PCORI’s Vision for Patient Centered Research

David Hickam, MD, MPH
New York, NY
November 21, 2014
Key Questions for this Presentation

- What are the important features of patient centered outcomes research (PCOR)?
- What funding programs has PCORI launched?
- How is PCORI promoting best practices in research?
  - Methodology standards
  - Methodological Research Program
- What types of projects have the best chance of receiving funding from PCORI?
About PCORI

- An independent research institute authorized by Congress through the Patient Protection and Affordable Care Act.

- Funds comparative clinical effectiveness research (CER) that engages patients and other stakeholders throughout the research process.

- Seeks answers to real-world questions about what works best for patients based on their circumstances and concerns.
What Types of Research Does PCORI Support

From the Authorizing Legislation:

“The terms ‘comparative clinical effectiveness research’ and ‘research’ mean research evaluating and comparing health outcomes and the clinical effectiveness, risks, and benefits of 2 or more medical treatments, services, and items…”
What is Evidence-based Information?

Clinical evidence: Valid data about the outcomes experienced by patients who receive medical care.
- The population is well defined.
- The clinical interventions are well defined.
- We have information about the most important outcomes (both benefits and harms).

Comparative effectiveness
- Starting point is the choices people make about the options for managing a disease.
- These choices inform the focus of new research.
- The research compares the benefits and harms associated with each option.
Comparative Effectiveness Research should be a public good that:

- Gives health care decision makers – patients, clinicians, purchasers and policy makers – access to the latest open and unbiased evidence-based information about treatment options
- Informs choices and is closely aligned with the sequence of decisions patients and clinicians face
What Healthcare Decision Makers Need To Know

- Can it work?
- Will it work?
  - For this patient?
  - In this setting?
- Is it worth it?
  - Do benefits outweigh harms?
  - Do benefits justify costs?
  - Does it offer important advantages over existing alternatives?
Necessary Steps in Developing New Comparative Effectiveness Research

- Understand the choices made by patients and clinicians
- Define the important patient sub-groups
- Define the outcomes (benefits and harms) that are important to patients
- Assess the available evidence about important outcomes
  - Systematic reviews
  - Evidence gaps that are important to decision makers
- Design a study that can feasibly close the evidence gap
  - If the gap is not important, the research will not be useful.
What is Patient-Centered Outcomes Research?

- Helps people and their caregivers communicate and make better-informed healthcare decisions.
- Actively engages patients and key stakeholders throughout the research process.
- Compares the effectiveness of important clinical management options.
- Evaluates the outcomes that are the most important to patients.
- Addresses implementation of findings in clinical care environments.
Key Features of Research Supported by PCORI

The research should:

- Study the benefits and harms of interventions and strategies delivered in real-world settings
- Be likely to improve current clinical practices

Special topics of interest:

- Conditions that heavily burden patients, families and/or the health care system.
- Chronic or multiple chronic conditions
- Rare and understudied conditions
- Conditions for which outcomes vary across subpopulations
- Conditions having important evidence gaps
Development of PCORI’s Funding Programs

- National research priorities (April 2012)
  - Broad framework that provides overall direction to the funding initiatives
  - Not based on clinical priorities
  - Majority of the funding thus far

- Initiatives based on stakeholder-derived research priorities
  - Single-cycle targeted announcements
  - Infrastructure: PCORnet
  - Pragmatic studies initiative (prioritized clinical topics)
Our National Priorities for Research

Assessment of Prevention, Diagnosis and Treatment Options

Improving Healthcare Systems

Communication & Dissemination Research

Addressing Disparities

Accelerating PCOR and Methodological Research
PCORI’s Research Programs

CER
- Assessment of Prevention, Diagnosis and Treatment Options
- Pragmatic Studies

Application of Best Evidence to Improve Care
- Communication and Dissemination Research
- Improving Healthcare Systems
- Addressing Disparities

Improving the infrastructure for CER
- Data Infrastructure (PCORNet)
- Methods
Snapshot of Funded Projects

