Getting to Know PCORI: From Application to Closeout

Patient and Stakeholder Engagement in Research
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Session Objectives

► Provide an overview of Engagement activities at PCORI
► Discuss the difference between patient-centeredness and patient engagement
► Provide an overview of PCORI’s Engagement Rubric
► Discuss the role of the Engagement Officer at PCORI
► Review additional engagement resources available through PCORI
We Engage Patients and Other Stakeholders at Every Step

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- Topic Selection and Research Prioritization
- Merit Review
- Study Design/Implementation
- Evaluation
Our Review Criteria

During a rigorous merit review process, proposals are evaluated to assess:

► Impact of the condition on health of individuals and populations
► Potential for improving care and outcomes
► Technical merit
► Patient-centeredness
► Patient and stakeholder engagement
What are Patient-Centeredness & Patient Engagement?
Patient-Centeredness vs. Patient and Stakeholder Engagement

► Patient-Centeredness: does the project aim to answer questions or examine outcomes that matter to patients/caregivers?

► Patient and Stakeholder Engagement: are patients/caregivers and other stakeholders involved as partners in research, as opposed to study participants?
Show Your Work
The Rubric

Why develop a rubric?

What is the rubric?

How will the rubric be used?
Overarching Rubric Principles

► The rubric is a collection of examples, intended to provide guidance to applicants, merit reviewers, awardees, and engagement/program officers
► It is not intended to be comprehensive or prescriptive
► Applicants can choose to include some (but not all) activities illustrated, and they can include additional innovative approaches not included
► The examples provided are from real PCORI-funded projects
Elements of the Rubric

- Planning the Study
- Conducting the Study
- Disseminating the Study Results
- PCOR Engagement Principles
### Planning the Study

**1. PLANNING THE STUDY:** Describe how patient and stakeholder partners will participate in study planning and design.

**Potential activities include:**
- Identifying the topic and developing the research question to be studied
- Creating the intervention
- Identifying the comparators
- Defining the characteristics of study participants

**Examples of how to demonstrate this in your proposal:**
- Provide Letters of Support from patient and stakeholder partners that clearly describe the origin of the study topic and the role of the patient partners in defining the question, outcomes, comparators, and goals/outcomes, etc.
- Describe meetings, focus groups, and other events convened to engage patient and stakeholder partners in the planning of your study, and include key guidance on study design offered by your patient and stakeholder partners.
- Discuss how the engagement of patients and other stakeholders helped to refine your study’s research question, outcomes, and comparators.

**Real-World Examples:**
- **Epilepsy study:** The patients and parents of patients with epilepsy pose the question: Which anti-epileptic drugs best preserve sufficient cognition to go to work or school and to function normally, while still preventing seizures adequately?
- **Diabetes study:** Clinicians who reviewed the initial study design indicated that clinical practice is quite variable and suggested that a three-arm approach would be more appropriate for the study. The study design was revised accordingly.
Planning the Study

Potential Activities Include

• Identifying the topic and developing the research question to be studied
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Planning the Study

Real World Examples:

• **Epilepsy study:** The patients and parents of patients with epilepsy pose the question: Which anti-epileptic drugs best preserve sufficient cognition to go to work or school and to function normally, while still preventing seizures adequately?

• **Diabetes study:** Clinicians who reviewed the initial study design indicated that clinical practice is quite variable and suggested that a three-arm approach would be more appropriate for the study. The study design was revised accordingly.

• **Cancer study:** Patient partners determine that all women with breast cancer would be eligible versus only women who had completed active treatment.
Conducting the Study

2. CONDUCTING THE STUDY: Describe how patient and stakeholder partners will participate in the study conduct.

Potential activities include:

- Participating in and monitoring the conduct of the project
- Assisting with the recruitment of study participants
- Assisting with data collection and data analysis
- Participating in the evaluation of patient and stakeholder engagement

Examples of how to demonstrate this in your proposal:

- Provide Letters of Support from patient and stakeholder partners that clearly describe the role of these partners in conducting and monitoring the study.

- Clearly articulate in the application the roles of the patient and stakeholders partners in each component of study conduct (e.g., helping to draft survey tools and focus group questions, reviewing participant materials for readability, etc.), including the dissemination and implementation assessment.

