

Planning for Successful Engagement in Research

Chinenye Anyanwu, PharmD, MPH

Engagement Officer

Patient & Public Engagement



PATIENT-CENTERED OUTCOMES RESEARCH INSTITUTE

Discussion for Today

- Better research through engagement
- Engagement tools and resources
- Elements of Engagement
- Q&A



Better Research Through Engagement



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We Fund Research That...

What we mean by...

“Patient-centeredness”

- The project aims to answer questions or examine outcomes that matter to patients within the context of patient preferences
- Research questions and outcomes should reflect what is important to patients and caregivers

“Patient and stakeholder engagement”

- Patients are partners in research, not just “subjects”
- Active and meaningful engagement between scientists, patients, and other stakeholders
- Community, patient, and caregiver involvement already in existence or a well-thought-out plan



Why Engage?

To influence research to be patient-centered, relevant, and useful

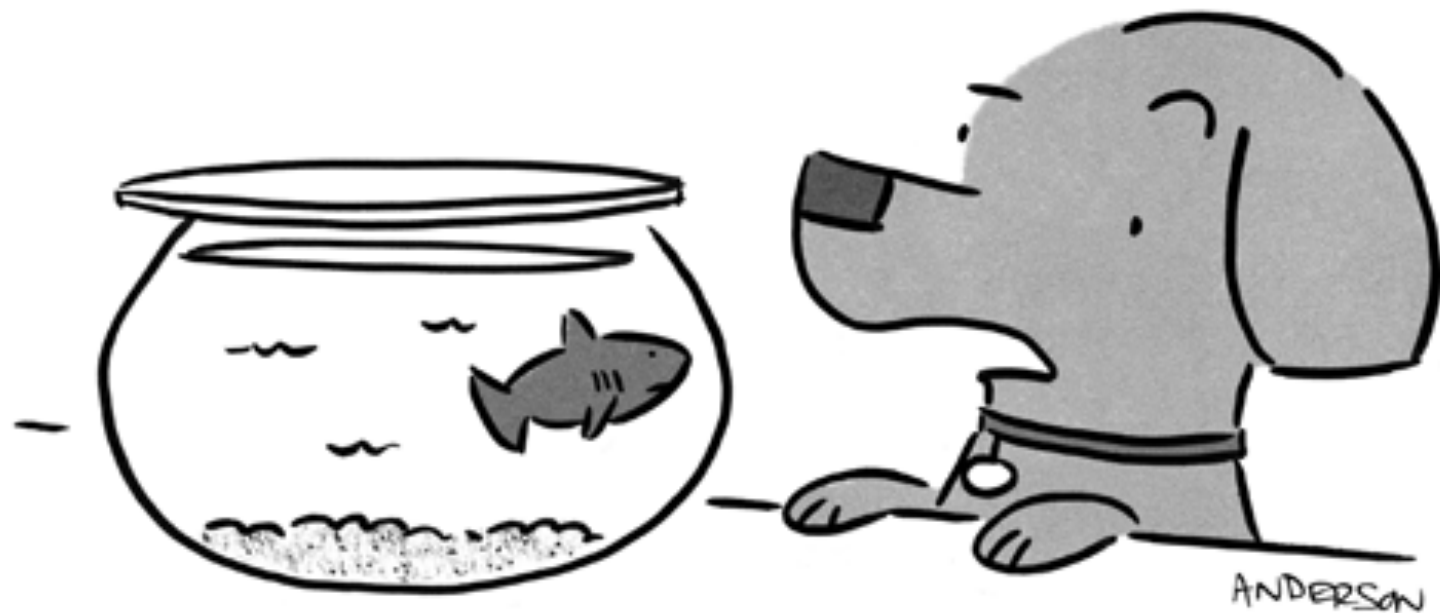
To establish trust and a sense of legitimacy in research findings

To encourage successful uptake and use of research results



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"You make a good point; we both hate the cat.
I'm just not sure what it is you'd bring to a partnership."