Number of projects: 360

Amount awarded: $671 million

Number of states where we are funding research: 39 (plus the District of Columbia and Quebec)

As of September 30, 2014
New Initiatives Derived from Stakeholder-Based Clinical Priorities

- Opportunity to identify important evidence gaps
  - Nomination of clinical topics
  - Advisory panels

- Pragmatic Studies Announcement
    - Third cycle is underway.
    - Fourth cycle in first half of 2015.
  - Competitive LOIs.
  - Larger budgets and longer project durations.
  - Up to $90 million per cycle.
Priority Topics for the Pragmatic Studies Program

- Management of ductal carcinoma *in situ*
- Treatments to prevent the transition from episodic to chronic migraine
- Smoking cessation therapies in high risk persons
- Treatments to prevent the transition from episodic to chronic low back pain
- Diagnosis and management of bipolar disorder in children and adolescents
- Treatment strategies for osteoarthritis
- Strategy for follow-up of incidentally discovered pulmonary nodules.
Priority Topics for the Pragmatic Studies Program

- Treatments for multiple sclerosis
- Treatment strategies for autism spectrum disorder
- Proton therapy for breast, prostate, and lung cancer.
- Treatment of opioid substance abuse
- Biological agents in Crohn’s Disease
- Hemodialysis vs. peritoneal dialysis
We Target Specific, High-Priority Topics

Assessment of Prevention, Diagnosis and Treatment Options
- PCOR Treatment Options in Uterine Fibroids*

Improving Healthcare Systems
- Clinical Trial of a Multifactorial Fall Injury Prevention Strategy in Older Persons**
- Effectiveness of Transitional Care

Addressing Disparities
- Treatment Options for African Americans and Hispanics/Latinos with Uncontrolled Asthma
- Obesity Treatment Options Set in Primary Care for Underserved Populations
- Clinical Interventions to Address Hypertension Disparities

* Administered by AHRQ
** Administered by the National Institute on Aging
Assessment of Prevention, Diagnosis, and Treatment Options

Seeks to fund investigator-initiated research that:

- Compares the effectiveness of two or more options that are known to be effective but have not been adequately compared in previous studies.

- Investigates factors that account for variation in treatment outcomes across patient groups.

Portfolio Snapshot

- 83 Projects
- $149 Million Awarded

By primary health topic
Clinical Focus of Previously Funded Projects
PCORI Assessment of Options Program

- Diagnosis: 15%
- Prevention: 12%
- Treatment: 73%
Communication and Dissemination Research

Seeks to fund investigator-initiated research in:

- Mechanisms for communicating complex information
- Risk communication, health literacy, and communicating uncertainty.
- Mechanisms to overcome issues of numeracy.

Portfolio Snapshot

- 33 Projects
- $56.7 Million Awarded
Addressing Disparities

Seeks to fund investigator-initiated research that:

- Compares interventions to reduce or eliminate disparities across different patient populations.
- Identifies/comparisons promising practices that address contextual factors and their impact on outcomes.
- Compares and identifies best practices within various patient populations for information sharing about outcomes and research.
Improving Healthcare Systems

Seeks to fund investigator-initiated research on effects of system changes on:

• Patients’ access to high quality, support for self-care, and coordination across healthcare settings.
• Overall health, functional ability, quality of life, stress, and survival.
• The efficiency of healthcare delivery, as measured by the amount of ineffective, duplicative, or wasteful care provided to patients.

53 PROJECTS $105.3M AWARDED

By primary health topic
The National Patient-Centered Clinical Research Network (PCORnet)

- Improve the nation’s capacity to conduct clinical research more efficiently, by creating a large, highly representative, national patient-centered clinical research network with a focus on conducting comparative studies – both randomized and observational.

- Support a learning US healthcare system, which would allow for large-scale research to be conducted with enhanced accuracy and efficiency within real-world care delivery systems.
11 Clinical Data Research Networks (CDRNs)
System-based networks, such as hospital systems
$76.8 million awarded

18 Patient-Powered Research Networks (PPRNs)
Patients with a single condition form a research network
$16.8 million awarded
Geographic Coverage of PPRNs and CDRNs
Some Projects are Outside of PCORI’s Priorities

• Cost-effectiveness analyses or studies that primarily address costs of care as an outcome.

