

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

Suzanne Bakken, RN, PhD, FAAN, FACMI, FIAHSI *Alumni*
Professor of the School of Nursing & Professor of Biomedical Informatics, Vagelos College of Physicians & Surgeons, Columbia University

Christin Veasley
Co-Founder & Director, Chronic Pain Research Alliance

NExTRAC

Novel & Exceptional Technology
and Research Advisory Committee

September 29, 2025

The ENGAGE Working Group



Jessica Ancker,
Vanderbilt University
Medical Center



María Aranda,
University of
Southern California



Suzanne Bakken*,
Columbia University



Cinnamon Bloss,
University of
California, San
Diego



**Roberta Diaz
Brinton,**
University of Arizona



Karen Caindec,
Southcentral
Foundation



Kristin Carman,
Patient-Centered
Outcomes Research
Institute



Tiffany Haynes,
University of
Arkansas for Medical
Sciences



Sally Hodder,
West Virginia
University



**Lance Jasper
Jones,**
Jasper House
Warriors



Annie Kennedy,
EveryLife
Foundation for Rare
Diseases



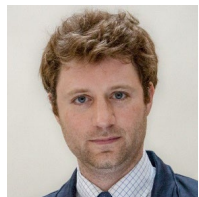
Kent Key,
Community Based
Organization Partners
& Michigan State
University



Alexa Kimball,
Harvard Medical Faculty
Physicians, Beth Israel
Deaconess Medical
Center



Esther Krofah,
FasterCures, Milken
Institute



Doug Lindsay,
Community Advisory
Board for Washington
University in St. Louis



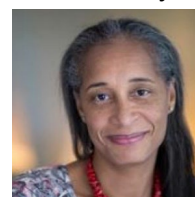
Marjorie Mau,
University of Hawai'i
at Mānoa



Kenneth Oye,
Massachusetts
Institute of
Technology



Judy Stecker,
Burson Global



Maria Trent,
Johns Hopkins
University



Christin Veasley*,
Chronic Pain
Research Alliance



Michelle Sie Whitten,
Global Down
Syndrome Foundation

*Indicates ENGAGE WG Co-Chair

How ENGAGE Approached its Charge



Develop
unified vision
and goal for
clinical
research
engagement
at NIH



Convene public
consultations to
inform framework
&
recommendations



Develop
framework for
including clinical
research
engagement in
NIH-funded
clinical research



Provide
recommendations
to the NIH on
how to improve
clinical research
engagement



Develop
unified vision
and goal for
clinical
research
engagement
at NIH

A light blue circle is connected by a thin grey line to a larger green circle. The green circle has a dark green center and a light green outer ring. A grey arc is positioned below the green circle.

How ENGAGE Approached its Charge

What is Clinical Research Engagement?

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 the disease for those who could benefit from the research



Relevant Partners

Vision and Goal for Clinical Research Engagement

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

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



Engagement: Benefits and Challenges

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

Some Challenges to Clinical Research Engagement



Lack of **financial resources** to support bi-directional engagement methods



Limited **organizational support** for bi-directional engagement



Organizational priorities dictating scientific priorities and topics that will receive funding



Lack of **training** for researchers and community members

How ENGAGE Approached its Charge



```
graph TD; A((How ENGAGE Approached its Charge)) --- B[Develop unified vision and goal for clinical research engagement at NIH]; A --- C[Convene public consultations to inform framework & recommendations];
```



Develop
unified vision
and goal for
clinical
research
engagement
at NIH



Convene public
consultations to
inform framework
&
recommendations

Methods for Gathering Public Input



**Request for
Information**



**Virtual Listening
Session**



**In-Person
Community
Conversations**

Five Key Themes

1

Centering communities in the research process

2

Relying on trusted voices to build relationships

3

Implementing engagement strategies with purpose

4

Investing in building sustainable capacity for engagement

5

Offering compensation and incentives for engagement



Examples of Key Themes Influencing Framework



Centering Communities

Outlines how researchers and communities should partner together



Sustainable Capacity

Provide suggestions for how organizations can develop infrastructure



Offering Compensation

Key considerations for fair and equitable compensation

How ENGAGE Approached its Charge



Develop
unified vision
and goal for
clinical
research
engagement
at NIH



Convene public
consultations to
inform framework
&
recommendations



Develop
framework for
including clinical
research
engagement in
NIH-funded
clinical research

Framework for Clinical Research Engagement





ORGANIZATIONS

Includes organizations that employ researchers to carry out clinical research (research-focused organizations) and organizations embedded within a specific community (community-based organizations)



RESEARCHERS

Individuals who have training and experience in designing and conducting health research



FUNDERS

Entities that provide financial resources to researchers or organizations to conduct clinical research



COMMUNITY

A group of people who share a common bond or interest (e.g., geography, health condition)



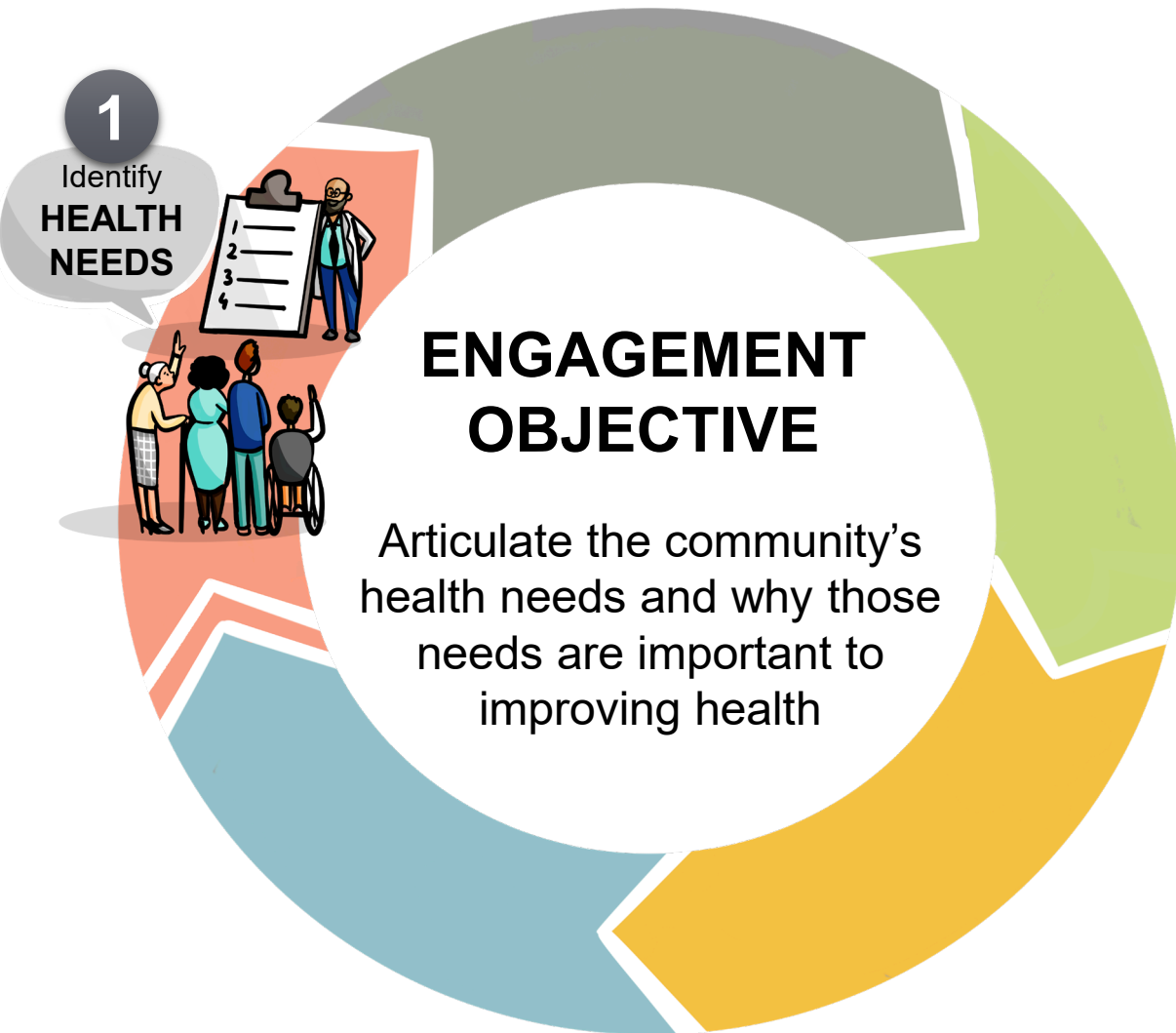
1

Identify
**HEALTH
NEEDS**



ENGAGEMENT OBJECTIVE

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



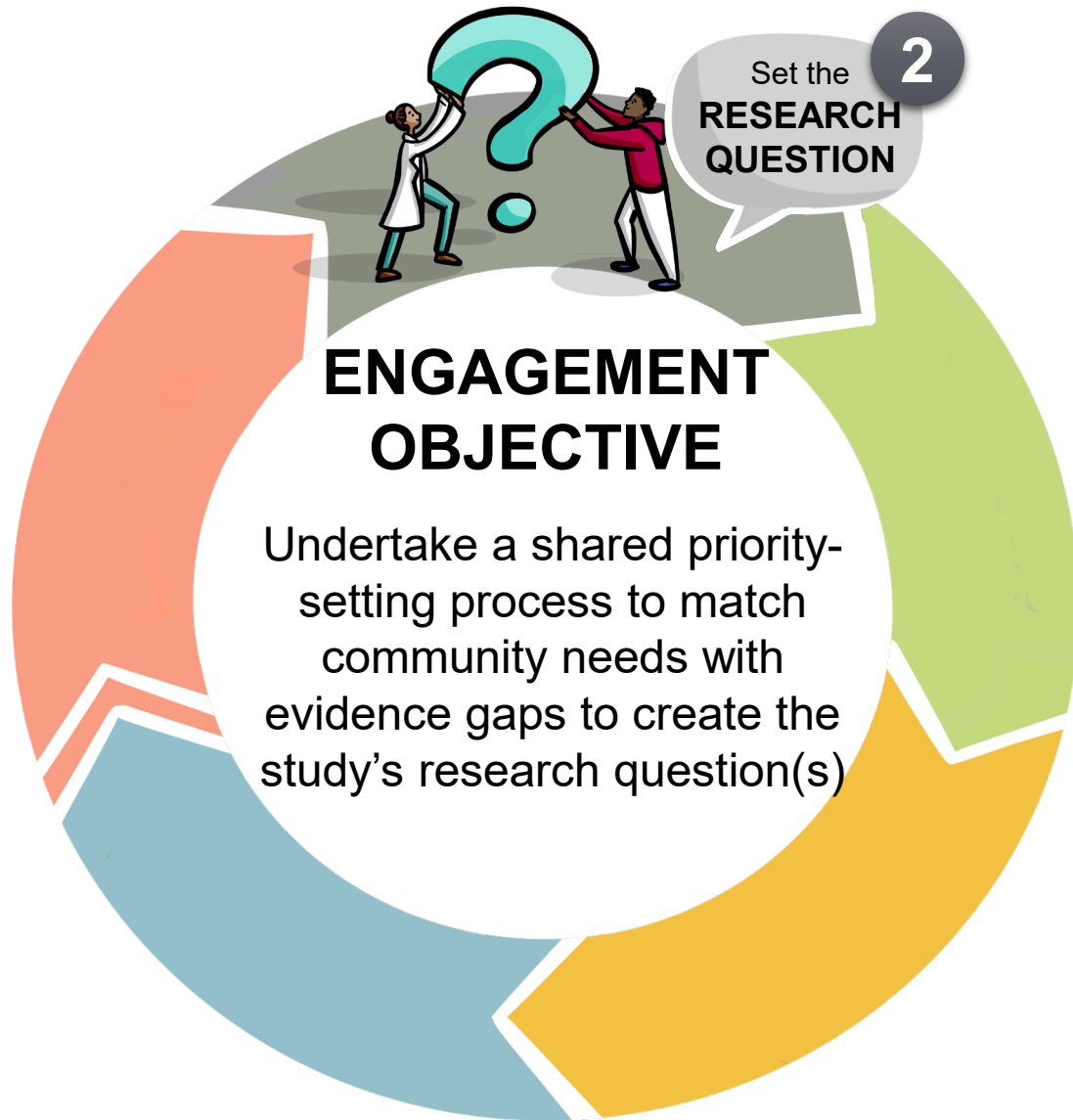
ACTION STEPS

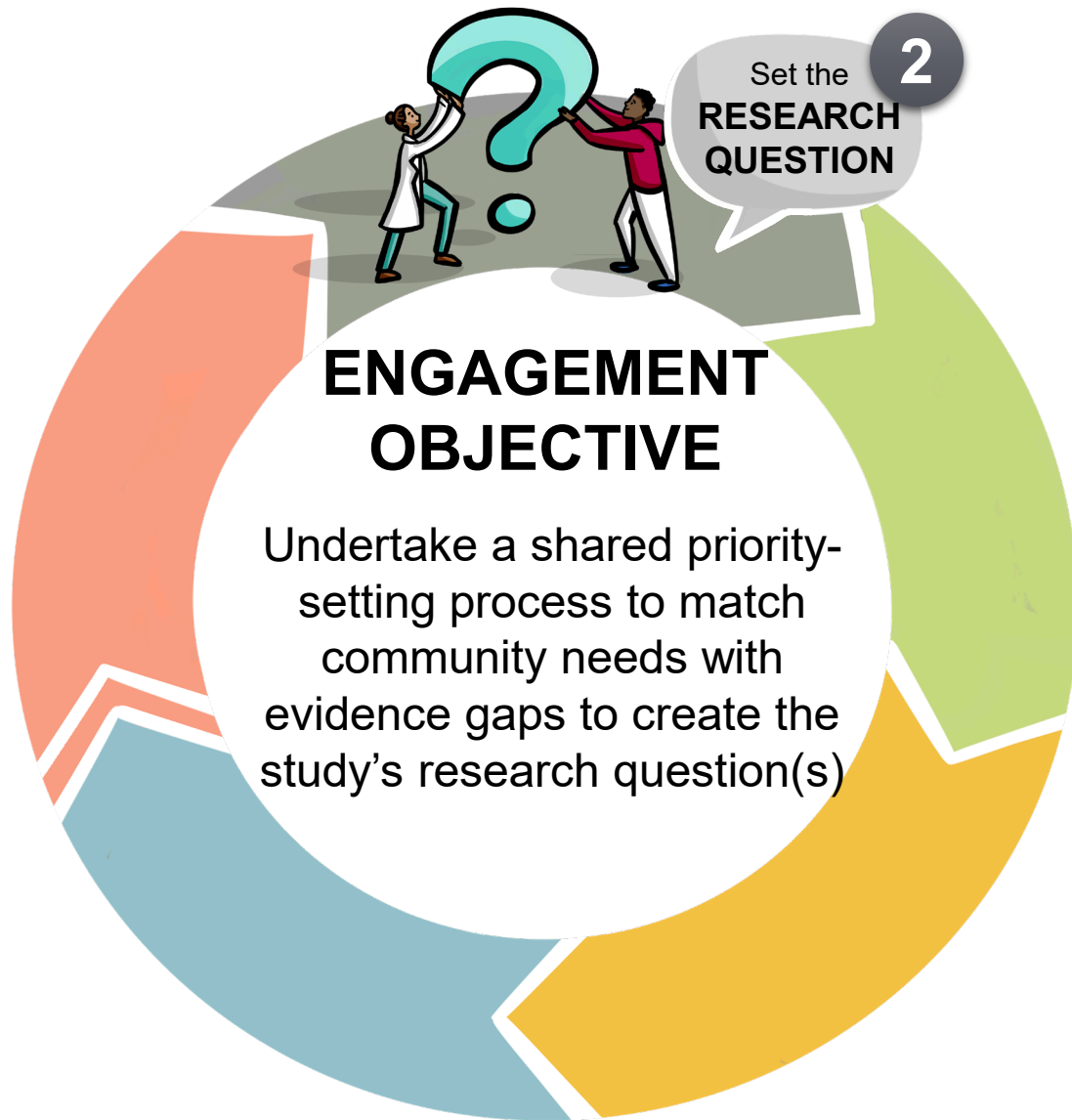
1

Ongoing and consistent collection and assessment of community health needs by researchers and communities

2

Develop understanding of the importance of the community health need(s)





ACTION STEPS

1

Execute a shared priority-setting process that includes both researcher and community participation

2

Clarify evidence gaps and possibilities for research

3

Craft the research question(s) and identify potential funding opportunities



ENGAGEMENT OBJECTIVE

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

PLAN
the Research

3

ACTION STEPS

ENGAGEMENT OBJECTIVE

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



PLAN
the Research

1

Reach agreement on community and researcher roles, responsibilities, and decision-making processes

2

Deliver study- or role-specific training to prepare community partners and researchers for collaborative design

3

Incorporate community expertise into study design to improve quality and feasibility