- Include a plan for “check-ins” with patient and stakeholder partners to monitor their perceptions of the extent to which (a) they are meaningfully involved in the study and (b) their participation is contributing to the study. Plan similar “check-ins” with other research team members to monitor and evaluate engagement in the project.

Real-World Examples:

- Chronic pain study: The informed consent document is developed with patient partners to make it understandable to study participants.

- Depression study: Patient advocacy groups assist with recruitment through their patient networks—the “book club” model.
Conducting the Study

Potential Activities Include:

• Participating in and monitoring the conduct of the project
• Assisting with the recruitment of study participants
• Assisting with data collection and data analysis
• Participating in the evaluation of patient and stakeholder engagement
Real World Examples;

- **Chronic pain study**: The informed consent document is developed with patient partners to make it understandable to study participants.
- **Depression study**: Patient advocacy groups assist with recruitment through their patient networks—the “book club” model.
- **Preeclampsia study**: Study team will recruit via a national network of local health departments and community health centers, as well as a preeclampsia advocacy group’s website, and Facebook page.
Disseminating the Study Results

3. **DISSEMINATING THE STUDY RESULTS**: Describe how patient and stakeholder partners will be involved in plans to disseminate study findings, and ensure that findings are communicated in understandable, usable ways.

**Potential activities include:**

- Identifying partner organizations for dissemination
- Planning dissemination efforts
- Participating in dissemination efforts, such as the authoring of manuscripts and the presentation of study findings

**Examples of how to demonstrate this in your proposal:**

- Clearly identify the role of patient and stakeholder partners in planning the dissemination of the study’s findings.
- Include patient and stakeholder partners on project committee that will oversee dissemination.
- Include patient and stakeholder partners in dissemination and implementation assessment.

**Real-World Examples:**

- **Trauma study**: The research team will convene a policy summit with relevant professional societies during the third year of the study to focus on identifying ways to speed the implementation of findings into practice.
- **Cardiac study**: A Patient Dissemination Board is helping to craft the dissemination plan and advise the research team on how to best share study findings.
- **Chronic pain study**: Patient partners co-author manuscripts, present at scientific and lay conferences, and share study findings through their networks.
Disseminating the Study Results

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Implementation of findings into practice:

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Engagement Principles

4. PCOR Engagement Principles:

**Reciprocal Relationships:** Describe the roles and decision-making authority of all research partners, including patient and stakeholder partners.

*Examples of how to demonstrate this in your proposal:*
- Explain how decision-making is made within your research team, including the decision-making authority that patient and stakeholder partners have and in what circumstances.
- Include patient and stakeholder partners as key personnel, with biosketches illustrating how the skills and experiences of the patient partners prepare them to function effectively in this role.

**Co-learning:** Describe plans to ensure that patient and stakeholder partners will understand the research process and researchers will understand patient and stakeholder engagement and patient-centeredness.

*Examples of how to demonstrate this in your proposal:*
- Training and educational opportunities are provided, such as patient and stakeholder partner training in human subjects protection.
- Training is provided by patient advocacy organizations, patients/survivors, and clinicians/caregivers for the researchers providing the intervention (e.g., training in better communication with patients, led by patient instructors).

**Partnership:** Describe how the time and contributions of patient partners are valued and demonstrated in fair financial compensation, as well as reasonable and thoughtful time commitment requests.

*Examples of how to demonstrate this in your proposal:*
- Compensation for patient partners is included in the budget at an appropriate level.
- Meetings are held at a time and in a location that accommodates patient and stakeholder partners. Compensation is provided for transportation and related expenses.
- Accommodations are made to encourage the full engagement of a diversity of patient and stakeholder partners, and the research team includes a diversity of members. For example, a
Engagement Principles

4. PCOR ENGAGEMENT PRINCIPLES:
Reciprocal Relationships: Describe the roles and decision-making authority of all research partners, including patient and stakeholder partners.

