage, monitoring for continued commitment to community-centeredness is important, especially as modifications to study procedures are made. Additionally, it is important that researchers and community partners are held accountable to their defined roles and responsibilities, including bi-directional and consistent communication. The frequency and approach to monitoring and communication should be tailored to the specific research study.

Possible Ways Key Partners Contribute to Stage 4

Community partners and **researchers** monitor study progress and address obstacles

Organizations provide resources to the research team, such as biostatistics experts

Funders participate in team meetings to ensure adherence to funding objectives and expectations

Implement Community-Informed Study Modifications to Address Obstacles

Even well-planned studies experience obstacles (e.g., addressing bottlenecks to study workflow efficiency) that result in delays and increased costs. Ongoing monitoring efforts help to identify these obstacles which can be addressed by modifying and optimizing study procedures. Community partners can provide valuable insight and suggestions on how to address study obstacles because they understand participants' potential competing priorities and concerns.

Co-interpret Study Results with Input from Both Community Partners and Researchers

After data collection is complete, the community partners and research team work together to interpret study results. During data analysis, potential issues with the data (e.g., outliers) that need to be addressed or additional analyses that may be valuable to pursue are identified. Researchers provide critical scientific expertise and conduct the analysis, while community partners provide critical insights and ideas based on their own experiences and expertise. Following analysis, the research team and community partners co-interpret the results, contextualizing them both within the scientific literature and community experience, to ensure relevance and accuracy for use in study result dissemination.

STAGE

5

SHARE THE FINDINGS

Engagement Objective: Collaboratively return research results to study participants, community of focus, scientific audiences, and the broader public

Sharing research results with study participants, their communities, others who could benefit from the results, and the broader scientific audience facilitates translation of discoveries into improved health. This fifth stage of the *Framework* is called 'Share the Findings.' The goal of this stage is to broadly and responsibly share the study's findings. Successful accomplishment of this objective requires three actions:

- Co-design tailored plans for returning results to participants, community(ies), scientists, and the public
- Co-create the dissemination products
- Co-communicate dissemination products through multiple channels

Co-Design Tailored Plans for Returning Results to Participants, Community(ies), Scientists, and the Public

It is important for community partners and research teams to co-design their plan for returning research results in a thoughtful, intentional manner early in the study design process. The plan should consider the research study, community(ies) of focus, and topic under investigation. In the planning phase, the research team and their community partners need to consider how to communicate research results – returning a summary of the study's overall results may be more general than returning an individual's personal research results – and the appropriate timing for return. Tailored plans may be necessary for different audiences. Each audience will vary in their understanding of health and science, which study findings are important, and why the information may be useful.

Possible Ways Key Partners Contribute to Stage 5

Community partners and **researchers** co-create dissemination products and co-communicate research results

Organizations provide resources to support dissemination

Funders set expectations for funded projects to share results

Co-Create the Dissemination Products

Community partners and the research team should collaboratively create study dissemination products to ensure they are scientifically accurate, health literate, culturally congruent, and provide meaningful information. In developing the dissemination products, community partners and research teams should consider the venue (e.g., scientific journal vs. community health fair), the health or scientific literacy of the audience, the audience's familiarity with clinical research, and any privacy or ethical implications of sharing results. Multiple different dissemination products are likely to emerge for different audiences and different purposes. Dissemination products should discuss the study's implications and limitations for both scientific and community audiences.

Co-Communicate Dissemination Products Through Multiple Channels

Study results should be shared through multiple channels to accommodate different preferences for receiving health information. These channels could include written summaries, infographics, short videos, on-demand audio (e.g., podcast), or presentations at community events, among others. The delivery of study results should come from individuals who the community trusts, like local healthcare workers or community leaders, and when appropriate but whenever possible, include researchers and community partners co-communicating study findings through these different dissemination channels.

Importance of Tailoring Engagement Methods and Approaching Engagement as an Ongoing Process

The *Framework* is intended to depict an ideal approach to clinical research engagement where community members partner with researchers across every stage of the research lifecycle. The WG recognizes, however, that engagement is not one-size-fits-all, and there are many ways to implement meaningful bi-directional partnerships. For example, one group of community partners may want to participate in every research team meeting, assist in writing grant applications, and preparing scientific manuscripts. In contrast, a different group of community partners may prefer occasional check-in calls to provide input and guidance on study design decisions, and weekly email updates on study progress. In both these examples, the research team is working in partnership with community members to ensure the research study is feasible and relevant to community needs, as well as fulfilling the engagement objectives outlined across the *Framework*. The most important consideration in implementing the *Framework for Clinical Research Engagement* is ensuring that community priorities, perspectives, and expertise are integrated into the study design, execution, and interpretation, as well as dissemination of study findings.

Regardless of the selected engagement methods and activities, the goal of the *Framework* is for the partnerships developed between researchers/research organizations and communities/community organizations to be maintained between the end of one study and the beginning of another, as represented by the double arrow between Stage 5 and Stage 1. At the conclusion of one study, it is important to begin the engagement process over (i.e., identifying health needs) to inform the next stage of the research. The engagement approaches in this next stage of research may look different as the research questions will have evolved. In many cases, the partnership developed for the first study will be maintained for future studies, but this may not always be the preferred option. If community partners and/or researchers feel that the best course of action is to conclude a partnership, it is critical to hold a “close-out” meeting following dissemination of the study results to discuss the conclusion of the study and the partnership.

Preparing Researchers and Communities to Implement *the Framework for Clinical Research Engagement*

Successful clinical research engagement requires a strong foundation. To ensure that the objectives and action steps of each stage of the *Framework* can be fully achieved, it is optimal and recommended that researchers, organizations, communities, and/or funders prepare for engagement and should, in advance:

- Establish bi-directional research-community partnerships
- Offer and agree on community partner compensation, identify available funding, and plan for resource allocation
- Develop baseline expectations for research-community processes and study oversight
- Educate and train community partners and researchers

Establish Bi-Directional Research-Community Partnerships

Before researchers and community partners can begin successfully collaborating on Step 1 of the *Framework*, they need to establish a bi-directional working partnership. This means creating a relationship in which both researchers and community partners contribute knowledge, share in decision-making authority, and collaborate to inform, design, and/or conduct research, as well as disseminate study findings. These partnerships are built on mutual respect, trust, transparency, and shared responsibility.