• Studies of the efficacy of unproven treatments.

• Natural history studies.
We Work to Improve Research Methodology

In any study, methods matter. That’s why we’ve developed methodology standards that all research should follow, at a minimum.

Methodology Standards: 11 Broad Categories

- Formulating Research Questions
- Patient-Centeredness
- Data Integrity and Rigorous Analyses
- Preventing/Handling Missing Data
- Heterogeneity of Treatment Effects
- Data Networks
- Data Registries
- Adaptive and Bayesian Trial Designs
- Causal Inference
- Studies of Diagnostic Tests
- Systematic Reviews
Characteristics of the Methodology Standards

- Are minimal standards for performing comparative effectiveness research.
- Are intended to provide helpful guidance to researchers and those who use research results.
- Reflect generally accepted best practices.
- Provide guidance for both project protocols and reporting of results.
- Are used to assess the scientific rigor of funding applications.
- Context of the research should drive use of the standards.
Improving Methods for Conducting Patient-Centered Outcomes Research

Seeks to fund investigator-initiated research that:

- Addresses gaps in methodological research relevant to conducting PCOR. Results of these projects will inform future iterations of PCORI’s Methodology Report.
- Focuses on Patient-Reported Outcome Measurement Information System (PROMIS)-related research.

- 58 Projects
- $54.8 Million Awarded
Which Strategies are Likely to be Successful when Seeking Funding?

- PCOR should compare clear clinical options.
  - Be cautious with a “usual care” comparator.
  - The clinical interventions should be easy to replicate: path to dissemination.

- Make sure that the outcomes are meaningful (both benefits and harms).

- Cover all of the Methodology Standards.

- Engagement, engagement, engagement.
Strategies for Preparing a Successful Funding Application

- Your proposal should tell the story of why the research study is important to all reviewers.
- Don’t assume reviewers know something about your project that you don’t address.
- Be clear on what is to be gained if your study is funded.
Conclusions

• Patient-centered outcomes research (PCOR) provides relevant information to help patients and providers choose among alternative clinical strategies.

• Applicants for funding should engage patients and stakeholders in identifying questions and defining important outcomes.

• Projects should directly address important clinical comparisons and examine meaningful outcomes.

• The PCORI Methodology Standards guide best practices for planning, conducting and reporting research.
Join Us at PCORI.org
Pipeline to Proposal Awards
NAPCRG Patient and Clinician Engagement (PaCE) Preconference

Courtney Clyatt, MPH
Senior Program Associate, Patient Engagement
Pipeline Origin

Proposed by participants at October 2012 Transforming Patient-Centered Research patient engagement workshop

Workshop participants identified that few resources have been directed to non-research entities for community development, capacity building, or for infrastructure development for engagement in research as partners.
Our Pipeline to Proposal Awards program aims to build a national community of patients, stakeholders, and researchers who have the expertise and passion to participate in patient-centered outcomes research (PCOR) and to create partnerships within that community that lead to high-quality research proposals.
Develop research partnerships among unlikely suspects to identify health issues that affect their community

Build strong partnerships between researchers, patients and other stakeholders to create a PCOR/CER question to address a health issue

Create a high-quality PCORI research proposal with a strong engagement plan that leads to...

Funded research that results in desired health outcomes for patients in their community
1) P2P helps foster capacity building for PCOR in the community before a study plan is even developed. This enables underserved/minority and otherwise “missing” communities to actively engage in the research process.

2) It has been shown that when patient partners are engaged early on and throughout the research process, they are more likely to help in the implementation and dissemination of study results in their communities.
<table>
<thead>
<tr>
<th>Summary of Funding Tiers</th>
<th>Funding Level</th>
<th>Purpose of Funding</th>
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</thead>
<tbody>
<tr>
<td>Tier I</td>
<td>Up to $15,000 per award for 9 months</td>
<td>Building of the community and capacity necessary to later develop a patient-centered comparative effectiveness research (CER) project addressing the issue of interest to the awardee.</td>
</tr>
<tr>
<td>Tier II</td>
<td>Up to $25,000 per award for 12 months</td>
<td>Maturation of research partnerships with the goal of receiving PCORI or other CER project funding. The funds are to be used to strengthen the partnerships and further develop the infrastructure and governance structures laid out during Tier I and to lay groundwork for the ultimate drafting of a patient-centered CER proposal.</td>
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<tr>
<td>Tier III</td>
<td>Up to $50,000 per award for 12 months</td>
<td>Proposal development, targeting advanced potential research partnerships (those who are “almost there”) that could benefit from working with awardee partners to draft a strong patient engagement plan and a rigorous science proposal.</td>
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P2P: Tier Design

- **Tier I**
  - Up to $15,000
  - 9 months

- **Tier II**
  - Up to $25,000
  - 12 months

- **Tier III**
  - Up to $50,000
  - 12 months

**PCORI Funding Announcement**

- Or other PCOR/CER Research

**Evaluation needed to move onto Tier II**

**Independent Funding Call**
## Review Process and Criteria for Each Tiers I & II

<table>
<thead>
<tr>
<th>Tier I</th>
<th>Tier II</th>
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<tbody>
<tr>
<td>1. Program Fit - does this fit the spirit of the Pipeline to Proposal Awards?</td>
<td>1. Adherence to Contract Requirements during the Tier I project period</td>
</tr>
<tr>
<td>2. Project Plan and Timeline</td>
<td>2. Intent to continue Partnership Development</td>
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<tr>
<td>3. Past Partnership or Community Engagement Experience</td>
<td></td>
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<tr>
<td>4. Budget/Cost Proposal</td>
<td>Reviewers will come from PCORI Staff and PAPO</td>
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Reviewers will come from PCORI Ambassadors, Merit Reviewers and PCORI Staff

Pipeline to Proposal Awardees who enter at Tier I will have an opportunity to develop their patient/stakeholder/researcher partnership over a 21-month period.
The ultimate goal of a Tier I Award is to form a team of patients and researchers who are focused on a common health issue and to demonstrate a commitment eventually to develop a patient-centered research proposal.

**Proposed Award Activities in Tier I**

In Tier I Awardees will:

- Build relationships with other patients, researchers, or stakeholders who are focused on the same health issue. Activities may include holding workshops, conferences, and meetings.

- Create a communication plan to help connect community members. Activities may include setting up a website with an inbox for receiving messages.

- Develop a governance or guidance structure such as an advisory council for making strategic decisions. Activities may include drafting a strategic plan or forming an advisory board.

- Complete PCORI Awardee training, which will include information about how to engage patients and stakeholders in research projects.
Regional Breakdown for Pipeline Awards
Pipeline Award Program Offices (PAPO)

PAPO will assist in the administration and management of the Pipeline to Proposal Awards.

Because PCORI has a limited headquarters workforce, the operational, programmatic, and fiscal duties associated with Pipeline Awards will be subcontract to PAPOs. The selected organizations all have public health, healthcare, or research familiarity, research, capacity-building, and award management experience.
The National PAPO works on nationwide projects

Tier I, Cycle 1
Pilot Phase with only the West PAPO, CFPHE
Program Start Date: February 2014

Tier I, Cycle 2
Nationwide Roll Out
Program Start Date: May 2015

PCORI

National PAPO

PAPO (West) 30 Awardees

PAPO (Midwest) 10 Awardees

PAPO (Northeast) 10 Awardees

PAPO (South) 10 Awardees
30 Tier I Projects in the Western Region projects completed as of 11/14/14

- Addressing Obesity in Latino Adolescents with Spina Bifida
- Building a Community of Safe Sleep for Infants
- Building Capacity for Novel Screening Delivery for Chronic Conditions to Benefit Miners in New Mexico
- Citizen PsScientist
- Connecting Research and Real Life: Building a Network in the Columbia River Gorge
- Creating Healthy Communities: Engaging Native American and Spanish-Speaking Families and Sharing Family Wisdom to Reduce Childhood Obesity
- Creating the Patient Centered Primary Care Council in the Highland Hospital Adult Medicine Clinic: Strengthening Primary Care Together
- Culturally Appropriate Options for Diabetes Prevention and Care for Low-Income Latinos
- Developing Infrastructure for Patient Centered Melanoma Research
- Development of Community Partnership for Patient Centered Outcomes Research in Type 2 Diabetes
- Empowering Patients and Their Families to Improve Outcomes That Are Most Important to Them after Lung Cancer Surgery
- Engaging Communities in the Fight Against Preterm Birth
- Establishing a Patient-Centered Research Community for Cystic Fibrosis
- Health Literacy and the Patient Perspective in Primary Care
- Healthy Outcomes for Older Foster Youth
- Improving the Lives of Alzheimer's Patients and their Caregivers: A Patient Centered Statewide Approach
- Increasing Patient Engagement and Capacity Building between Community Stakeholders and Patients in order to Improve Diabetes Education and Management among School-Aged Children
- Making Stomach Cancer a Health Priority among Asian Americans
- Mobilizing Community Engagement for Health in a Southern New Mexico Border Region Colonia
- New Mexico LGBT Health Improvement Network
- Patient-Centered Outcomes for the Parkinson’s Disease Community in Wyoming
- Patient-Centered Transitions for Episodes of Surgical Care
- Preventing Missed Appointments for HIV Patients
- Puget Sound Asthma Coalition: A Community, Clinical, and Academic Partnership
- Sepsis Survivors Engagement Project (SSEP) - https://www.youtube.com/watch?v=HDODVQ6kqNQ
- Taking Care of Our Parents: Improving the Coordination of Care for Elderly Community Members
- The 'CISE' Project for Family Caregivers
- The Hispanic Family Asthma Outcomes Research Network
- Usefulness of Prediabetes Management in Breast Cancer Care
- YOU COMPLETE ME! Demonstrating the Efficacy of An Innovative Medical Appointment Model to Support Aging Patients
Who Can Apply for a Pipeline to Proposal Award

Tier 1
Up to $15,000
Up to 9 month term

Tier 2
Up to $25,000
Up to 12 month term

Tier 3
Up to $50,000
Up to 12 month term

PCORI Funding Announcement

Researchers who unsuccessfully submitted a PFA and need to improve proposal

Or submissions to other PCOR/CER Funders
When to Apply for a Tier I Award

The graphic below shows the important dates for the Tier I Award program.

[Diagram showing dates]

LOI Portal Opens: 11/24/14
Application Portal Opens: 12/23/14
Last day to submit proposal: 2/16/15
Awards announced: 3/31/15
Projected start date: 5/1/15
Are you ready to Apply?

PCORI Tier I Pipeline to Proposal Award Checklist

Use the checklist below to assess your readiness to apply for a PCORI Tier I Pipeline to Proposal Award.

- I am an individual or I represent a group of patients, stakeholders, or researchers and I/we are focused on a health related issue.
- The health issue I am focused on could lead to a comparative effectiveness research (CER) question. (The CER does not need to be identified right now.)
- I can demonstrate how I have been successful in previous community engagement. (This does not need to be healthcare related.)
- I want to create a patient-researcher partnership with the intention of working together to eventually submit a proposal for a patient-centered CER.
- I can explain how I would use the funding.
- I am willing to complete all the Tier I award requirements, including:
  - Commit to taking PCORI Pipeline Tier I Awardee training
  - Be willing to work closely with and engage in regular communication with my Regional Pipeline Award Program Office
  - Agree to participate in forums to share experiences and lessons learned with other Tier I Pipeline Awardees
  - Be willing to provide reports giving details on the activities that have taken place during the contract period
Be sure to visit our P2P website