Examples of how to demonstrate this in your proposal:

• Reciprocal Relationships
• Co-learning
• Partnership
• Trust
• Transparency
• Honesty
Engagement Principles

Real World Examples

• Compensation for patient partners is included in the budget at an appropriate level.
• Meetings are held at a time and in a location that accommodates patient and stakeholder partners. Compensation is provided for transportation and related expenses.
• Training and educational opportunities are provided, for patient and stakeholder partners such as training in human subjects protection.
• Training is provided for researchers such as instruction in better communication with patients, led by patient instructors.
Elements of the Rubric

- Planning the Study
- Conducting the Study
- Disseminating the Study Results
- PCOR Engagement Principles
Putting the Rubric to Work

Greater understanding of engagement

Stronger engagement in proposals

Strong engagement during research?
Engagement Officers

Engagement Officers, working closely with Program Officers, will support active portfolio management by:

• Helping Awardees to outline engagement milestones
• Participating in the Awardees' kick-off and interim phone calls, as well as in separate calls with key patient and stakeholder partners
• Facilitating communication between Awardees to troubleshoot engagement challenges
• Gathering promising engagement practices from the portfolio to feature in webinars and for use in updating or expanding the Engagement Rubric
PCORI’s Commitment to Engagement in Research

ENGAGEMENT IN RESEARCH

Since our establishment, PCORI has been committed to funding research that includes meaningful involvement by patients and other stakeholders in all steps of the process. Bringing together all healthcare stakeholders to help set research priorities—with patients at the center—is our formula for ensuring we fund and conduct the most relevant research possible. We believe that including patients and other stakeholders in the research process will lead to trustworthy and usable information more likely to be taken up in practice, and we pick the proposals we fund accordingly.
Engagement Resources

PCORI Applicant FAQs (Engagement): [http://www.pcori.org/funding-opportunities/funding-center/faqs-for-applicants/#engagement](http://www.pcori.org/funding-opportunities/funding-center/faqs-for-applicants/#engagement)


PCORI Town Halls: [http://www.pcori.org/funding-opportunities/funding-announcements/applicant-training/b](http://www.pcori.org/funding-opportunities/funding-announcements/applicant-training/b)

- PCORI will host Town Halls for applicants on Patient and Stakeholder Engagement; these sessions will be recorded and archived as resources for current and future applicants
Engagement Webinars

Observing PCORI Funded Engagement in Action

Partnering With Patients to Drive Shared Decisions, Better Value and Care Development

Transforming Patient-Centered Research: Building Partnerships and Promising Models
ENgagement ACTivity (ENACT) Inventory

- Who is engaged
- Partnership characteristics
  - How formed, length, frequency of engagement, etc.
- Level of engagement
- When in the research process they are engaged
- Perceived level of influence of partners
- Perceived effects of engagement on research questions, study design, study implementation, and dissemination of results
- Challenges, facilitators
- Lessons learned for engagement
- PCOR principles – respect, co-learning, etc.
We Engage Patients and Other Stakeholders at Every Step
Ambassador Program Overview

The volunteer initiative that trains, equips, and mobilizes patients, caregivers, organizations and other stakeholders to share PCORI’s vision, mission and PCOR principles with their respective communities, participate as full partners in research and to help assure the sharing and uptake of information generated from PCORI funded projects.

► Train…Ambassador Training: Five modules of training focused on PCORI, their role, PCORI funding, and working in research teams
► Equip…Ambassador Toolkit: Provides support material such as talking points, presentation template, social media guide
► Mobilize…Ambassador Yammer Community: Online community that encourages the exchange of best practices in different communities
Ambassadors by Stakeholder Group

To Date: 135 Individuals invited to take Ambassadors training
Ambassadors by Ethnicity and Region

- Asian (Not Hispanic or Latino): 7%
- Black or African American (Not Hispanic or Latino): 8%
- Hispanic or Latino American: 12%
- American Indian or Alaska Native (Not Hispanic or Latino): 3%
- White (Not Hispanic or Latino): 66%
- Native Hawaiian: 1%
- Prefer Not to Answer: 2%
- Two or More Races: 1%

Map showing distribution by region:
- West: 13
- South: 24
- Midwest: 44
- Northeast: 37
- Southeast: 17

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The Engagement Awards Program

► Provides a platform to expand the role of all stakeholders in research and to support PCORI’s Engagement Priorities

► Launched in February 2014

► $15.5 Million (FY 2014)

► Awards up to 2 years, $250,000

• Knowledge, Training and Development, Dissemination Awards

• EAIN: Patient-Centered Outcomes Research/Clinical Comparative Effectiveness Research Meeting and Conference Support

• EAIN: Supporting Dissemination and Implementation Activities of the PCORI Pilot Projects Learning Network
Engagement Awards Strengthen the PCORI Research Enterprise

- **Build knowledge** about how consumers of healthcare information view PCOR/CER; how they receive and make use of PCOR/CER findings; and/or what evidence they need to reach health and healthcare decisions.