Partnerships are not one-size-fits-all as their length and structure depend on the goals, settings, and preferences of those involved. Some may be short-term and focused on a single study, while others may be broader and of longer duration, such as collaborations between community organizations and research organizations that span multiple projects.

While there are many ways to build and maintain strong partnerships,[14] two common approaches are the formation of organizational partnerships and Community Advisory Boards (CABs):

- **Organizational partnerships** involve collaboration between a research organization (e.g., university) and a community-based organization. These are often more sustainable than individual partnerships as they do not depend on one person remaining in a specific role over time. Organizational representatives can also act as liaisons between researchers and community members, helping to connect community members to specific research efforts. These partnerships are also more likely to be long-lasting, building critical trust over time and serving as a consistent channel for communication between community leaders and researchers.
- **Community Advisory Boards (CABs)[36]** are groups of individuals who represent a particular population – such as residents of a geographic region or people living with a certain health condition. CABs partner with researchers to plan and execute studies as well as disseminate the findings of the studies to communities and the public. Some CABs are maintained by organizations to focus on a general topic area (e.g., diabetes research, pediatric health), and can provide guidance on multiple studies within that area. Other CABs are developed to provide guidance and input for a single research study.

Offer and Agree on Community Partner Compensation, Identify Available Funding, and Plan for Resource Allocation

Clinical research engagement requires time and expertise; everyone must be offered fair and equitable compensation for their contributions, including community partners. The type of compensation (e.g., monetary, professional opportunity) and amount should be based on the community partners' specific role, expected contributions, and their preferences. Some community partners may prioritize non-monetary compensation, such as access to university resources (e.g., libraries) or having research staff volunteer at a community event or program. If monetary compensation is the preferred method, research teams and research organizations should work with community partners to ensure the amount does not jeopardize qualifications for other benefits (e.g., disability).

Before undertaking engagement, researchers and their organizations need to identify funding to support community partner compensation and other engagement activities. Ideally, community partners should be compensated from the beginning stages of the research lifecycle (i.e., identifying health needs) and throughout the entire research process. However, current funding models make it challenging to provide funding during the study planning stages, making compensation for early engagement activities (i.e., pre-award phase) difficult. Two potential options to support early engagement efforts include:

- **Leveraging internal organizational resources** – some research organizations and companies maintain budgets that could be used to compensate community partners' efforts. Additionally, an organization's established community partnerships, like a CAB funded through sources not specific to an individual research study, could also support early engagement activities.

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[36] There are many different terms used to refer to community advisory boards, such as patient or stakeholder advisory boards, citizen advisory boards, community advisory committees, or board of community advisors.

- **Applying for research planning grants** – some funders support early-stage research planning efforts separate from the execution of an actual research study. These planning grants historically have been used to test a study design on a smaller scale to ensure it works, but increasingly they support the early engagement activities that occur before securing a full research grant.

If these options (or others) are not available to support early-stage engagement efforts, it is critical that research teams articulate this to potential community partners in advance and explain if and when funding or other means of compensation may be secured. This enables community partners to make informed decisions on whether they can or want to partner with researchers.

Develop Baseline Expectations for Research-Community Processes and Study Oversight

The *Framework* has multiple action steps related to priority-setting, decision-making, and other processes. Once these are underway, the focus shifts to executing these processes rather than creating them. As such, it is important to create baseline expectations for these processes in advance.

The WG recommends developing *baseline* expectations because each study is unique and likely requires tailored procedures. Below is a brief description of a general approach to developing these expectations:

- Researchers and community partners should define roles and responsibilities. There should be a clear, agreed-upon understanding of how researchers and community partners will collaborate, as well as what each partner's roles and responsibilities will be.
- Community partners, research organizations, and/or researchers should develop a shared understanding of community culture and values. This ensures the use of proper language, reduces the likelihood of individual or group harm, and helps to develop more relevant research studies.
- Research organizations, researchers, and/or community partners should communicate all regulations, laws, policies, or guidelines that may limit or inform potential community or researcher roles.
- Community partners and researchers should agree on acceptable approaches for decision-making, ongoing bi-directional communication, and how concerns or disagreements will be addressed should they arise during the partnership.
- Community partners and researchers should create study oversight procedures to ensure all partners are held accountable to their responsibilities and studies are conducted according to the co-designed protocol.

Taken together, these procedures support transparent and accountable research that helps to build trust in the research process and its outcomes.

Educate and Train Community Partners and Researchers

Before beginning Step 1 of the *Framework*, all partners (e.g., researchers, community organizations, community members) should have the opportunity to gain knowledge and skills that support a strong, respectful, and effective partnership. Training helps ensure everyone has a shared understanding of the research process, engagement principles and best practices, and how to partner in ways that are inclusive, equitable, and avoid unintended harm.

Successful engagement depends on this foundational knowledge. To build it, research teams should first identify what each partner group already knows, where there are gaps, and then deliver appropriate education and training to meet those needs.

Training should be flexible in format and widely accessible to accommodate a range of learning styles and experiences. For community partners, this may include introductions to clinical research, how studies are designed and conducted, information on the health condition being studied, and what it means to serve as a partner on a research team. For researchers and academic organizational staff, training may focus on how to build and maintain respectful partnerships, engagement best practices, plain language communication, and how to share power and make collaborative decisions with communities.

Some training resources on these topics already exist. Others may need to be co-created as new needs are identified. Importantly, training should not be treated as a one-time event, but as an ongoing part of capacity building and strengthening meaningful bi-directional relationships across the partnership lifetime.

Conclusion

ENGAGE Vision and Goal for Clinical Research Engagement at NIH

GOAL: for people and communities to influence the agenda and direction of, as well as have meaningful input into, research that is relevant and impactful to them

VISION: a future where clinical research engagement is standard practice, promoting responsiveness to community needs, accountability, and transparency while helping turn discoveries into improved health

This *Framework* supports the ENGAGE WG's vision of a future where meaningful clinical research engagement is standard practice in NIH-funded clinical research. This *Framework* provides the necessary roadmap towards this goal – it provides clear objectives and action steps with opportunities for tailoring its implementation based on study design, population of focus, and/or resources. The objectives and action steps outlined in the *Framework* will only be successful to the extent that there is accountability to its integration into NIH-funded clinical research. In the next section, the ENGAGE WG provides their recommendations for how to integrate the *Framework* into NIH-funded clinical research, create an environment where bi-directional engagement becomes the norm, and implement engagement activities across the NIH.

V. Recommendations to the NIH to Standardize Meaningful Clinical Research Engagement in NIH-Funded Clinical Research

Introduction

The *Framework for Clinical Research Engagement* presents a best practice approach for integrating research-community partnerships throughout the research lifecycle. To establish a vision for clinical research engagement and enable NIH-funded clinical researchers to integrate the developed *Framework* into their studies, the WG crafted four bold recommendations to the NIH. Each bold recommendation includes multiple targeted strategies which, if implemented, will enable the NIH to achieve the recommendation's objectives and ensure measurable impact.

Recommendations

Recommendation 1: NIH should require and support the integration of the *Framework for Clinical Research Engagement* into its funded clinical research by providing financial and training resources

Putting the *Framework* into practice requires the time and financial support to implement it in a meaningful way. High-quality, meaningful clinical research engagement does not occur by accident. It requires prospective planning, sufficient resources, and a continued commitment to collaborative study planning and execution. To advance the pursuit of meaningful engagement by clinical researchers and their academic organizations, the NIH needs to set new requirements and provide financial and training support.

NIH should require those applying for funding of clinical research studies to demonstrate how community perspectives and ideas influenced the development of the proposal itself and how researchers plan to integrate engagement throughout the entire research lifecycle. To support this requirement, NIH should clearly define their expectations for the integration of engagement activities into the clinical research lifecycle. Additionally, the NIH needs to ensure that there is additional funding in study budgets so that they can support both rigorous study conduct and high-quality engagement. NIH should also provide guidance to investigators on how to plan for and allocate funds for engagement into study budget proposals, particularly to ensure that community-based organizations or other partnering organizations have the funding needed to support engagement activities. Finally, the NIH should provide training materials to assist investigators in planning for and implementing the *Framework for Clinical Research Engagement.*

To achieve this bold recommendation, the NIH should:

- **Strategy 1A:** Define for applicants the requirements for incorporating and budgeting for engagement into proposal development, study design, and study execution for NIH-funded clinical research studies
- **Strategy 1B:** Require and fund clinical research studies to return research results to participants, the community of focus, and the broader public using methods that make results accessible and meaningful, protect participant privacy, and prevent group harm
- **Strategy 1C:** Require that study leaders and community-facing personnel to be trained in clinical research engagement best practices

Recommendation 2: NIH should actively foster an environment in which bi-directional researcher-community partnerships are standard practice

Clinical research engagement has a high return on investment because it reduces inefficiencies, builds trust, provides accountability, improves study feasibility, and improves results dissemination. However, despite being the largest public funder of biomedical research, the NIH does not have a unified, agency-wide approach to clinical research engagement, and its funded investigators experience numerous barriers to implementing engagement in their own work. Resource constraints, inflexible timelines, and organizational roadblocks (e.g., IRB interpretations of the role of community partners) commonly prevent researchers from incorporating engagement activities. The NIH is well-positioned to foster an environment in which clinical research engagement is a standard practice through targeted investments.

The NIH and academic organizations need to shift incentives and reallocate some resources in such a way that bi-directional research-community partnerships are encouraged because researchers and community members need sufficient support to undertake high-quality clinical research engagement. For many scientists, academic organizations, and peer reviewers, clinical research engagement is a new concept. Additionally, many community members require information on what clinical research is and how it's planned and executed. Training, educational opportunities, tools, and resources for clinical research engagement and how to judge its quality are needed to fully implement the *Framework for Clinical Research Engagement*. It is also critical that they are made available to researchers and community partners in a way that's easy to access and navigate (see Appendix D for the proposed organizational and tagging system to use in an online repository or other searchable database of engagement resources).

To achieve this bold recommendation, the NIH should:

- **Strategy 2A:** Ensure that funding opportunities support the development and maintenance of researcher-community partnerships before, during, and after a clinical research study, including providing adequate funding for community organizations to execute engagement activities
- **Strategy 2B:** Create a comprehensive repository(ies) of clinical research engagement resources (e.g., trainings, best practices, templates) for both researchers and community partners
- **Strategy 2C:** Integrate into the peer review process an assessment of academic and other research organizations' engagement resources and practices (e.g., engagement cores)

Recommendation 3: NIH should create a process to ensure robust community input on NIH initiatives from a broad range of community organizations and advocates

Clinical research engagement is not only valuable to a single clinical researcher or an individual research study. Engaging community members, advocates, and the broader public can help inform large-scale strategic priority-setting and initiative planning. As the NIH requires its funded researchers to integrate clinical research engagement into their studies, it is essential that NIH also undertake its own engagement efforts. The NIH and its Institutes, Centers, and Offices play a central role in identifying priority areas for scientific investigation and creating large, impactful scientific initiatives. These efforts should be informed by affected communities.

Some of the NIH Institutes, Centers, and Offices, like the National Institute of Neurological Disorders and Stroke, have prioritized the inclusion of community partners as experts and their input already impacts research priority setting. Other NIH-wide efforts, like the NIH Helping to End Addiction Long-term (HEAL) initiative launched in 2018, utilize community partner committees to ensure research results are relevant to affected communities. But these practices are not consistently used across all of NIH. It is important that NIH create a process to integrate community input into its organization-level priority setting and scientific initiative planning as well as the priority-setting and initiative planning of the individual Institutes, Centers, and Offices.

To achieve this bold recommendation, the NIH should:

- **Strategy 3A:** Establish a coordinated agency-wide approach for engagement activities, including technical support and resources, across the Institutes, Centers, and Offices
- **Strategy 3B:** Ensure NIH staff, NIH leaders, and peer reviewers are knowledgeable about the benefits of clinical research engagement, best practices, and methods for incorporating community input
- **Strategy 3C:** Require each Institute, Center, or Office that supports clinical research to integrate community input in their next (and all subsequent) strategic plans and other initiatives

Recommendation 4: NIH should invest in the continuous evolution and improvement of its clinical research engagement methods and processes

Evidence already suggests that engagement improves research efficiency and uptake of evidence-based interventions. But which clinical research engagement approaches work best in which circumstances are less understood. Additionally, as clinical research engagement is increasingly integrated into NIH-funded clinical research, it is important to recognize the need for continuous learning and iterative evolution. Investigators will need time and support to become more familiar with the communities affected by their research and identify the ideal strategies for partnering with them. As such, the NIH should invest in assessing clinical research engagement methods and processes with the goal of continuous improvement.

Undertaking a meaningful assessment of clinical research engagement methods must start with operationalizing the *Framework for Clinical Research Engagement.* Additionally, it should identify the appropriate metrics for assessing how the *Framework* improves scientific research, community health, and community-research partnerships. Once these metrics are selected, it is then incumbent on the NIH to provide the modest but essential financial resources needed so that researchers can undertake their own internal assessments of progress on these metrics. There must also be larger-scale assessments that examine the effects of different engagement strategies on these identified metrics.

To achieve this bold recommendation, the NIH should:

- **Strategy 4A:** Operationalize the *Framework for Clinical Research Engagement* and develop associated metrics to assess improvement in scientific research and community health
- **Strategy 4B:** Support researchers to monitor, assess, and report their engagement methods and progress on *Framework* metrics (from Strategy 4A) at annual reviews to inform future improvements
- **Strategy 4C:** Develop procedures to hold researchers accountable to engagement expectations and identify consequences for non-adherence
- **Strategy 4D:** Develop targeted funding opportunities to support larger-scale assessments of different clinical research engagement methods and their impact on *Framework* metrics (from Strategy 4A)

Conclusions

If implemented, these recommendations will ensure that the ENGAGE WG's vision – a future where meaningful clinical research engagement is the norm rather than the exception – becomes a reality. The recommendations lay out four critical elements to implement this vision, including requirements for integration of the *Framework for Clinical Research Engagement,* the fostering of an environment where barriers to engagement are minimized, the integration of community input in NIH's own priority-setting and initiative planning, and investments into continuous improvement and evolution of engagement methods. This approach will lead to meaningful improvements in public trust, enhanced transparency and accountability, and ultimately improved health for all Americans.

VI. Acknowledgements

First and foremost, the ENGAGE Working Group would like to recognize the individuals from around the United States who joined the Community Conversations, submitted written comment to the RFI, or participated in the virtual listening session. This feedback was essential to the development of the *Framework for Clinical Research Engagement* and the WG's final recommendations. Secondly, the ENGAGE WG would also like to acknowledge the contributions of the NIH staff who supported its efforts, staff from Pyxis Partners who assisted with planning and facilitating the Community Conversations, and the individuals who participated in the early stages of the Working Group. They are listed in alphabetical order below:

1. Julia Bakay, Keynote Artist and Visual Strategist
2. Gina Beller, Pyxis Partners
3. Thomas Boddie, NIH
4. Michelle Culp, NIH
5. Kate Davis, former NIH intern
6. Bayli DiVita Dean, former NIH AAAS Science and Technology Policy Fellow
7. Nicole Dickerman, NIH
8. JP Flores, former NIH intern
9. Venus Ginés, Día de la Mujer Latina [former ENGAGE WG member]
10. Amesha Green, Pyxis Partners
11. Matt Holzapfel, Pyxis Partners
12. Jonathan Jackson, Harvard Medical School [former ENGAGE WG member]
13. Tyler Kasperbauer, NIH
14. Alissa Meister, NIH
15. Loriane Ngarambe, Pyxis Partners
16. Grisel Marie Robles-Schrader, Pyxis Partners
17. Monica Rodriguez, Pyxis Partners
18. Somava Saha, Well-being and Equity (WE) in the World [former ENGAGE WG member]
19. Elizabeth Siembida, NIH
20. Ronnie Tepp, Pyxis Partners
21. Brandy Thibodeaux, Pyxis Partners
22. Yuri Velasquez, Pyxis Partners

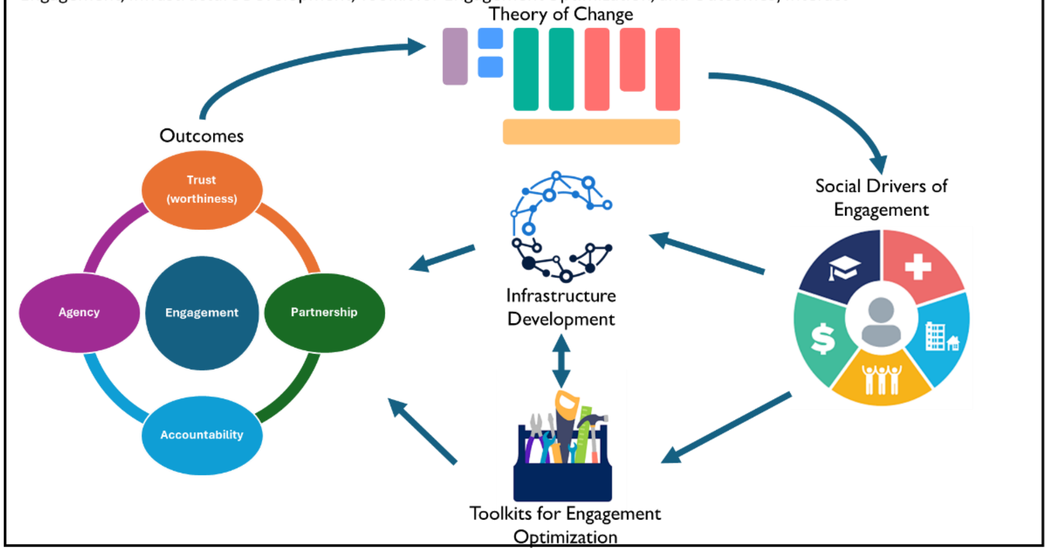
Appendix A: Theory of Action – An Aspirational View to Realizing Clinical Research Engagement

Introduction to a Theory of Action

A Theory of Action (ToA) is a logical chain of reasoning that explains how change will lead to improved practices. It explains in a commonsense way specific features that are expected to produce results, leading to a final desired outcome.[37] A ToA is valuable at the early stages of an initiative's work as it can help create a common understanding, communicate the initiative's intentions, define assumptions, and inform decisions. The ENGAGE WG created a ToA to serve as an overarching view of the domains that need to interact to realize the goal of meaningful bi-directional engagement in clinical research. The ENGAGE ToA was developed in a stepwise process over several months with input from the full WG.

ENGAGE Theory of Action

Figure 7. A Visual Depiction of the ENGAGE Theory of Action and How the Domains (Theory of Change, Social Drivers of Engagement, Infrastructure Development, Toolkit for Engagement Optimization, and Outcomes) Interact



The ENGAGE ToA (Figure 7) outlines a set of interconnected actions designed to achieve its primary goal: fostering an environment in which people and communities can shape the research agenda and direction to ensure it is relevant and impactful to them. The ENGAGE WG recognized that the ToA is aspirational and beyond the scope of the WG's timeline and activities which focused primarily on developing a Theory of Change, i.e., the *Framework for Clinical Research Engagement* (Section IV), with consideration of elements of the other domains including social drivers of engagement, infrastructure development, outcomes, and toolkits for engagement optimization.

Conclusion

The domains of the ToA are reflected in the final *Framework* (Theory of Change) described in Section IV, the results of public input (Social Drivers of Engagement) described in Section III, the outline for tool development (Toolkits for Engagement Optimization) described in Appendix D, and recommendations for needed Infrastructure Development and Outcome measurement included in Section V.

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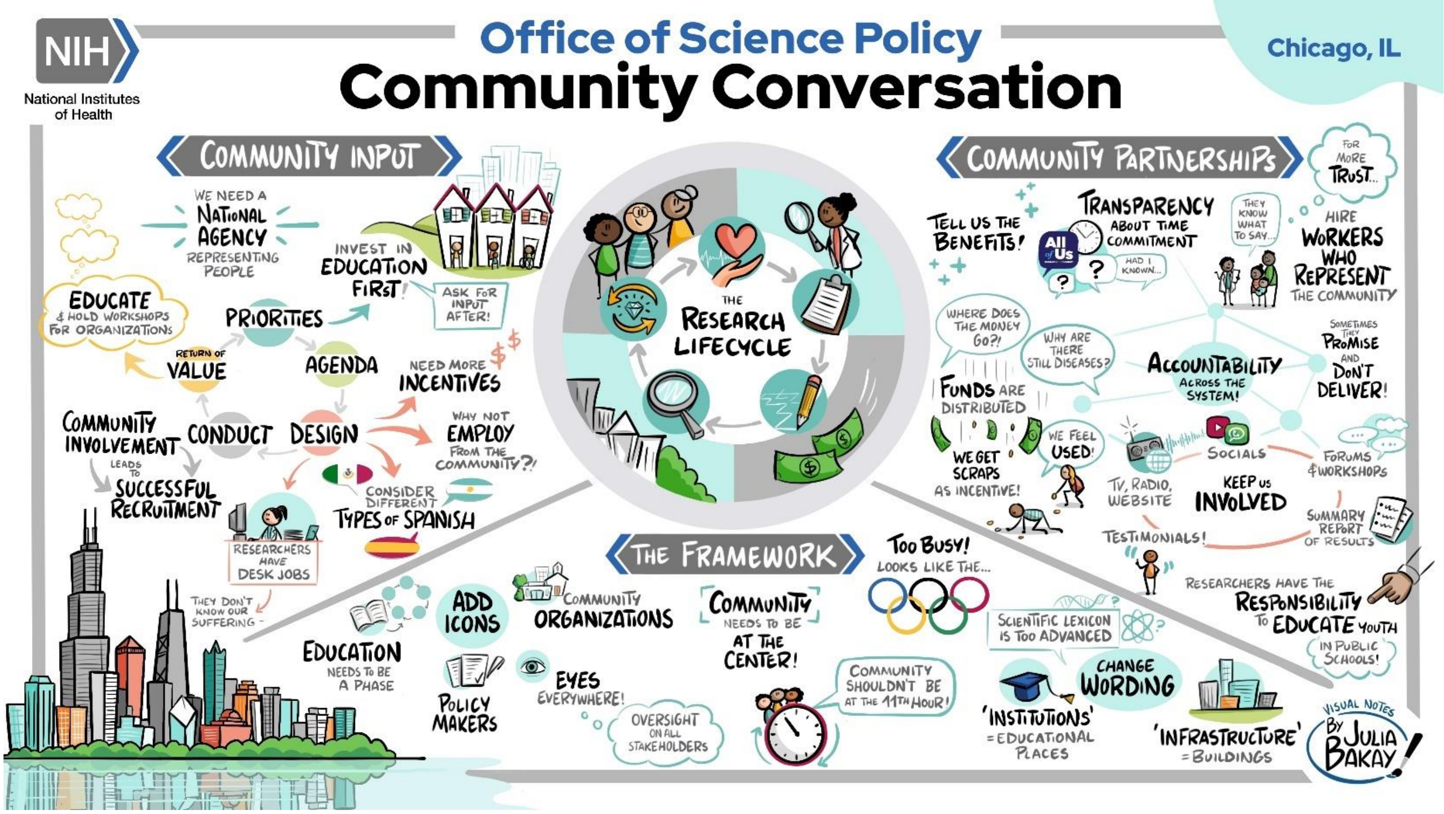
[37] Haertel EH. Letter from the National Academies Division of Behavioral and Social Sciences and Education Board of Testing and Assessment Providing Comment on the Department of Education's Proposed Regulations on the Race to the Top (RTT) fund of the American Recovery and Reinvestment Act of 2009. Updated on October 5, 2009. Accessed on September 8, 2025 at: https://nap.nationalacademies.org/read/12780/chapter/1

Appendix B: Visual Summaries of the Six Community Conversations

An illustrator attended each Community Conversation and took live visual notes throughout each event. The illustrations were intended to provide a visual summary of the key points discussed in each event. Below are the final visual summaries for each Community Conversation.

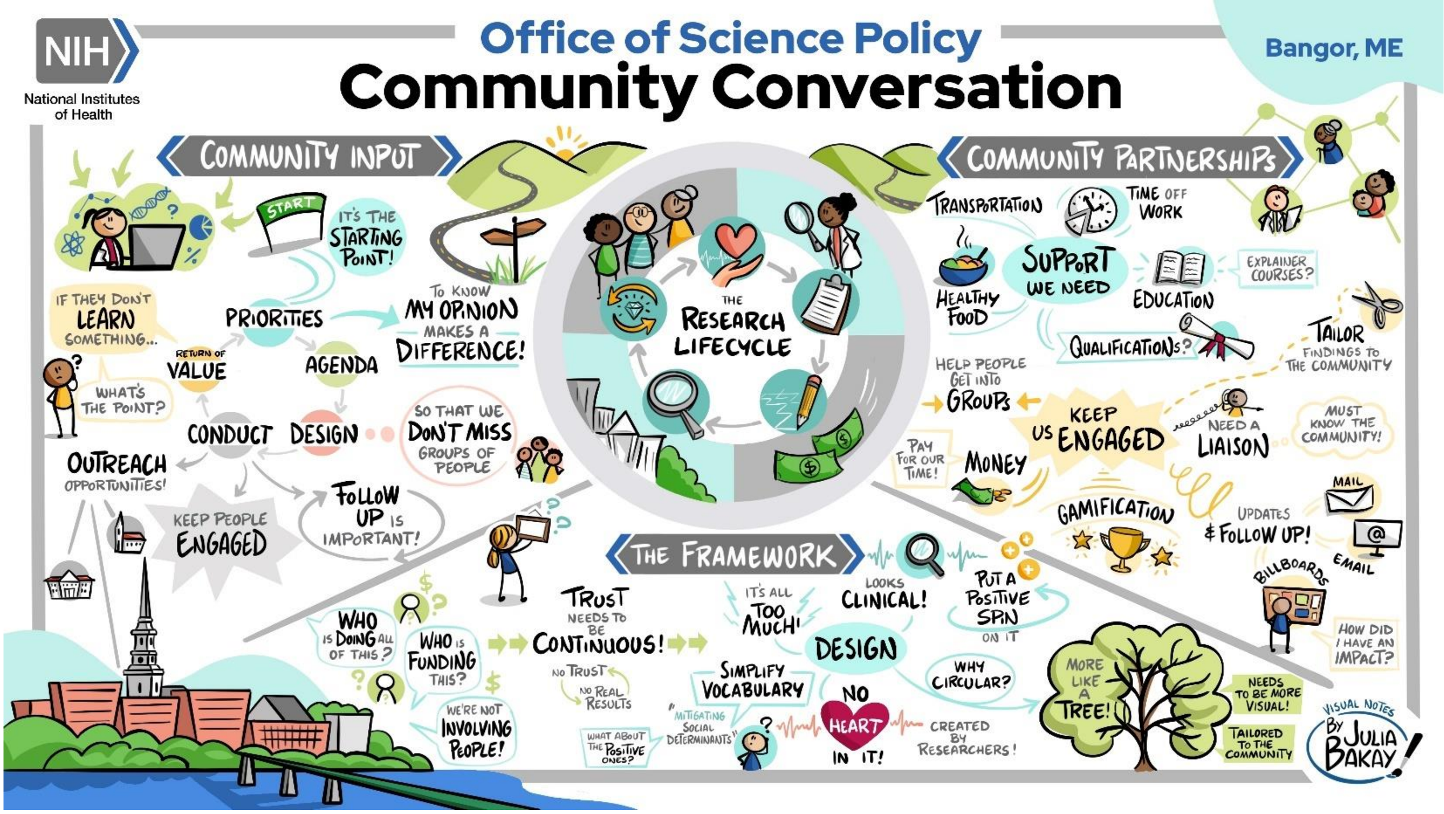
Washington, DC – October 2, 2024

Chicago, IL – October 7, 2024

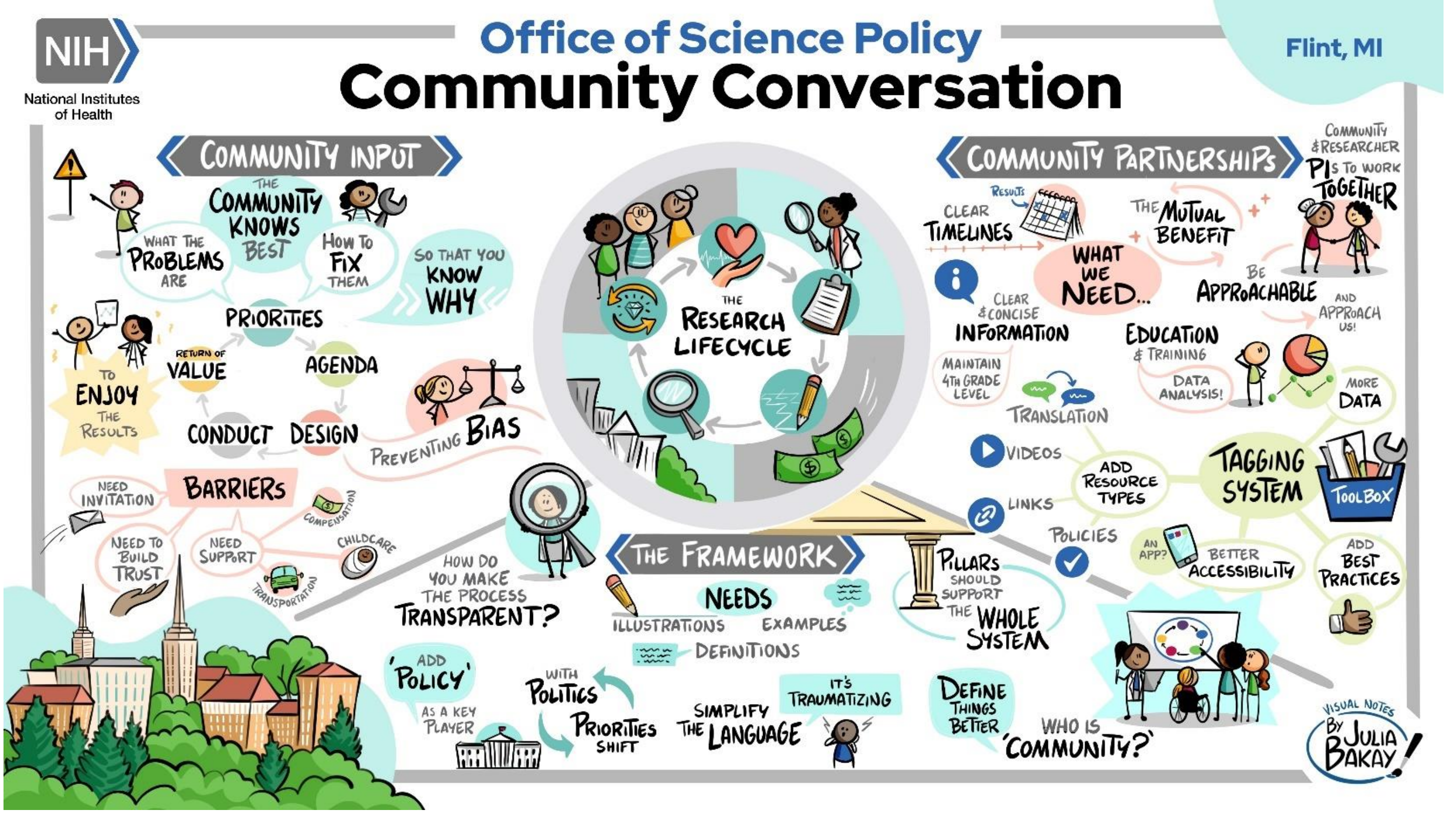


Idaho Falls, ID – October 30, 2024

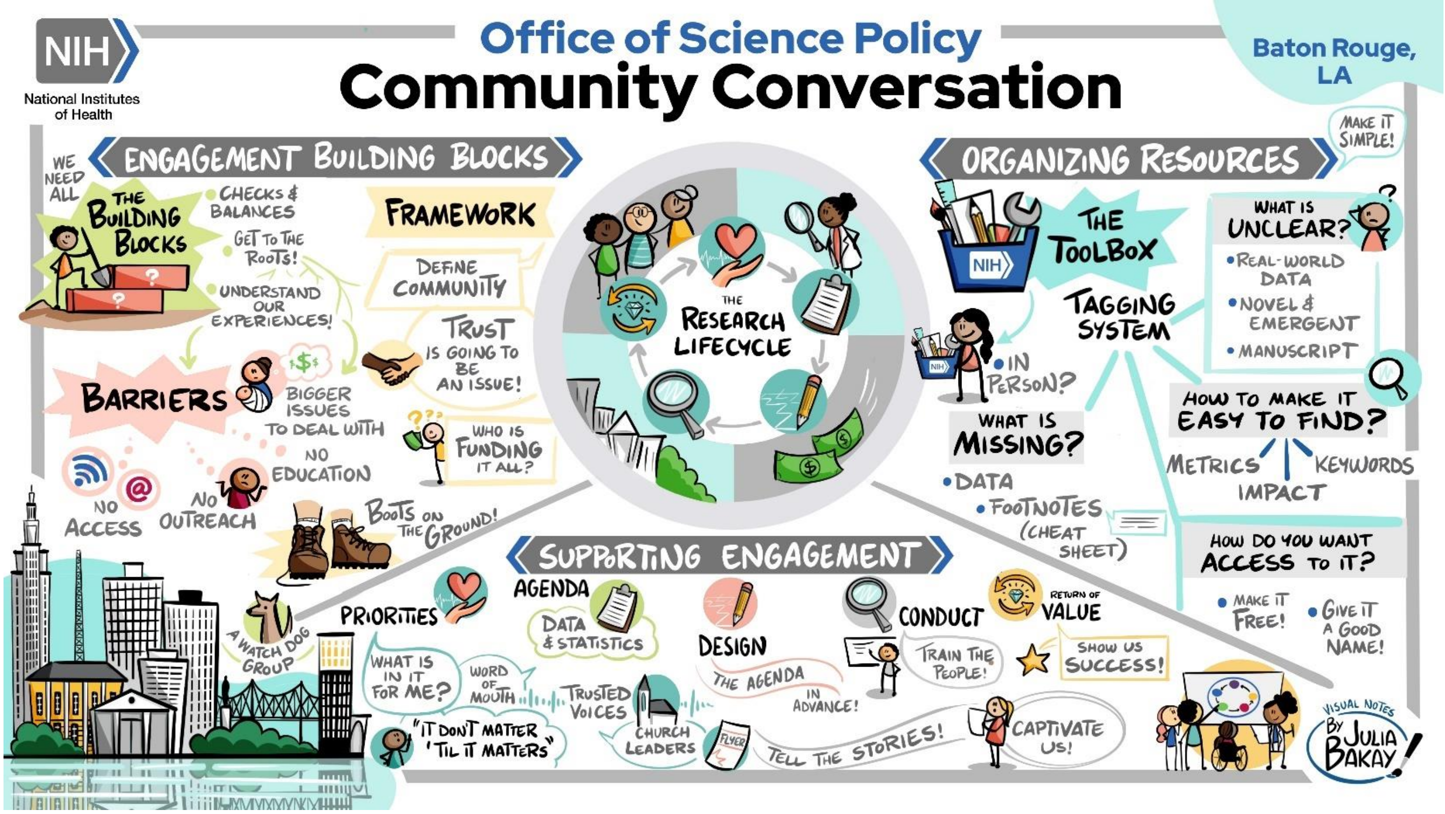
Bangor, ME – November 12, 2024



Flint, MI – December 13, 2024



Baton Rouge, LA – January 9, 2025



Appendix C: Goals and Principles that Informed the *Framework for Clinical Research Engagement*

The ENGAGE Working Group created the following set of ten goals and principles to inform development of the *Framework for Clinical Research Engagement*:

1. Clinical research 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.
2. Effective and equitable research design requires bi-directional engagement among everyone involved in the research enterprise, including, but not limited to individuals, communities, organizations, academic organizations, funders, and policymakers.
3. The goal of clinical research 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.
4. Clinical research engagement is not one-size-fits-all, and opportunities for tailoring and growth need to be integrated throughout the research endeavor.
5. Clinical research engagement efforts must incorporate the context of existing societal values and work to shift these values to be more equitable and inclusive.
6. Clinical research engagement requires investment in resources and infrastructure that reduce barriers, are culturally-tailored to the needs of communities, increase community building, and allow for long-term, sustainable efforts.
7. It is the obligation of researchers to ensure communities are aware of, and equitably included in, all stages of the research process.
8. Individuals and communities have the right to either agree or decline to engage with researchers and the research process.
9. The principles do not support tokenistic engagement but rather focus on developing a meaningful and equitable partnership.
10. Equitable health outcomes result from engagement efforts that consistently and equitably partner with people, communities, organizations, and academic institutions involved in clinical research.

Appendix D: Draft Organizational Structure and Tagging System for a Proposed Online Engagement Resource Repository

Introduction

The ENGAGE WG's second recommendation to NIH is to "actively foster an environment in which bi-directional researcher-community partnerships are standard practice." To implement this recommendation, the WG suggested the NIH "create a comprehensive repository(ies) of clinical research engagement resources (e.g., trainings, best practices, templates) for both researchers and community partners." To support this recommendation and strategy, the WG created a draft organizational structure and tagging system for a comprehensive repository. Below is an overview of how the system was developed, along with four example resources to demonstrate the need for simple, user-friendly categorization.

