Update from the Working Group on Engaging the Public as Partners in Clinical Research

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NExTRAC
Novel & Exceptional Technology
and Research Advisory Committee

December 3, 2024

Agenda

- ☑ Foundational principles of ENGAGE initiative
- ☑ Working group’s progress to date
- ☑ Community conversations and other avenues for public input
- ☑ Next steps and plan of action

Foundational Principles of ENGAGE

What is guiding our work?

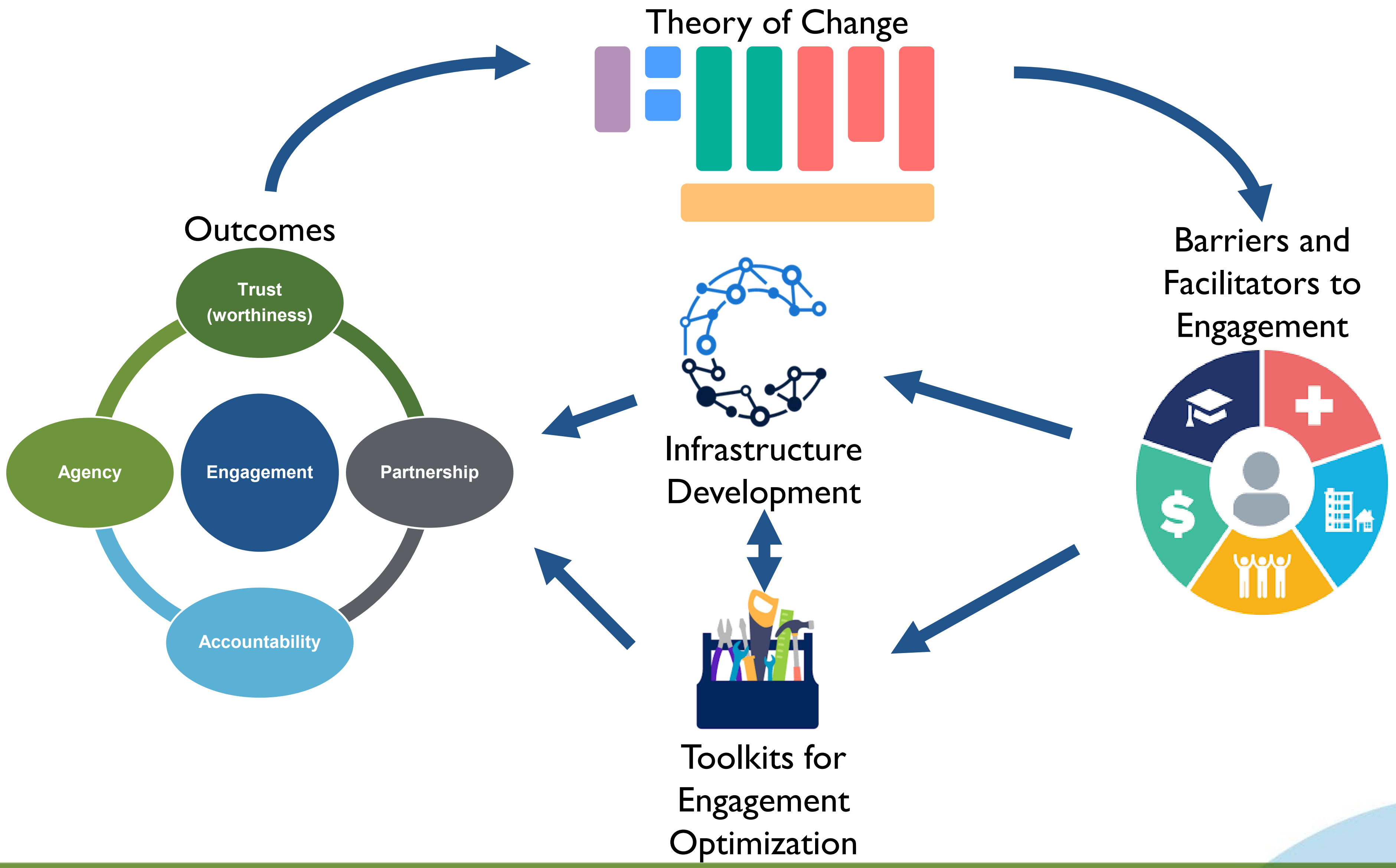
What is Clinical Research Engagement?