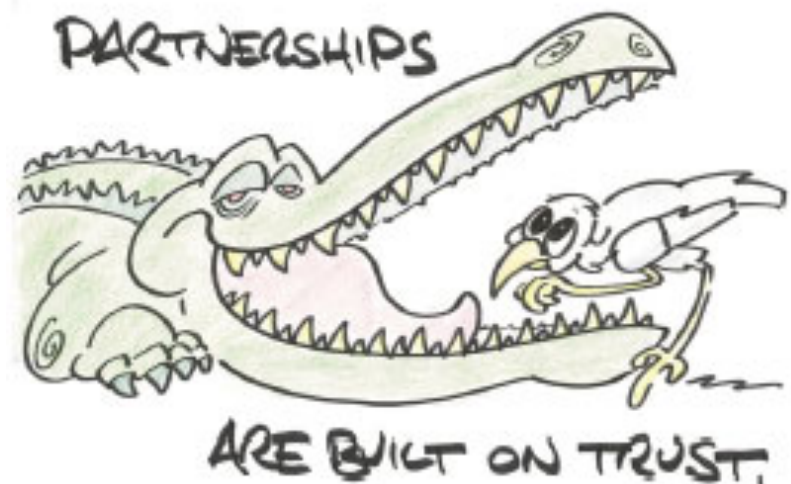
What We Mean by Engagement...

- Meaningful involvement of patients, caregivers, clinicians, and other healthcare stakeholders throughout the research process
- Detailed, well-thought-out, and creative engagement plan
- Diverse groups of stakeholders
- Engagement takes many shapes and sizes, not one size fits all!



Core Engagement Principles

- Reciprocal relationships
- Co-learning
- Partnership
- Trust, transparency, honesty



PCORI projects engage many stakeholders

PCORI Projects ensure results are **USEFUL** by actively involving the **PEOPLE WHO KNOW**

Top 5 Engaged Stakeholder Communities:

(by percent of projects)