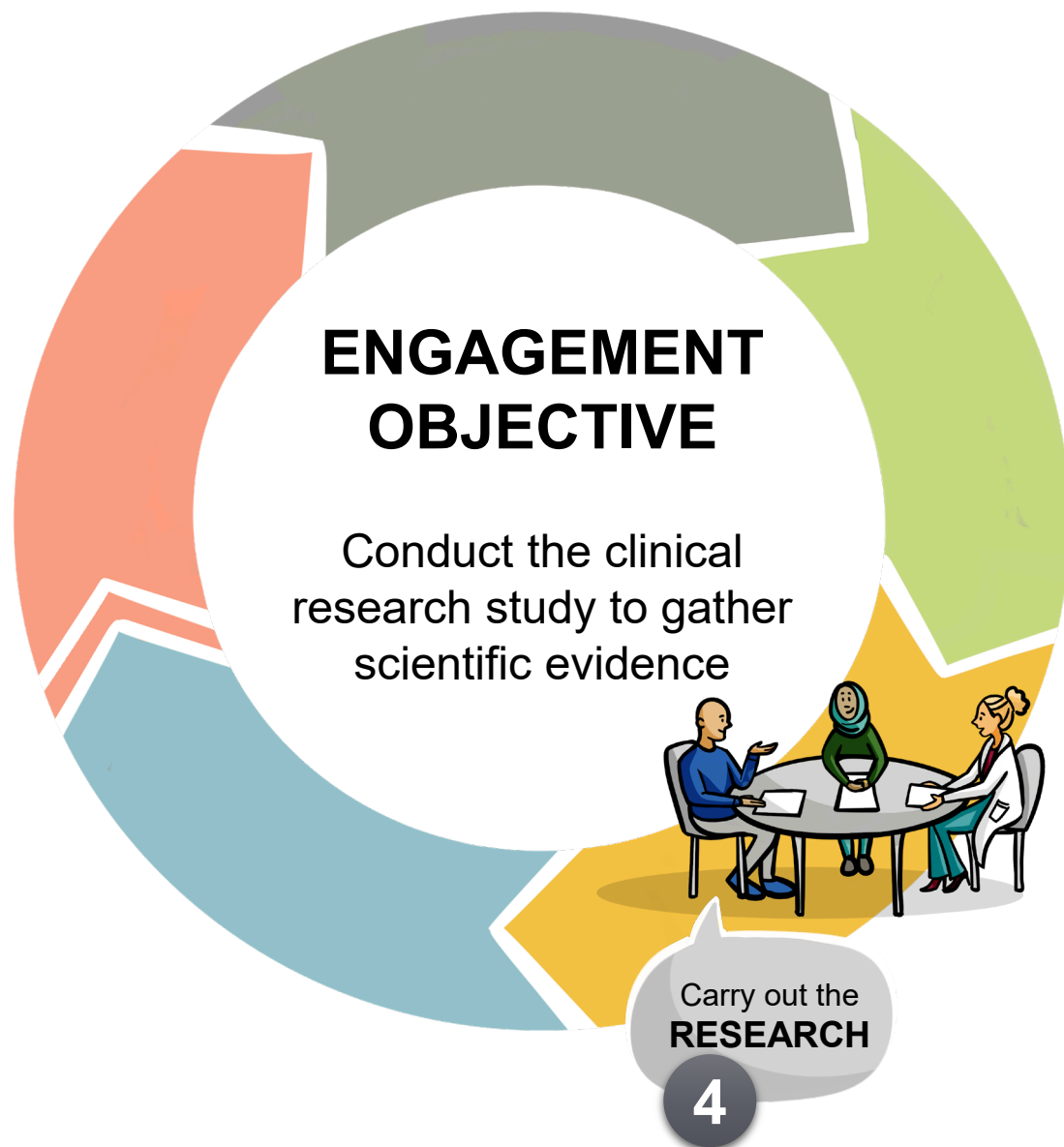


ENGAGEMENT OBJECTIVE

Conduct the clinical
research study to gather
scientific evidence

Carry out the
RESEARCH

4



ACTION STEPS

1

Monitor study progress to ensure community-centeredness and fulfillment of responsibilities

2

Implement community-informed study modifications to address obstacles

3

Co-interpret study results with input from both community partners and researchers