- **Grow capacity** for healthcare community engagement in PCOR/CER; train patients and other stakeholders to participate in PCOR/CER; create methods to connect patients and other stakeholders with the research community; and/or facilitate patient and other stakeholder engagement in PCOR/CER.

- **Develop channels** for D&I of PCOR/CER evidence; identify, build, and strengthen partnerships and facilitators for spreading PCOR/CER findings; and/or D&I PCOR/CER findings in creative ways, especially within PCORI’s priority populations.
Engagement Awards Strengthen the PCORI Research Enterprise

Build Knowledge

Grow Capacity

Develop Channels
Engagement Award Program Processes

► Standing call for LOIs for Engagement Awards and Applications for PCOR/CER Meeting and Conference Support
  • Will review quarterly (Jan, April, July, Oct), beginning Oct 2
► Internal merit review by Engagement team; consult with Science
► CMA conducts budget review and makes awards
► Engagement Team Program Officer(s) monitor projects
► Evaluation plan in development
► Program platform - SalesForce Foundation Connect
► Opportunities for new EAINs
Engagement Awards to Date

- The University of Alabama - The Alabama Initiative for Integrated Primary Care-Behavioral Health Services
- Franciscan Hospital for Children - Empowering Adolescents with Asthma and their Caregivers to Make Shared Decisions with their Doctors
- Health Research and Educational Trust - Integrating Patient-Centered Outcomes Research into Hospital CHNAs
- National Academy for State Health Policy - PCOR Roadmap for State Policy Makers
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Engagement Awards to Date (cont’d)

► National Association of Medicaid Directors - **Engaging Medicaid Clinical Leaders**

► National Research Center for Women & Families - **PCOR New Medical Products Project: Strengthening Patient Voices on Research Criteria**

► Clinical Directors Network, Inc. - **Enhancing Community Health Center PCORI Engagement**

► North American Primary Care Research Group - **Engaging Patients and Providers in Patient-Centered Outcomes Research Training**

► Center for Medical Technology Policy - **Core Outcomes Sets in Effectiveness Trials: A Multi-Stakeholder Training and Development Workshop**

► PhRMA Foundation - **PhRMA Foundation Curricular Advances for Patient-Centered Comparative Effectiveness Research (CER) Education Conference**
Pipeline to Proposal Awards

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<tr>
<th>Tier</th>
<th>Description</th>
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<tbody>
<tr>
<td>Tier 1</td>
<td>Up to $15K, Up to 9 month term</td>
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<tr>
<td>Tier 2</td>
<td>Up to $25K, Up to 12 month term</td>
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<tr>
<td>Tier 3</td>
<td>Up to $50K, Up to 12 month term</td>
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Researchers who unsuccessfully submitted a PFA and need to improve proposal

Or submissions to other PCOR/CER Funders
Pipeline to Proposal Awards

▶ **Tier I**: building community and capacity around a topic of interest to patients, researchers or other stakeholders.

▶ **Tier II**: formalizing partnerships, identifying potential CER question to be researched, developing infrastructure or governance processes.

▶ **Tier III**: creating research proposal, including robust engagement plan for later submission to PCORI or other funders of PCOR.
First Thirty Tier I Awards Announced
December 23, 2013

Western Region Tier I Pipeline Pilot
Pipeline to Proposal Program Offices
Upcoming Opportunities

- Tier I funding will be available in Fall 2014
- Awards will be available through four regional (South, Northeast, Midwest, and West) and one national Pipeline Award Program Office(s)
Questions?
Thank You!

Suzanne Schrandt
Deputy Director of Patient Engagement