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

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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

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
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

• CCH Website: http://www.feinberg.northwestern.edu/sites/cch/

• PCORI website: www.pcori.org

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