Organizational Structure and Tagging System Development

A critical component for any repository or library of resources is a systematic method for users to search and retrieve items they are interested in. To inform this component, the WG aimed to create a tagging system to categorize resources. The initial tagging system was extensive and included seven different dimensions:

- Resource User – the individual(s) who would utilize the tool or resource during engagement efforts
- Intended Audience – the individual or groups who would be the recipient of the information provided in the tool
- When – the point(s) within the research lifecycle when the resource may be used
- How – the method of engagement detailed in the resource or tool
- Novel or Emerging Technology – categories of new or emerging technologies that may be utilized in clinical research
- Resource Format – the structure of the resource (e.g., website, video)
- Resource Type – the elements of the resource (e.g., template, glossary)

During internal deliberations, the WG decided to eliminate the 'How' category because it is ultimately up to the user to decide how a particular resource may be used. Additionally, the WG felt that 'Resource Format' and 'Resource Type' had substantial overlap. Finally, the WG revised the options within the 'When' category to align with the research lifecycle depicted in early drafts of the *Framework for Clinical Research Engagement*.

During the last two Community Conversations, the NIH Office of Science Policy gathered individual public input on this revised tagging system – which included the Resource User, Intended Audience, When, Novel or Emerging Technology, and Resource Type dimensions. Community members found the tagging system confusing (e.g., unclear on difference between resource user and intended audience) and suggested that the system be simplified to improve usability and accessibility. There was also concern that the system, as currently envisioned (i.e., online repository), may not be a good fit for community partners. Discussions focused on whether community partners would actively seek out an online repository of resources or if an alternative format may be preferable. The WG took this feedback and further simplified their final organizational tagging system (shown in Table 3), recommending the inclusion of a short description of each resource, a flag if there is a cost to use the resource, and a URL or instructions on how to locate the resource.

Table 3. Proposed Organizational Tagging System for Online Repository of Clinical Research Engagement Resources

Category	Definition	Response Options
User Type	Provides information on the individual(s) who may find the resource or tool useful based on the role they would fill within the researcher-community partnership	• Patients/advocacy groups • Community • Researcher/clinician • Organization/institution • Funder • Unknown • Other
Stage of Research Lifecycle	Provides information on the point or points within the research lifecycle this tool or resource is likely to be useful	• Preparing for engagement • Identify health needs • Set the research question • Plan the research • Carry out the research • Share the findings • Unknown • Other
Resource Type	Describes the format of the resource or tool	• Flowchart • Guidelines • Manuscript • Example • Template • Training • Repository • Case study • Glossary • Other

Overview and Application of the Organizational Tagging System

Overview of the Final Organizational Tagging System

The WG found that a tagging system with many dimensions was more confusing and less useful than a simple, easy-to-understand approach. They refined their system to focus on the most critical characteristics of a tool or resource. The User Type dimension will allow for quick filtering by the role of a potential user. The Stage of the Research Lifecycle dimension will make the repository a better complement to the *Framework for Clinical Research Engagement* as it maps resources directly to the *Framework*. Finally, the Resource Type dimension provides information on the format of the resource, allowing potential users to identify what would be most helpful for them given their knowledge, experience, and engagement methods.

The Organizational Tagging System in Practice – An Example

To demonstrate how the tagging system may be put into practice, the ENGAGE WG categorized four existing resources into their proposed organizational tagging system (see Table 4). They also include additional information that could be useful in a future repository, such as a brief description of the resource.

Table 4. Application of the Proposed Organizational Tagging System with Four Clinical Research Engagement Resources

Resource Name	Brief Description	User Type	Stage of Research Lifecycle	Resource Format	Available for Free	Link to Resource
Advocate-Researcher Working Together Toolkit	Toolkit to assist researchers and advocates seeking to work together on research projects	• Researcher/clinician	• Identify health needs • Set the research question • Plan the research • Carry out the research • Share the findings	• Guidelines • Template • Other – toolkit	• Yes	URL
National Institutes of Aging Outreach Pro	Helps create customized outreach materials for clinical trials on Alzheimer's and related dementias	• Organization/institution • Researcher/clinician • Funder	• Carry out the research	• Template	• Yes	URL
Patient Centered Outcomes Research Institute Updated Engagement Plan	Template for updating required engagement plans at month 6 of the project	• Organization/institution • Researcher/clinician • Other – PCORI applicants	• Preparing for engagement • Carry out the research • Share the findings	• Template	• Yes	URL
MRCT Clinical Research Glossary	A plain language glossary of clinical research terms	• Patient/advocacy groups • Community • Organization/institution • Researcher/clinician • Funder	• Identify health needs • Set the research question • Plan the research • Carry out the research • Share the findings	• Glossary	• Yes	URL

Next Steps in Resource Repository Development

The ENGAGE WG's proposed organizational tagging system represents only one part of a broader need to create a robust and comprehensive repository of clinical research engagement resources and tools. Future efforts need to focus on building a user-friendly, searchable repository and ensuring that both researchers and community partners can access the identified engagement resources.

The ENGAGE WG identified two existing NIH-supported repositories or collections of clinical research engagement resources – the ADORE (Alzheimer's & Dementia Outreach, Recruitment, and Engagement resources)[38] and the HEAL Initiative Patient and Community Engagement Resources.[39] Each of these examples has its benefits and drawbacks. The ADORE repository is searchable and has some filtering capabilities, but it is limited to resources tailored for Alzheimer's and dementia research. The HEAL Initiative on Patient and Community Engagement Resources provides more universally applicable resources, but the website lacks search and filtering capabilities. The NIH should enhance these existing repositories and collections to create a more comprehensive, research topic-agnostic, and user-friendly online repository.

During the community conversations where the draft organizational tagging system was presented, individuals were uncertain about how they were supposed to use the online repository and tagging system. There was also a desire to tailor the repository format for local needs. A critical next step in this effort will be for the NIH to collaborate with patient advocacy and community-based organizations to identify the best approach for creating a usable, community-friendly collection of clinical research engagement resources.

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[38] Alzheimer's & Dementia Outreach, Recruitment, and Engagement (ADORE) Resources. National Institute on Aging. Accessed on September 8, 2025 at: https://www.nia.nih.gov/research/alzheimers-dementia-outreach-recruitment-engagement-resources.

[39] Patient and Community Engagement Resources. The National Institutes of Health HEAL Initiative. Updated on May 21, 2025. Accessed on September 8, 2025 at: https://heal.nih.gov/resources/engagement.