87%

PATIENTS



59%

ADVOCACY ORGS



50%

CAREGIVERS



88%

CLINICIANS



56%

HEALTH SYSTEMS



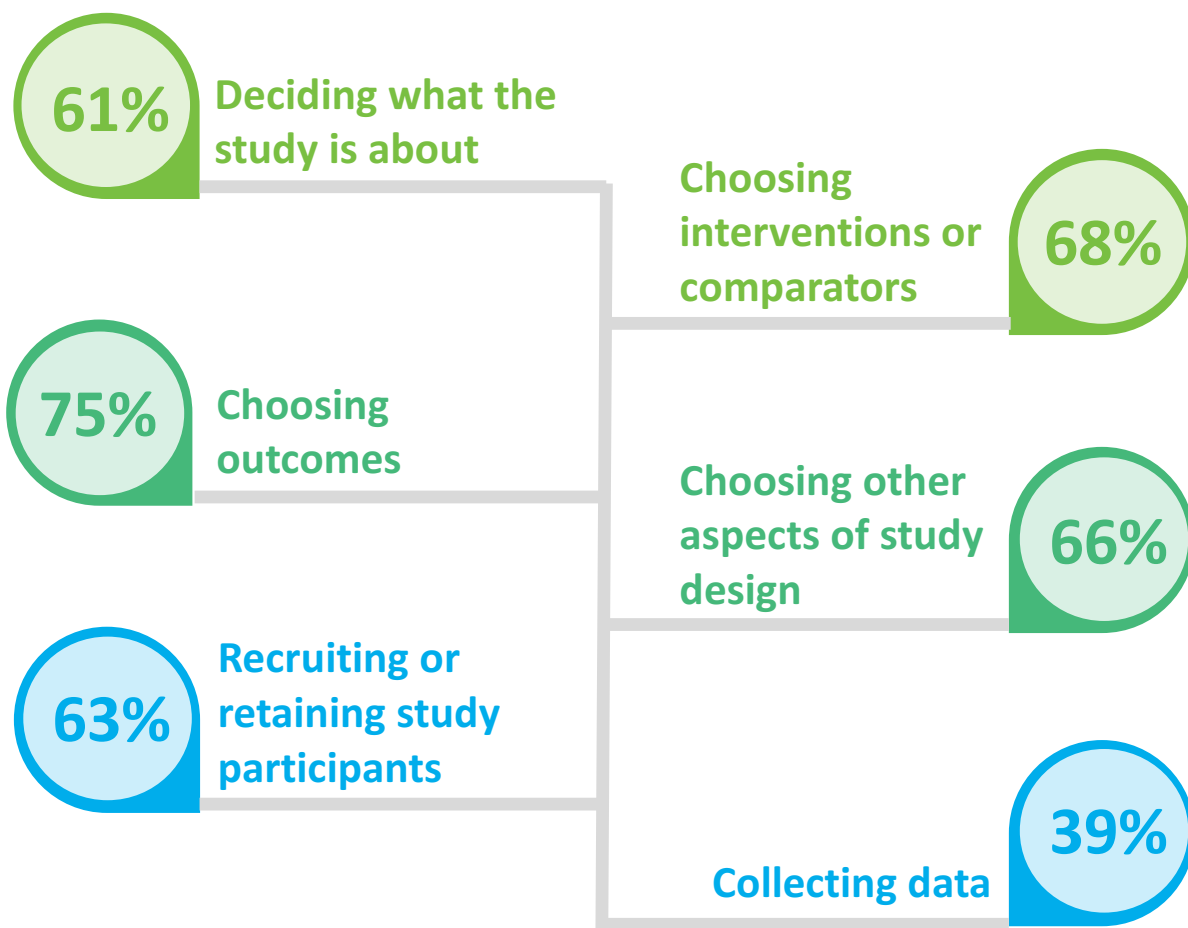
PCORI projects engage stakeholders throughout the entire research process.

3 out of 5

PCORI projects engage stakeholders in *every* early phase of research so that the studies matter to patients

Research Phases Engaging Stakeholders:

(by percent of projects)



PCORI research partners change the research



Provide personal perspectives (*e.g., priorities, experiences*)



Give guidance to improve research project processes and materials (*e.g., outcomes studied, recruitment strategies*)



Active participation in conduct and dissemination (*e.g., recruiting participants, collecting data, presenting results*)



Engagement makes a Difference in PCORI Projects



Better understanding of stakeholders' personal perspectives
(*e.g., priorities, experiences*)



Refined study that is more patient-centered

- Research questions
- Interventions and/or comparators
- Outcomes and measures
- Data collection
- Recruitment/retention strategies



Enhanced study participant enrollment rates



Letters

RESEARCH LETTER

Improving Surgical Research by Involving Stakeholders

Enrolling patients in prospective surgical trials is difficult, especially in the urgent and/or emergent care setting. However, there is growing support for including patients, caregivers, and other health care stakeholders in all phases of research to assist with identifying and incorporating outcomes important to the public, developing strategies to improve enrollment and retention rates, and accelerating the dissemination and implementation of results.¹⁻⁵ We report the effect of stakeholder involvement in an ongoing randomized clinical trial (RCT) (ClinicalTrials.gov, [NCT02110485](https://clinicaltrials.gov/ct2/show/study/NCT02110485)) of pediatric appendicitis.

*Minnecci PC, Nacion KM, Lodwick DL, Cooper JN, Deans KJ.
Improving Surgical Research by Involving Stakeholders.
JAMA Surgery. June 2016.*

A 20-member multidisciplinary stakeholder group was engaged in all phases of the randomized controlled trial (RCT) investigating the effects of a patient activation tool in uncomplicated pediatric appendicitis.

