Introduction to the Patient-Centered Outcomes Research Institute

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About PCORI
pcori.org/about
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.
PCORI helps people make informed health care decisions, and improves health care delivery and outcomes, by producing and promoting high integrity, evidence-based information that comes from research guided by patients, caregivers and the broader health care community.
“(g) FINANCIAL AND GOVERNMENTAL OVERSIGHT. …

(2) REVIEW AND ANNUAL REPORTS. …

(iv) Not less frequently than every 5 years … the overall effectiveness of activities conducted under this section … such review shall include an analysis of the extent to which research findings are used by health care decision-makers, the effect of the dissemination of such findings on reducing practice variation and disparities in health care…”

-- from Patient Protection and Affordable Care Act
What is Patient-Centered Outcomes Research?

Evaluation of questions and outcomes meaningful and important to patients and caregivers

Who Are Our Stakeholders?

PCORI Community

- Patient/Consumer
- Caregiver/Family Member of Patient
- Hospital/Health System
- Training Institution
- Policy Maker
- Industry
- Payer
- Clinician
- Patient/Caregiver Advocacy Org
- Purchaser

PCORI
Community

Patient-Centered Outcomes Research Institute
Engagement as a Path To Useful, High-Quality Research

- Proposal Review; Design and Conduct of Research
- Dissemination and Implementation of Results
- Evaluation
- Topic Selection and Research Prioritization

Patient-Centered Outcomes Research Institute
Research We Support
pcori.org/research-we-support
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
**Key Features of Our Funded Research**

<table>
<thead>
<tr>
<th>Feature</th>
<th>Description</th>
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<tbody>
<tr>
<td>Studies the benefits and harms of interventions and strategies</td>
<td>delivered in real-world settings</td>
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<tr>
<td>Compares at least two alternative approaches</td>
<td></td>
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<tr>
<td>Adheres to PCORI’s Methodology Standards</td>
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<tr>
<td>Is based on health outcomes that are meaningful to the patient population</td>
<td></td>
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<tr>
<td>Engages patients and other stakeholders at every stage</td>
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<tr>
<td>Is likely to improve current clinical practices</td>
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We Pay Particular Attention to...

<table>
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<tr>
<th>Conditions that heavily burden patients, families and/or the health care system</th>
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<tbody>
<tr>
<td>Chronic or multiple chronic conditions</td>
</tr>
<tr>
<td>Rare and understudied conditions</td>
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<tr>
<td>Conditions for which outcomes vary across subpopulations</td>
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We Advance Research Methodology

We have adopted 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
How to Submit an Application

Visit pcori.org/apply

- Key Dates
- Funding Announcements
- Application Guidelines and Templates
- Guidance on the PCORI Methodology Standards
- Sample Engagement Plans
- Frequently Asked Questions

Patient-Centered Outcomes Research Institute
## Annual Funding Cycles

<table>
<thead>
<tr>
<th>Funding Cycle</th>
<th>Application Opens</th>
<th>Application Closes</th>
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<tbody>
<tr>
<td>Winter</td>
<td>November</td>
<td>February</td>
</tr>
<tr>
<td>Spring</td>
<td>February</td>
<td>May</td>
</tr>
<tr>
<td>Summer</td>
<td>May</td>
<td>August</td>
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<tr>
<td>Fall</td>
<td>August</td>
<td>November</td>
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Applications are reviewed against five criteria:

- Impact of the condition on the health of individuals/populations
- Potential for the study to improve healthcare and outcomes
- Technical merit
- Patient-centeredness
- Patient and stakeholder engagement

- Applications are reviewed by a panel of two scientists, one patient, and one other stakeholder.
- PCORI’s Board of Governors makes funding decisions based on merit review and staff recommendations.
Funded Projects to Date

Total number of research projects awarded: **313**

Total funds awarded: **$548.9 million**

Number of states where we are funding research: **38 states** (plus the District of Columbia and Quebec)
FUNDED PROJECTS BY DISEASE/CONDITION AND PROGRAM AREA (N=222)*

*excludes all Methods projects
FUNDED PROJECTS BY DISEASE/CONDITION AND CYCLE (N=221)*

- Cycle I
- Cycle II
- Cycle III
- August 2013
- Winter 2014
- Spring 2014

Diseases:
- Allergies and Immune Disorders
- Cancer
- Cardiovascular Health
- Digestive System Diseases
- Infectious Diseases
- Kidney Disease
- Liver Disease
- Mental/Behavioral Health
- Multiple/co-morbid chronic conditions
- Muscular and Skeletal Disorders
- Neurological Disorders
- Nutritional and Metabolic Disorders
- Other
- Rare Diseases
- Reproductive and Perinatal Health
- Respiratory Diseases
- Skin Diseases
- Trauma/Injury

*excludes all Methods projects and NIA/PCORI collaboration
Mental Health Conditions Represented in PCORI Projects

- Mood/Anxiety: 27
- PTSD: 7
- Schizophrenia/Bipolar: 10
- Substance Abuse: 9
- Neurocognitive/Dementia: 5
- Unspecified MH: 15
- Other: 4

** Projects may include more than one condition.
** As of 8/30/2014. