

Understanding Patient and Stakeholder Engagement Roles for Participating in “Research Done Differently” with the Patient-Centered Outcomes Research Institute (PCORI)

Members of PCORI’s Advisory Panel on Patient Engagement

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This document discusses the potential role of patients and other stakeholders in a PCORI submission and the process involved in obtaining patient and other stakeholder input during the planning process and throughout a funded PCORI project.

Objectives

- Provide overview of how PCORI defines patient and stakeholder engagement
- Illustrate types of stakeholders that could/should be engaged in PCORI project
- Offer concrete suggestions on how to obtain patient and stakeholder engagement pre-award and after obtaining funding

- Independent non-profit research organization authorized by Congress as part of 2010 Patient Protection and Affordable Care Act (ACA)
- PCORI helps people make informed healthcare decisions and improves healthcare delivery and outcomes, by producing and promoting high-integrity, evidence-based information that comes from research guided by patients, caregivers, and the broader healthcare community



PCORI Funding Opportunities

- Five portfolios/priorities for research:
 - Assessment of Prevention, Diagnosis, & Treatment Options
 - Improving Healthcare Systems
 - Communication and Dissemination Research
 - Addressing Disparities
 - Improving Methods for Conducting Patient-Centered Outcomes Research
- Other funding opportunities outside the five portfolios

Outside PCORI's 5 Portfolios



Northwestern University Feinberg School of Medicine

Center for
Community Health

Funding for pre-research & non-traditional researchers (e.g. patient groups & community-based organizations seeking partnerships w/academic medical centers)

-Pipeline to Proposal Awards to develop partnerships and patient-centered research proposals

<http://www.pcori.org/funding-opportunities/eugene-washington-pcori-engagement-awards/>

PCORI Review Criteria

(Basis of awarding PCORI contract to researcher/patient/stakeholder teams)

- Five main review criteria
 - Impact of the condition on health of individuals and populations
 - Potential for study to improve health care and outcomes
 - Technical merit
 - **Patient-centeredness**
 - **Patient and stakeholder engagement**

PCORI Review Process

- All proposals reviewed by four individuals: two researchers, one patient, one stakeholder
- **Patient-centeredness** and stakeholder engagement reviewed by all individuals; other aspects of research plan only reviewed by researchers

Patient-Centeredness

(as defined by PCORI)

Proposal demonstrates patient-centeredness at every stage of research. Addresses the following questions:

- Is the research focused on questions that affect outcomes of **specific interest to patients and their caregivers?**
- Does the research address one or more of the key questions mentioned in PCORI's definition of **patient-centered outcomes research?**
- How **credible are claims that engaged patients and stakeholders** will exert meaningful influence on the design and conduct of the research, to ensure patient-centeredness of the questions and outcomes addressed?

Patient & Stakeholder Engagement

(as defined by PCORI)

The proposal **integrates patients and stakeholders** in the **development of research plan and in key elements of conducting the research**. Addresses the following questions:

- Does proposal describe **how patients and stakeholders were or will be identified and engaged** in the research?
- Are **roles of patients and key stakeholders significant** in formulating study's research questions, hypotheses and design and in the study's conduct and dissemination of results?
- Are **roles proposed for patients and stakeholders** in any planned dissemination or implementation plans **meaningful** and likely to be **effective?**
- If **engagement is not applicable** to proposed research, does the application justify **why it is not?**



Recruiting Patients, Caregivers, Stakeholders

Pastors in PCOR Research Ministry

Southland Ministerial Health Network

Partnering for Patient-Centered Outcomes Research

Apostle Carl L. White, CEO and Ministers of the SMHN



Defining Terms

- Who is the community?
- Who are considered patients, caregivers, stakeholders?
- What is comparative effectiveness research (CER)?

Why should patients/ caregivers/stakeholders/communities be interested in research? PCORI?

- Describe scope of health priorities/issues in their communities
- Answer questions about their health conditions or communities
- Conduct evaluation of current programs/treatments
- Develop/adapt new programs/treatments/services that are culturally appropriate for their communities
- Collect data/stories that help make the case for policy advocacy/funding of their health issue/condition

Who are the patients/ stakeholders that need to be engaged?

Considerations in selecting:

- Funder requirements (e.g., PCORI, NIH)
- Objectives of project
- Type of input needed
- Importance of obtaining broad spectrum of perspectives
- What type of input is needed pre-award, during project, and post-award

What can maximize likelihood that patients/stakeholders will collaborate?

- Clearly defining roles and responsibilities of patients/stakeholders
- Clearly articulating what they will gain-
“what’s in it for me?”
- Developing sound bites/materials that can be used to recruit
 - Linked to project goals, roles/responsibilities, and what members will gain

Approaching patients/stakeholders

- Build on Existing Relationships
- Referrals/recommendations from colleagues*
- Shared Interest/Common Goals
- Commitment and Willingness
- Equal Standing
- Shared Decision-Making

*CCH can provide assistance

Questions patients/stakeholders may ask researchers

- Who are you?
- Why are you here?
- What's your experience/relationship with us and how a disease/condition impacts us? Experience with engagement?
- Are you committed to a long-term relationship after the research?
- What is the research topic/project?
- What's in it for us/our community? Is the research of interest to us? How will we benefit from the research project/findings?
- What are my roles and responsibilities?
- How do we equally engage/participate?
- What does our relationship look like?



Developing Patient/Stakeholder Engagement Plans



THE S.T.A.R. INITIATIVE

STRATEGICALLY TARGETING APPROPRIATE RESEARCHERS



First Lady Pamela White and Victory Christian International Ministries
S.T.A.R. Group Breast Cancer Engagement Cluster
November 26, 2013

Framework for Developing Patient/Stakeholder Engagement

- Engagement plans should discuss patient/stakeholder involvement during three phases:
 - Pre-award
 - During project
 - Post-award

Mechanisms for facilitating engagement pre-award

- Getting to know each other/building relationship
- Input on additional patients/stakeholders to involve
- Feedback on proposal design, description of patient/stakeholder groups
- Data collection on interest in/issues related to issue being researched (focus groups, survey, town hall)
- Review of drafts/proposal components. Provide letters of support.

Mechanisms for facilitating engagement pre-award

- Develop a Memorandum of Understanding or Letter of Agreement to document agreements concerning roles/responsibilities, data use/access, etc.
- Establish mechanisms for communication among researchers/partners during project
- Form an engagement advisory or steering committee to provide feedback/input throughout project

Types of Engagement During Project

- Input on:
 - Data collection methods
 - Study protocols
 - Measures/instruments that are feasible/ acceptable
 - Recruitment/retention strategies
 - Preparation of study materials
 - Sites for study implementation
 - Data interpretation
- May be able to hire patients/stakeholders as part of research team to collect data or implement interventions
- Continuation of advisory/steering committee comprised of key stakeholders

Types of Engagement Post-Award

- Developing sustainability plan for program/service/intervention
- Assisting in dissemination of study findings to key stakeholders (e.g., patients, patient advocacy organizations, policy-makers)
 - Dissemination plan a requirement of PCORI applications

Contacts

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<http://www.feinberg.northwestern.edu/sites/cch/>

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