CLINICAL RESEARCH ENGAGEMENT: involvement that varies by level and type depending on research and community needs, with individuals, groups of people, communities, and/or organizations across the various stages of clinical research so that the research and its outcomes are meaningful and actionable to relevant partners.

Various Stages of Clinical Research

Relevant Partners

How Are We Approaching Our Work?



Theory of Change

Barriers and Facilitators to Engagement

Infrastructure Development

Toolkits for Engagement Optimization

Outcomes

Trust (worthiness)

Agency

Engagement

Partnership

Accountability

Utilizing a Broad Definition of Clinical Research

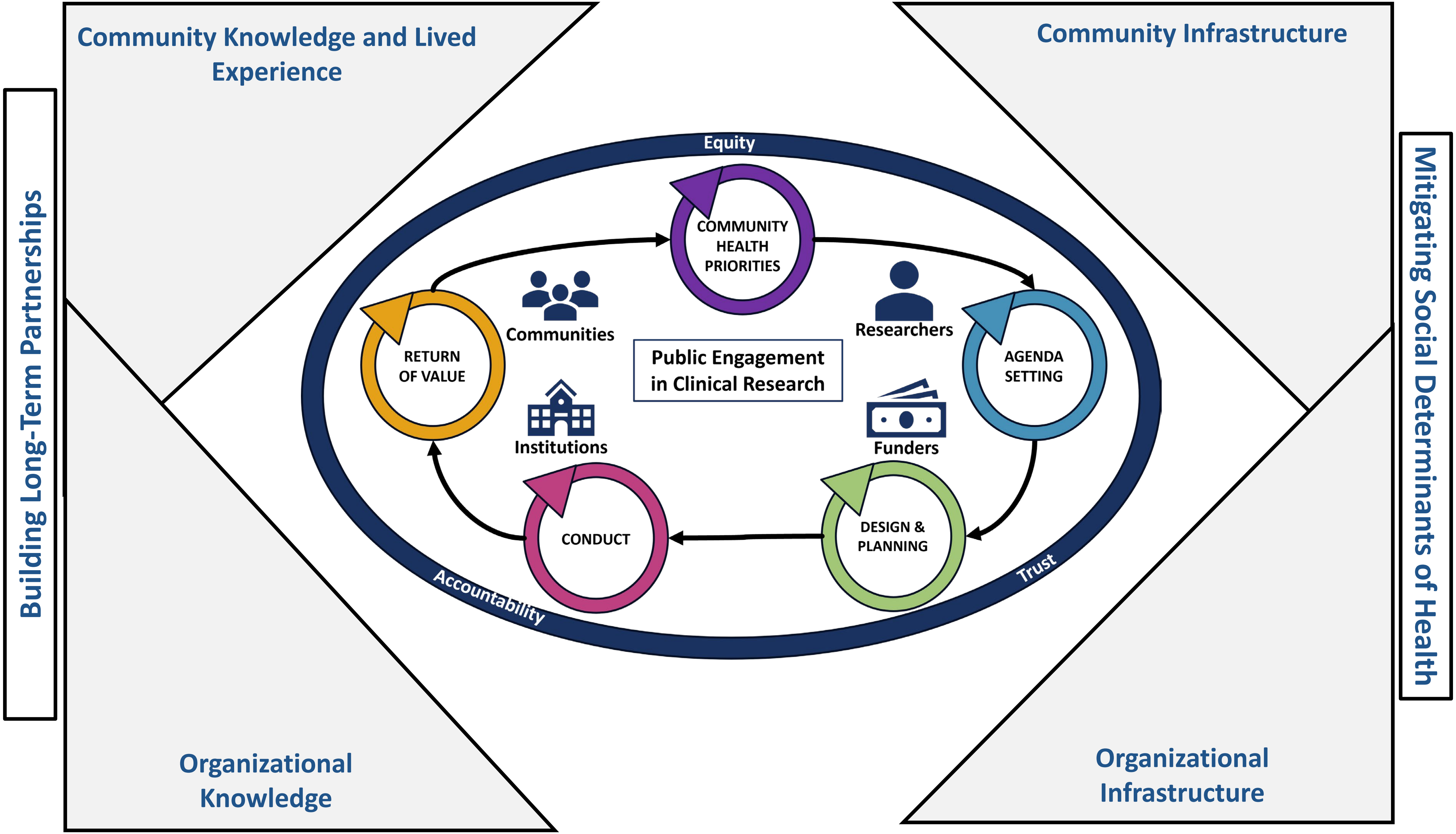
Research Phase	Possible Study Designs	Potential Types of Data Used
Discovery Science	Retrospective Cohort	Health records
	Basic Science Experiments	Biospecimens, genomic data
	Observational Study	Surveys, clinical data
Clinical Trials	Clinical Trial - Drug	Clinical tests, surveys
	Clinical Trial - Behavior	Surveys, data from wearables
Translational Science	Health Services	Health records, surveys
	Post-Market Surveillance	Clinical data, adverse events

Working Group’s Progress

What have we been up to?

Framework Focused Topic Area

- Roadmap for engagement
- Suitable for a broad audience
- Actionable Domains
- Complementary Maturity Model


Community Knowledge and Lived Experience
Community Infrastructure
Building Long-Term Partnerships
Mitigating Social Determinants of Health
Equity
COMMUNITY HEALTH PRIORITIES
AGENDA SETTING
DESIGN & PLANNING
CONDUCT
RETURN OF VALUE
Communities
Researchers
Institutions
Funders
Public Engagement in Clinical Research
Accountability
Trust
Organizational Knowledge
Organizational Infrastructure

Draft Objectives

COMMUNITY HEALTH PRIORITIES

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

AGENDA SETTING

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

DESIGN & PLANNING

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

Toolbox Topic Area

- Creating a preliminary library of engagement resources
- Tagging system to improve ease of searching
- Align resources with framework
- Variety of resource types

Resource Tagging System

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

Resource User

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

Audience

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

When

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

Novel or Emerging Tech

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

Resource Type

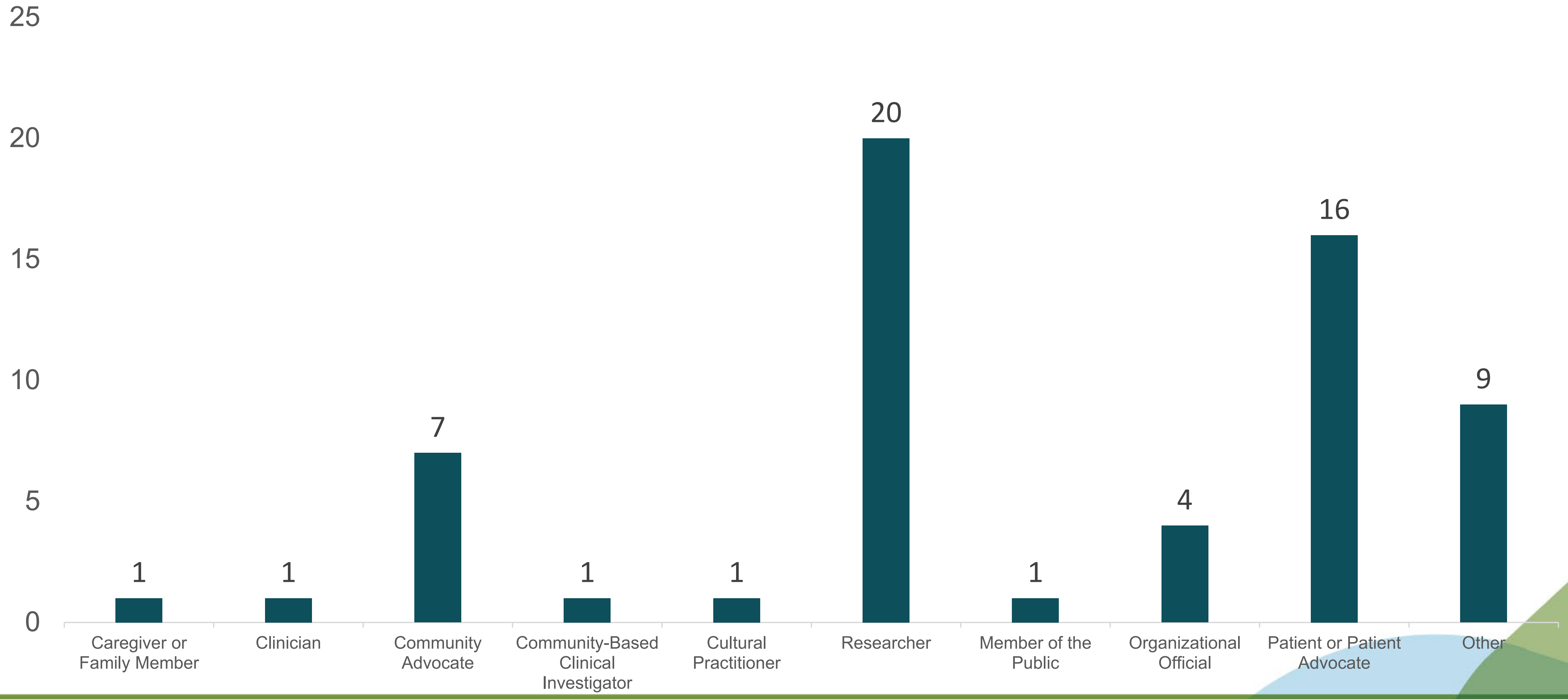
Community Conversations

How are we getting public input?

Request for Information & Listening Session

1. Strategies for researchers to best partner and work with people & communities
2. Ways for institutions to support partnerships between researchers & communities
3. Approaches for funders to incorporate partnerships between people & researchers
4. Things that make people more likely to engage with researchers
5. Things that make people less likely to engage with researchers

Role Respondent Identifies With



Key Themes Across All Respondents

Incorporating patient and community input into research

Requiring incentives and compensation for engagement

Lack of resources and infrastructure are key barriers

Key Themes by Respondent Type

Community Members

Plain language communication

Understand real-world impacts

Building inclusive environments

Researchers

Relationship building with communities

Fostering trust between researchers and communities

Community Conversations

GOAL: Gather individual perspectives on different engagement methods, the optimal timing for engagement, and how to ensure engagement is equitable and inclusive.

PLAN: Facilitate 12 conversations with different communities:

- 10 in-person conversations
- 2 virtual conversations

Considerations for Selecting In-Person Locations

Communities underrepresented in clinical research

Existing clinical research infrastructure

WG connections

Geography

Washington, DC

Chicago, IL

Idaho Falls, ID

Bangor, ME

AI/AN Advocacy Organizations

COMMUNITY CONVERSATION PLAN

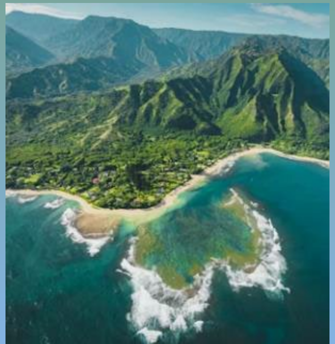
Flint, MI

Baton Rouge, LA

Wichita, KS

Los Angeles, CA

Honolulu, HI



Houston, TX

Research Community

Approach to Each Conversation

Pre-Conversation

- Partner with community org
- Facilitation guide
- Questionnaire

During Conversation

~25 attendees

Live Illustrator

Post-Conversation

- Thank you email
- Reports
- Updating website

High-Level, Initial Takeaways

1. Every detail of the framework graphic should be implemented with purpose. Terms used in the graphic should speak to the community and to researchers.
2. Communities should be central in the research framework, prioritizing their needs and providing oversight throughout the research process, and should particularly be involved in design and planning.
3. Rely on trusted community voices to work to overcome skepticism and distrust in science and/or the federal government.

Some Unique Ideas

1. **Washington, DC:** Use of pictures that represent the community in the framework visual to improve understandability.
2. **Chicago:** Oversight and monitoring of all partners (researchers, organizations, community members, funders) is critical at all phases.
3. **Idaho Falls:** Community voices cannot overshadow scientific rigor and credibility.
4. **Bangor:** Need for accessibility considerations at all phases to ensure equitable engagement opportunities.

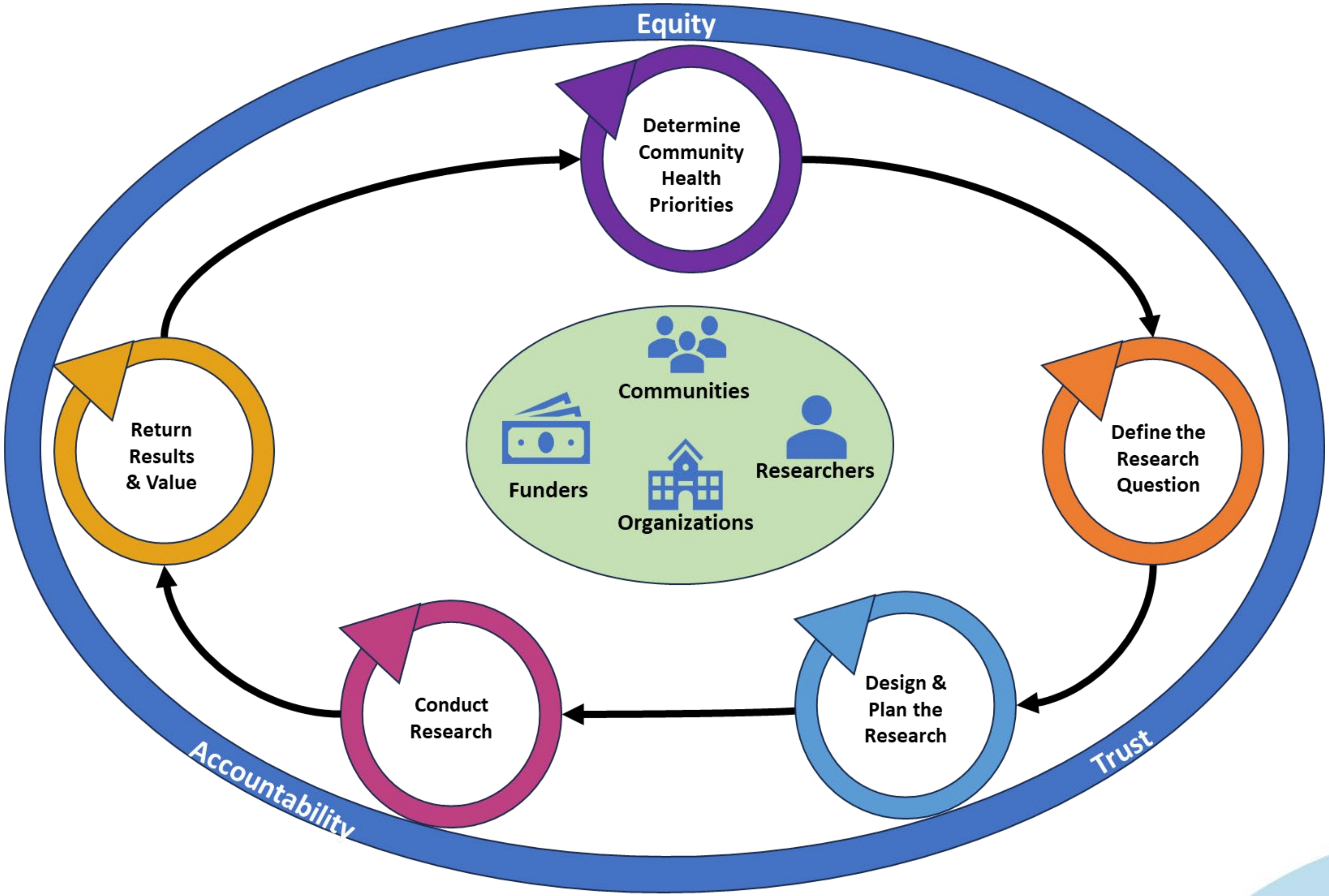
Next Steps and Plan of Action

How are we meeting our goal of a summer 2025 report?