Stakeholders involved:

- Children ages 7 to 17 and their families
- Community-based pediatricians
- Emergency medicine physicians, surgeons, nurses
- Patient educators
- Payers



Minnecci et al. 2016 JAMA

“Participant enrollment and 30-day retention rates in the RCT of pediatric appendicitis improved significantly after the adoption of stakeholder recommendations.”

Stakeholder Recommendation:

Change the
enrollment script



Enrollment in RCT
increased from
65% to 95%

Offer an online
option to
complete follow-
up questionnaires



Rate of completion
for 30-day follow-
up increased from
58% to 85%

Impact:



Most Common Effects of Engagement on Partners

- **Established new relationships**
- **Improved personal health management**
- **Made a difference in the lives of others**
- Personal growth or self-improvement
- Gained new knowledge and insights about research
- New professional opportunities
- Belief in patient/stakeholder representation in research



Effects of Engagement on Partners

Understanding the various health disparities leading to diabetes, kidney disease **has made me assess my personal life, my level of physical activity and my food intake. I have made changes in my lifestyle** which include exercising 3 x per week and encouraging my family to take part in physical activities such as hiking, basketball and so forth... **This was an eye opener.**

–Other type of Stakeholder

Patients I've been working with have taught me to be a better patient, to self advocate. – *Caregiver/Family Member*

As an 'older' citizen, with mobility limitations, **this involvement has allowed me to ... contribute "to the better good"**. Although I have personal medical issues and challenges, ... doing what I can in my very limited capacity to improving opportunities for broader patient involvement in healthcare decision making and the shaping of healthcare to reflect patient needs.

– Patient/Consumer



Engagement Tools and Resources



“Engagement is hard...”

- Relationship building, maintaining throughout and between projects
- Budgeting for engagement expenses
- Feasibility of incorporating feedback
- Training and skill development needs (for partners and researchers)
- Compensation
- Determining level and depth of engagement of stakeholders
- Engaging hard to reach and vulnerable populations



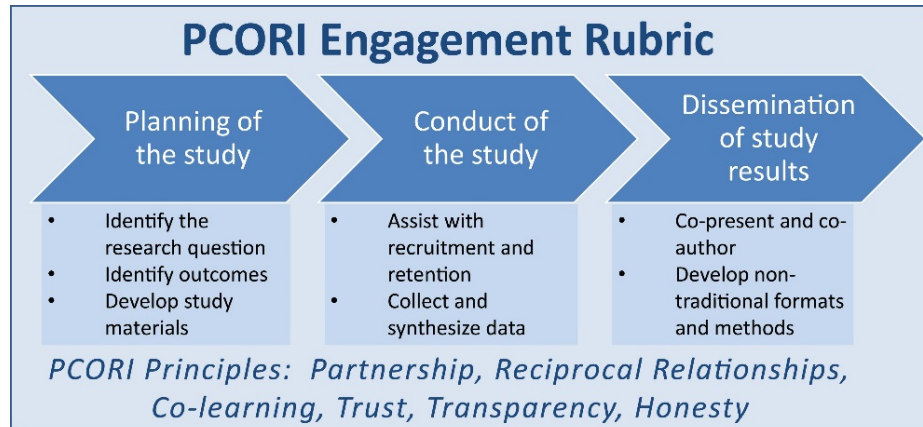
Engagement Rubric

Provides practical guidance to applicants, merit reviewers, awardees, and engagement/program officers on effective engagement in research

- **Planning the Study:** How patient and stakeholder partners will participate in study planning and design
- **Conducting the Study:** How patient and stakeholder partners will participate in the conduct of the study
- **Disseminating the Study Results:** How patient and stakeholder partners will be involved in plans to disseminate study findings and ensure that findings are communicated in understandable, usable ways
- **PCOR Engagement Principles:** Reciprocal relationships, co-learning, partnership, trust, transparency, honesty



Additional Tools to Support Engaged Research



*Created and first implemented in PCORI's February 2014 funding cycle

Patient-Centered Methodology Standards and Merit Review Criteria established

2013

Initial review of Engagement Plans in portfolio, posted exemplar plans to PCORI website

2014

Creation of Engagement Officer, staff tasked with ensuring and supporting engagement in funded awards

2015

Partner Biosketches, template created to capture expertise of patient/caregiver partners

2016

Engagement Webinar Series, highlighting emerging promising practices of patient and stakeholder engagement from PCORI-funded projects

PCORI Compensation Framework, a tool for evaluating the effort and appropriate financial compensation for patient/caregiver partners

Engagement Toolkit (under development), a comprehensive package of materials on patient-engaged research

Engagement Budgeting Document, a resource that provides guidance on how to appropriately budget for engagement activities



Elements of Engagement



Elements of Engagement to Consider

- Structure
- Budget
- Level of involvement
- “Representativeness”
- Training
- Maintaining engagement through study conduct
- Evaluation
- Dissemination



Structure of Engagement

- Advisory Body Categories
 - single advisory group with patients and stakeholders
 - stakeholders/patients blended with core study team
 - stakeholder-only advisory group
 - patient-only advisory group
 - Other....
- Frequency of convenings
- Location of convenings (neutral? virtual?)
- Leadership
 - Designated engagement lead/point of contact
 - Representation of lead on key decision-making committee?
 - Engagement outsourced or subcontracted to a separate institute/institution/organization



Structure of Engagement

- Ongoing Communication
 - Mechanism in place to ensure transparency and equal access to information for all members of the research team including patient/stakeholder partners
- Roles and Responsibilities
 - Shared understanding and documentation of patient/stakeholder partners' roles and responsibilities



Study Advisory Committee (SAC)

Co-leads: Matt Michaels & Eliza Singleton
Specific members TBD
Facilitated by: Samantha Moore
Meets twice per year

Study Patient Panel

Lead: Beth McAdams
Facilitated by: Norman Bates
Meets quarterly

Study Caregiver Panel

Lead: Jim Sanders
Facilitated by: Norman Bates
Meets quarterly

Core Research Team

ALPHA Org

Matt Michaels
Lee Rogers
Beth McAdams
Jim Sanders
John Levingston

XYZ Health System

Eliza Singleton (PI)
Andrew Fisher
Steve Miller
Alberto Sing

Acme Research University

Bob Jacobs
Meredith Miller

Facilitated by: Samantha Moore

Meets every two weeks; participants vary based on agenda items

Study Clinical Stakeholder Panel

Lead: John Levingston
Facilitated by: Samantha Moore
Meets quarterly

Study State Stakeholder Panel

Lead: Lee Rogers
Facilitated by: Samantha Moore
Meets quarterly

Established Panels & Workgroups

ALPHA Patient Engagement Panel (PEP)

Norman Bates (Co-Chair)
Jim Sanders (Member)
Beth McAdams (Member)
Meets monthly

The investigators will update PEP quarterly, solicit feedback and report back to Research Team

ALPHA Practice-Based Research Network (PBRN)

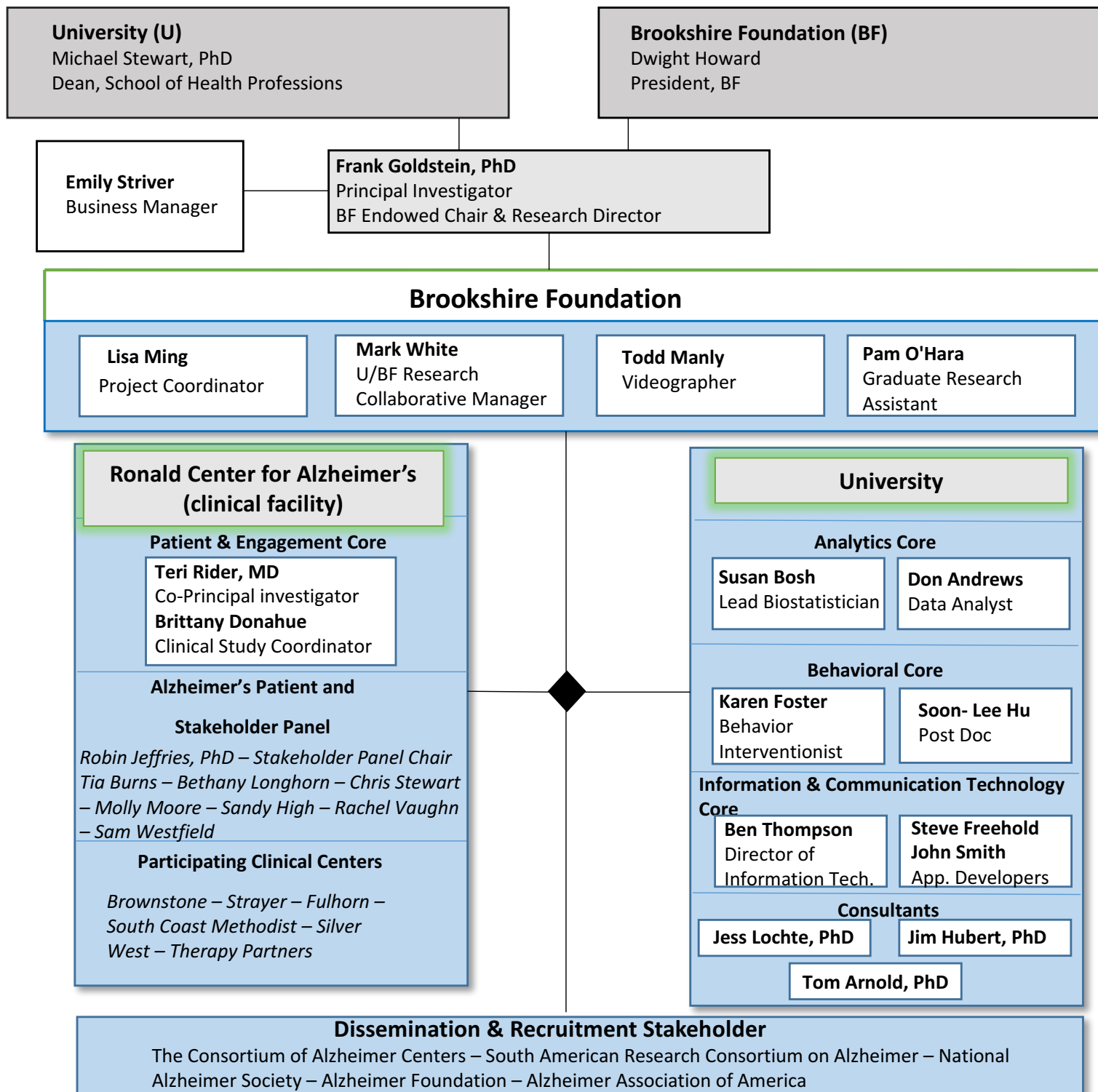
Matt Michaels (Co-Chair)
John Levingston (Member)
Meets monthly

The investigators will update the PBRN quarterly, solicit feedback and report back to Research Team

Medicaid Evidence-based Decisions Project (MED)

Jessica McDonald (Member)
Meets monthly

The investigators will update the MED quarterly, solicit feedback and report back to Research Team