Please visit the P2P website for more information on how to apply for awards and more about our initiative.

http://www.pcori.org/content/pipeline-proposal-awards

Please keep in mind the following dates:

November 24th - Request for LOI’s (this Monday!)
December 3rd – Webinar for Tier I Applicants
Question and Answer Session
Thank You

Courtney Clyatt
Senior Program Associate, Engagement
cclyatt@pcori.org
PCORI’s Merit Review Process

A. Tsahai Tafari, Ph.D.
Associate Director, Merit Review
Research Integration and Evaluation
The goal of PCORI Merit Review is to identify applications that have the strongest potential to improve patient outcomes.
Engagement as a Path To Useful, High-Quality Research

- Review, Design, and Conduct of Research
- Dissemination and Implementation of Results
- Evaluation
- Topic Selection and Research Prioritization
PCORI Merit Review Process

- PCORI merit review panels include scientists, patients, and other stakeholders to bring diverse perspectives to the review process.
- PCORI’s unique merit review criteria ensure that research funded by PCORI is scientifically rigorous and patient-centered.
PCORI Funding Announcement (PFA) Development

**BROAD**
- Align with our National Priority Research Areas

**TARGETED**
- Research Topic Database reviewed by programs
- Program staff prioritize topics
- Additional evidence collected, shared with Advisory Panels
- Advisory Panels rank topics
- Program staff provide Board with rationale for topic funding
  - Board reviews research topics
  - Approved topics incorporated in funding announcement

**PREVIOUS STEPS**
- Board of Governors Funding Slate Review and Approval
- Selection Committee Meeting
- Funding Slates Set by Programs
- In-Person Meeting
- Programs Set Discussion Line
- Preliminary Review
- Application Assignment to Reviewers
- Full Application Receipt
- Letter of Intent (LOI) Receipt
- RESEARCHER RECRUITMENT
- START
- SUMMARY STATEMENT PRODUCTION
Broad PCORI Funding Announcements Are Aligned With Our National Priority Areas

- Assessment of Prevention, Diagnosis, and Treatment Options
- Improving Healthcare Systems
- Communication & Dissemination Research
- Addressing Disparities
- Accelerating PCOR and Methodological Research
We Target Specific, High-Priority Topics

Assessment of Prevention, Diagnosis and Treatment Options
- PCOR Treatment Options in Uterine Fibroids*

Improving Healthcare Systems
- Clinical Trial of a Multifactorial Fall Injury Prevention Strategy in Older Persons**
- Effectiveness of Transitional Care

Addressing Disparities
- Treatment Options for African Americans and Hispanics/Latinos with Uncontrolled Asthma
- Obesity Treatment Options Set in Primary Care for Underserved Populations
- Clinical Interventions to Address Hypertension Disparities

Large Pragmatic Studies
* Administered by AHRQ
** Administered by the National Institute on Aging
**Letter of Intent (LOI) Receipt**

- Both targeted and broad PFAs use a competitive LOI screen
- Programmatically responsive LOIs are invited to submit a full application
- Screen for comparative effectiveness research
- Exclude/screen out applications that include cost-effectiveness research
- Reviewer recruitment begins
- Reviewer training made available to recruited reviewers

**PCORI Funding Announcement (PFA) Development**

**Letter of Intent (LOI) Receipt**

**Full Application Receipt**

**Application Assignment to Reviewers**

**Preliminary Review**

**Programs Set Discussion Line**

**In-Person Meeting**

**Funding Slates Set by Programs**

**Selection Committee Meeting**

**Board of Governors Funding Slate Review and Approval**

**SUMMARY STATEMENT PRODUCTION**

**MERIT REVIEW CYCLE**
Responsiveness Review

Letters of intent (LOIs) are reviewed based on criteria detailed in each PCORI Funding Announcement (PFA)

Additional screening for

- Comparative effectiveness research
- Exclusion of cost-effectiveness analysis

Only responsive LOIs will be invited to submit a full application

Based on the topic areas of the received LOIs, reviewer recruitment will begin
What is Expected of a PCORI Reviewer?