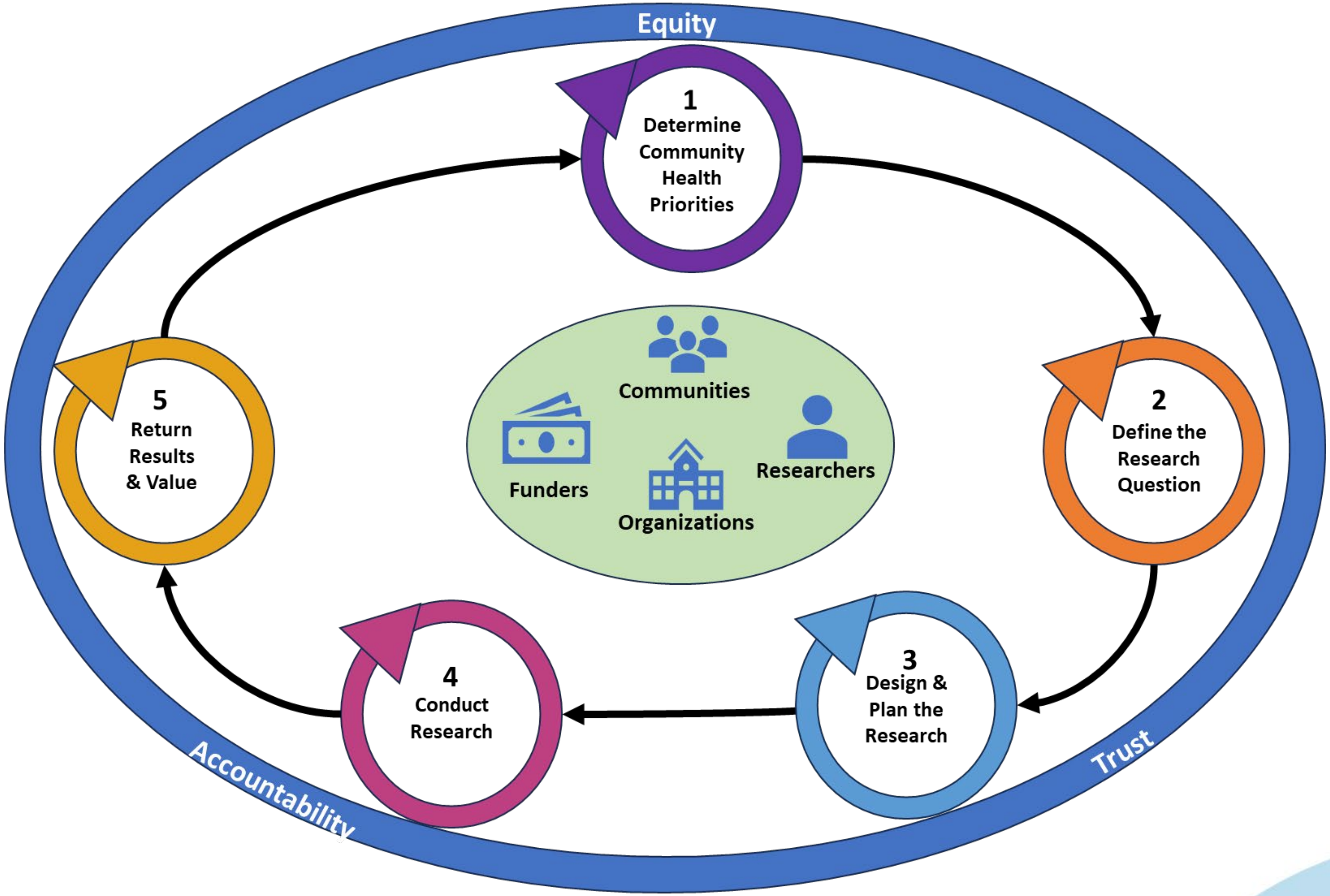
Planned Framework Iteration

- Simplify framework visual
- Make small adjustments to improve clarity
- Revise language