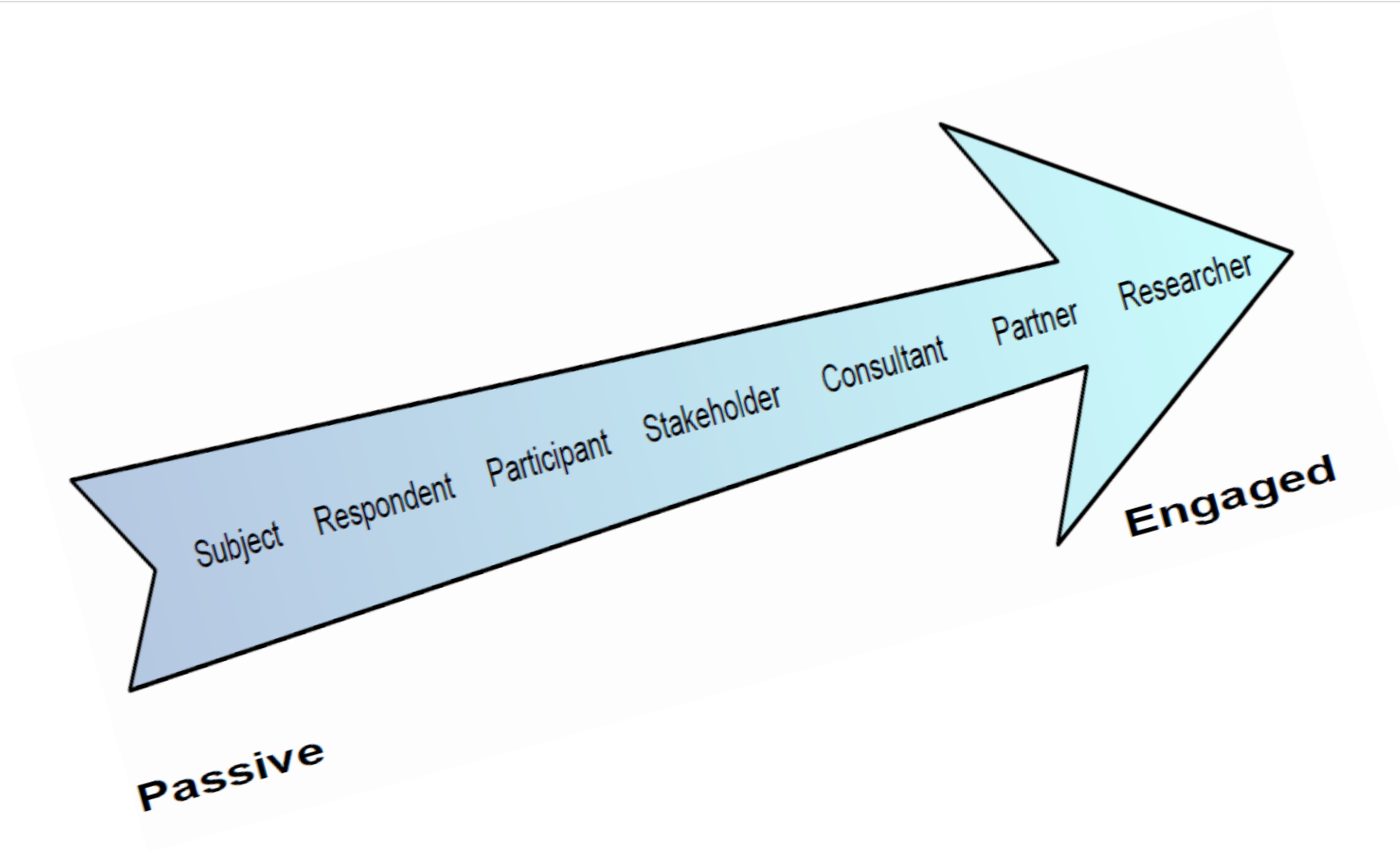


Budget

- Adequate budgeting for engagement activities (e.g., compensation of partners, meeting support, etc.)
- Equity in partner compensation
- Support all aspects of partners' roles (e.g., meeting preparation support, stipend, childcare, travel, presentations, etc.)