- **All reviewers**
  - Understand and apply PCORI’s mission, vision, and review criteria
  - Bring experience and a perspective that enhances the quality of the review
  - Dedicate time and agree to review all assigned applications and participate in a one- or two-day peer-review panel meeting

- **Patient and Stakeholder Reviewers**
  - Ability to represent the perspective of broad or specific patient and stakeholder groups
  - Ability to contribute a unique healthcare system perspective

- **Scientist Reviewers and Chairs**
  - Advanced degree in health or research-related field
  - Publication of relevant peer-reviewed articles/studies
  - Current or recent funding in a relevant field of study
**Full Application Receipt**

- Referral of applications to panels based on topic areas
- Conflicts of interest screen and expertise rating by reviewers
Application Assignment to Reviewers

- Based on reviewer-indicated expertise
- Up to 6 applications per reviewer
- Approximately 4 weeks to review assigned applications
Application Assignments

- Assignments made based on
  - Expertise
  - COI review

- Up to 6 applications per reviewer

- Reviewer training is provided for ALL panel members
  - Mentor program supplements training for patient and stakeholder reviewers
  - Web-based
  - Program and Merit Review Officer-led webinars
Mentor Program

Provides patient and stakeholder reviewers the support they need to

- Complete written critiques that are informative for applicants and program staff
- Participate effectively at the panel meeting
- Enjoy participating in the PCORI merit review process
Application Assignments

Each application is assigned to 4 reviewers*

- 2 scientist reviewers
- 1 patient reviewer
- 1 stakeholder reviewer

*Reviewer types are PFA-specific; some targeted announcements may have different reviewer requirements
Preliminary Review

- Evaluation of adherence to methodology standards
- Evaluation using merit review criteria
- Critiques submitted
- Score reports sent to programs
- Critique and score monitoring by MROs
Critique Review by MROs and Mentors

All reviewers write a critique for each of their assigned applications and provide both criteria and overall scores.

ALL reviewers will receive ongoing support and feedback on written critiques.

Mentors and MROs review critiques as panel members complete them, and provide feedback:
- Clarifies goals of PFA and content of critiques
- Helps reviewers express their unique perspective in a manner that is actionable by the applicant
- Ensures fair and consistent review
Merit Review Criteria

**Criterion #1:** Impact of the condition on the health of individuals and population

**Criterion #2:** Potential for the study to improve healthcare and outcomes

**Criterion #3:** Technical merit

**Criterion #4:** Patient-centeredness

**Criterion #5:** Patient and stakeholder engagement

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<tr>
<th>Patient and Stakeholder Reviewers</th>
<th>Scientist Reviewers</th>
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We Require Patient-Centeredness and Patient and Stakeholder Engagement

Patient-Centeredness
- Does the project aim 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
### Scoring Range

The scoring range consists of a nine point scale.

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<th>Range</th>
<th>Score</th>
<th>Descriptor</th>
<th>Characteristics</th>
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<tr>
<td>High</td>
<td>1</td>
<td>Exceptional</td>
<td>Exceptionally strong with essentially no weaknesses</td>
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<tr>
<td></td>
<td>2</td>
<td>Outstanding</td>
<td>Extremely strong with negligible weaknesses</td>
</tr>
<tr>
<td></td>
<td>3</td>
<td>Excellent</td>
<td>Very strong with only some minor weaknesses</td>
</tr>
<tr>
<td>Medium</td>
<td>4</td>
<td>Very Good</td>
<td>Strong but with numerous minor weaknesses</td>
</tr>
<tr>
<td></td>
<td>5</td>
<td>Good</td>
<td>Strong but with at least one moderate weakness</td>
</tr>
<tr>
<td></td>
<td>6</td>
<td>Satisfactory</td>
<td>Some strengths but also some moderate weakness</td>
</tr>
<tr>
<td>Low</td>
<td>7</td>
<td>Fair</td>
<td>Some strengths but with at least one major weakness</td>
</tr>
<tr>
<td></td>
<td>8</td>
<td>Marginal</td>
<td>A few strengths and a few major weaknesses</td>
</tr>
<tr>
<td></td>
<td>9</td>
<td>Poor</td>
<td>Very few strengths and numerous major weaknesses</td>
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A score of 1 indicates an exceptionally strong application.