Option 1


Equity
Determine Community Health Priorities
Define the Research Question
Design & Plan the Research
Conduct Research
Return Results & Value
Communities
Funders
Researchers
Organizations
Accountability
Trust

Option 2


Equity
1
Determine Community Health Priorities
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Define the Research Question
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Design & Plan the Research
4
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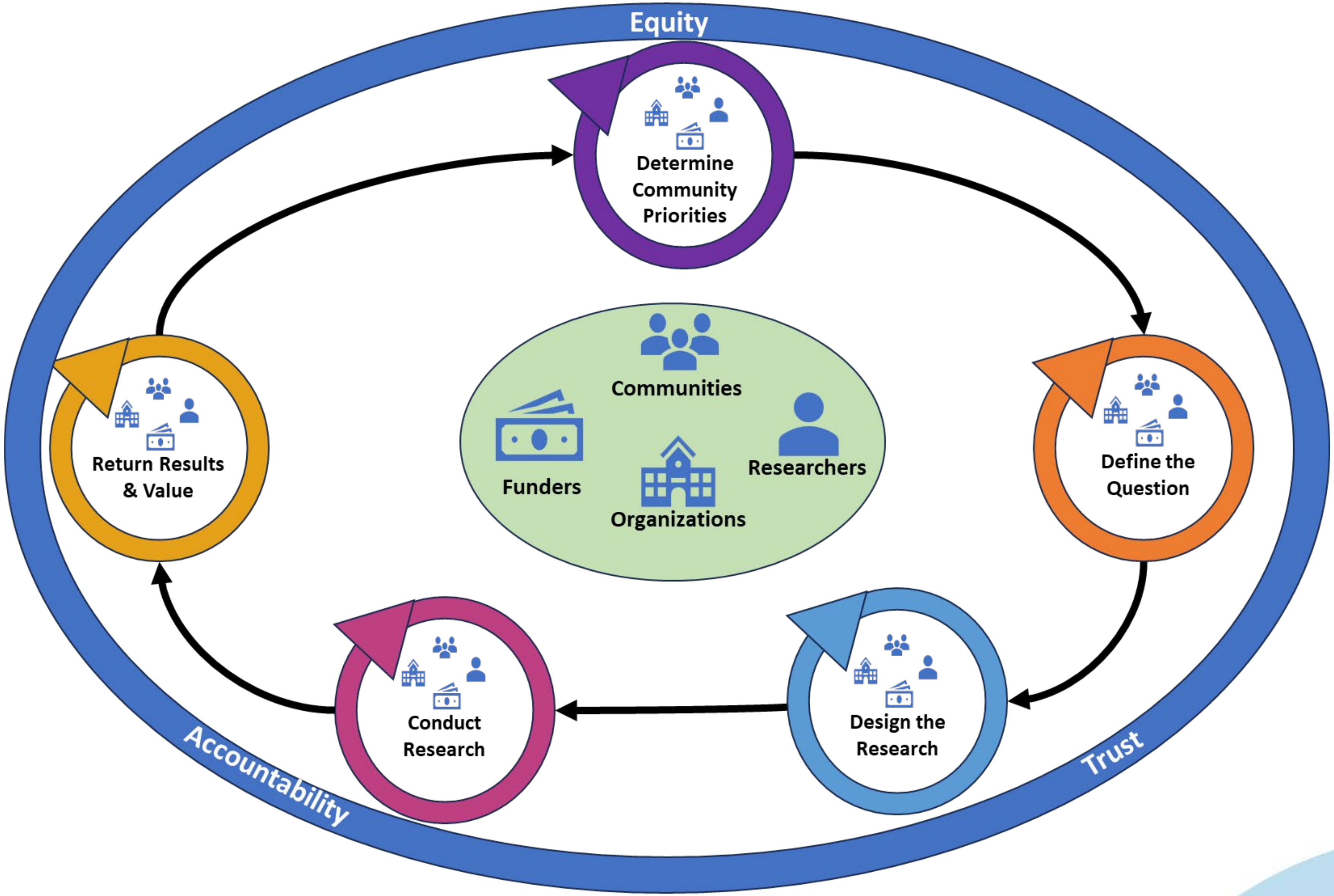
Option 3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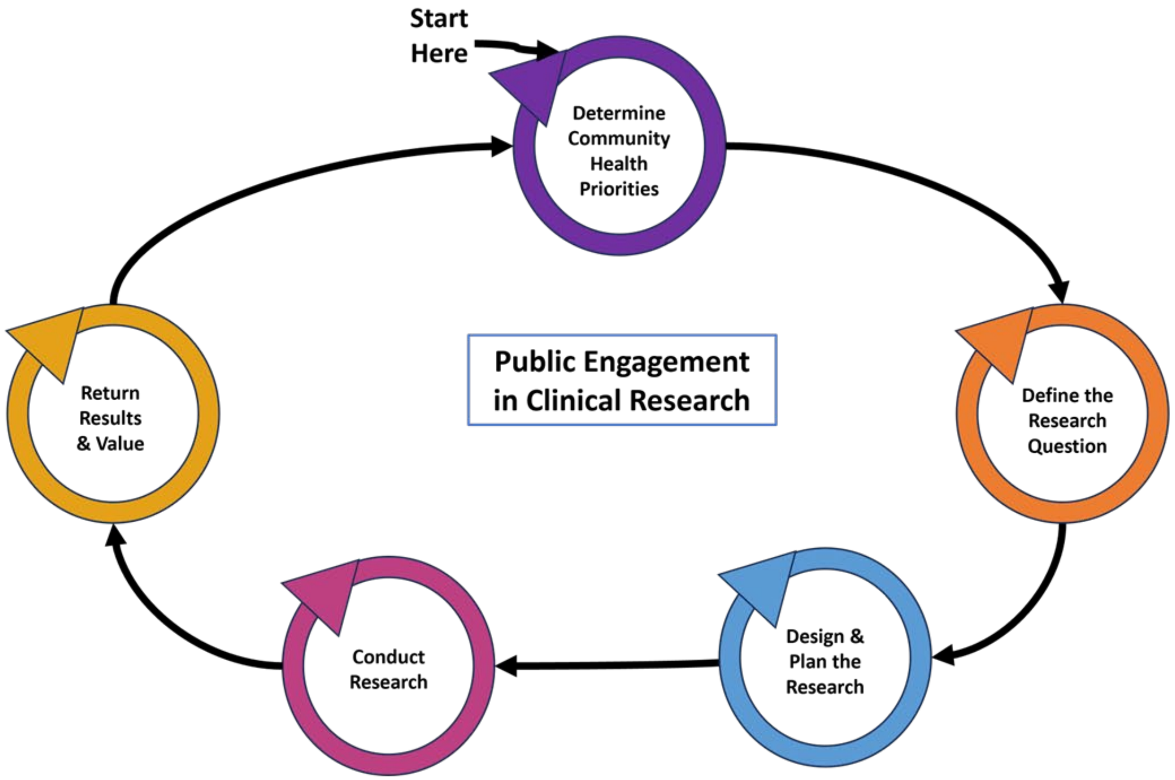
Option 4

Partners in Public Engagement in Clinical Research

- Communities
- Researchers
- Organizations
- Funders



Start Here

Determine Community Health Priorities

Define the Research Question

Design & Plan the Research

Conduct Research

Return Results & Value

Public Engagement in Clinical Research

Key Pillars of Public Engagement in Clinical Research

Plan of Action

Community Conversations	Draft and Revise Report	Additional Public Input	Finalize Report	**Present to NExTRAC**
Oct. 2nd – mid-Feb.	**Mid-March to late May**	**RFI, listening session, etc. March - May**	**Finalize report in late June or early July**	**Late summer 2025**

Thank you!

Questions?

Follow ENGAGE’s progress at:

PartnersInResearch.nih.gov