Level of Involvement



Adapted from Hassan Murad et al. (2012). Eliciting Patient Perspective in Patient-Centered Outcomes Research: A Meta Narrative Systematic Review. Rochester, MN: Mayo Clinic. See also Arnstein SR. A ladder of citizen participation. Journal of the American Planning Association. 1969;35:216–24

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Level of involvement: Patient

- Information: Researcher(s) describe decisions to patients after decisions are made.
- Consultation: Patients provide input to researchers that may inform decision-making but have no representation within study leadership (steering, executive, or investigator committee)
- Collaboration: Patients work directly with the researcher, may be invited to participate in leadership meetings (e.g., steering, executive, investigator committees) in active partnership, to ensure that their perspectives are incorporated in decision-making.
- Patient/stakeholder direction: Also known as “user control,” patients have control over the research process and the final decision-making. Co-I or Co-PI



Level of involvement: Stakeholder

- Information: Researcher(s) describe decisions to stakeholders after decisions are made.
- Consultation: Stakeholders are consulted for their input but have no representation within study leadership
- Collaboration: Stakeholders work directly with the researcher, may be invited to participate in leadership meetings (e.g., steering, executive, investigator committees) in active partnership, to ensure that their perspectives are incorporated in decision-making.
- Patient/stakeholder direction: Stakeholder level of involvement exceeds serving in an advisory capacity and includes any of the following; covering intervention costs, supporting study sites, overseeing data coordinating centers, serving on study leadership committees, is a Co-Investigator/Co-Principal Investigator,



“Representativeness”

- The extent to which members serving on advisory committees or in any partnership capacity are representative of the study population or range of end users
- Challenging issue in engaged research

Also... think about
adequate balance of
interests



In this study, what are the anticipated central issues at stake for each of the stakeholders?

Which Stakeholder?					
What is at stake?	(1)Patients	(2) ED Clinicians	(3) Primary care physicians	(4) Health policy decision makers/ Payers	(5) Cardiologists
Access to outpatient care	X	X	X		X
Quality & safety of care	X	X		X	
ED operations (flow, utilization)		X		X	
Cardiology procedural services (e.g., stress testing, catheterization)				X	X
Healthcare utilization/costs	X			X	

Given these anticipated issues and the potentially affected parties, which individuals will comprise the patient and stakeholder advisory group?



Training

- Patient/Stakeholder training on research, human subjects protection and/or ethics
- Study team member skill-based training on engagement (e.g. meeting facilitation, developing consensus etc.)
- Combined training of partners and researchers on team science, basics of engaged research



Maintaining Engagement

- Involvement in Recruitment
 - developing and reviewing recruitment materials
 - developing recruitment strategies
 - collecting data from study participants
 - training staff on recruitment process
- Data Analysis
 - Training/preparing
 - Interpretation



Evaluation

- Mechanism in place to assess patient/stakeholder partner involvement throughout the course of the study

Consider...

- periodic survey of patient/stakeholder partners to gather feedback/satisfaction
- assessment of patient/stakeholder engagement via validated survey instrument or semi-structured interviews to continuously improve engagement



Dissemination

- Patient and stakeholder partners have a defined role in disseminating study findings (e.g. beyond professional society memberships, social media postings, website postings)



Additional Engagement Resources

- [PCORI's Methodology Standards PC-1 to PC-4](#)
- PCORI has developed other resources to help guide your engagement activities, housed on the "[What We Mean by Engagement](#)" page on the PCORI website
- Engagement Resources include:
 - [Framework for Financial Compensation of Patient, Caregiver and Patient Organization Stakeholders](#)
 - [Engagement Rubric](#)
 - [Sample Engagement Plans](#)
 - [PCORI Stakeholder Groups](#)
 - Short Videos on Engagement in Research



Engagement is hard....but not Impossible!

- Communication is KEY!
- Always keep the end user in mind (clinicians, patients, caregivers, stakeholders, etc.)
- Mistrust takes seconds to form and years to deconstruct
- Training, training, training!
- Engagement is relational, not transactional
- Create equity—environment that supports partnerships, bi-directional learning, etc.
- Mentorship
- Culture shift—Researchers are afraid of patients, patients are afraid of researchers



Questions?

Chinenye Anyanwu
Engagement Officer
Patient & Public Engagement
canyanwu@pcori.org