A score of 9 indicates an application with serious and substantive weaknesses.
Programs Set Discussion Line

- PCORI staff use overall and criterion scores provided by assigned reviewers to identify applications that will move forward in the process.

- Identifies applications that will move forward to be discussed at the in-person meeting

- Applications that fall below the discussion line do not move forward in the process
**In-Person Meeting**

- Applications discussed and provided a final overall score
- MROs take discussion notes
**Merit Review In-Person Meeting**

**Reviewer 1:** Scientist 1  
**Reviewer 2:** Patient  
**Reviewer 3:** Stakeholder  
**Reviewer 4:** Scientist 2

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<tr>
<td>Chair briefly introduces application</td>
</tr>
<tr>
<td>Scientific Reviewer #1: summarizes application strengths/weaknesses and score</td>
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<tr>
<td>Patient reviewer: summarizes application strengths/weaknesses and score</td>
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<tr>
<td>Stakeholder Reviewer: summarizes application strengths/weaknesses and score</td>
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<tr>
<td>Scientific Reviewer #2: summarizes application strengths/weaknesses and score</td>
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<tr>
<td>General panel discussion</td>
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<tr>
<td>Chair summarizes panel discussion of application</td>
</tr>
<tr>
<td>Full panel scores application in PCORI Online</td>
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</tbody>
</table>
**Funding Slates Set by Programs**

- Score reports and portfolio balance part of consideration when proposing the funding slates
Selection Committee Meeting

- Programs present funding slates to the Selection Committee
- Selection Committee reviews slates, merit review scores, and recommends slates for approval
Funding Slates and Selection Committee

Portfolio information presented to Selection Committee, along with

- Proposed slate
- Rationale for application selection

Facilitates selection of applications that best support our mission for recommendation to the Board
Board of Governors
Funding Slate Review and Approval

- Summary statements released
- Recommended funding slates and rationale presented to the Board for review and approval
- Funded awards announced to public
Summary Statements

All applicants receive a summary statement at the end of the review cycle.

If the application is discussed, summary statement includes:

• Preliminary reviewer critiques
• Notes from application discussion
• Final panel average overall score

If the application is not discussed, summary statement includes:

• Preliminary reviewer critiques
Become a Reviewer

- PCORI review panels include scientists, patients, and other stakeholders to bring diverse perspectives to the review process.
- We continue to welcome applications to become a reviewer in all categories—scientists, patients, and stakeholders, including payers, employers, industry and health system representatives, clinicians, and policy makers.
How to Apply to be a PCORI Reviewer

Visit: www.pcori.org/content/become-reviewer

- Qualifications
- Reviewer Expectations
- Compensation
- Standing Panelists
- Training Materials
- Frequently Asked Questions
PCORI Funding Opportunities
Broad PFAs – Spring 2015

- Assessment of Prevention, Diagnosis, and Treatment Options
- Improving Healthcare Systems
- Communication and Dissemination Research
- Addressing Disparities
- Accelerating PCOR and Methodological Research

- PFAs post 2/4/2015
- LOIs due 3/6/2015
- Applications due 5/5/2015

http://www.pcori.org/funding/opportunities
http://www.pcori.org/content/faqs-applicants
Large Pragmatic Studies

- PFA first released in January 2014
  - Third cycle is underway.
  - Fourth cycle in first half of 2015.
  - Competitive LOIs.
  - Larger budgets and longer project durations.
  - Up to $90 million per cycle.

- [http://www.pcori.org/funding/opportunities](http://www.pcori.org/funding/opportunities)
- [http://www.pcori.org/content/faqs-applicants](http://www.pcori.org/content/faqs-applicants)
Have a Question?

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Administrative/Financial/Technical Questions
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