ENGAGEMENT OBJECTIVE

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

5

Share the
FINDINGS





ENGAGEMENT OBJECTIVE

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

5

Share the
FINDINGS

ACTION STEPS

1

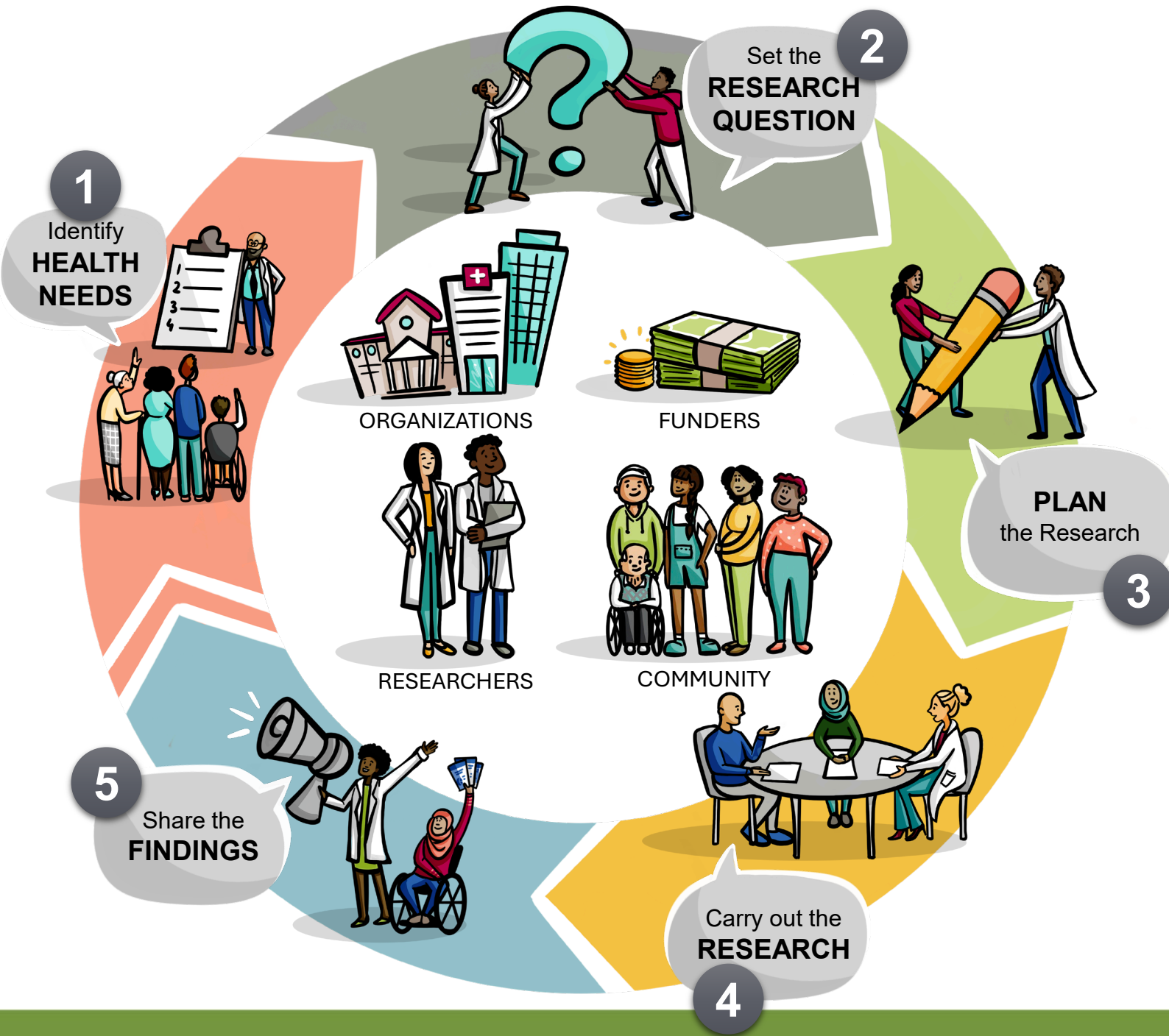
Co-design tailored plans for returning results to participants, community(ies), scientists, and the public

2

Co-create the dissemination products

3

Co-communicate dissemination products through multiple channels



Clinical research engagement is an ongoing process and not one-size-fits-all

Preparing for Engagement



Establish Partnerships

Create relationship in which all partners contribute knowledge, share decision-making, and collaborate to design and conduct research

1



Compensation & Resources

All partners should be offered fair and equitable compensation that is based on their role, expected contributions, and preferences.

2



Establish Expectations

All partners should create baseline expectations for how they will work together, make decisions, and manage disagreements.

3



Deliver Training

Teams should identify what each partner already knows, where there are gaps, and deliver appropriate education and training to meet those needs.

4

How ENGAGE Approached its Charge



Develop
unified vision
and goal for
clinical
research
engagement
at NIH



Convene public
consultations to
inform framework
&
recommendations



Develop
framework for
including clinical
research
engagement in
NIH-funded
clinical research



Provide
recommendations
to the NIH on
how to improve
clinical research
engagement

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

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



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 more accessible and meaningful, protect participant privacy, and prevent group harm

1C

Require that study leaders and community-facing personnel 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

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

2B

Create a comprehensive repository(ies) of clinical research engagement resources (e.g., trainings, best practices, templates) for both researchers and community partners

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

3A

Establish a coordinated agency-wide approach for engagement activities, including technical support and resources, across the Institutes, Centers, and Offices



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

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

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

4A

Operationalize the *Framework for Clinical Research Engagement* and develop associated metrics to assess improvement in scientific research and community health

4D

Develop targeted funding opportunities to support larger-scale assessments of different clinical research engagement methods and their impact on *Framework* metrics

4B

Support researchers to monitor, assess, and report their engagement methods and progress on *Framework* metrics at annual reviews to inform future improvements

4C

Develop procedures to hold researchers accountable to engagement expectations and identify consequences for non-adherence



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

RECOMMENDATION

2

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

RECOMMENDATION

3

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

RECOMMENDATION

4

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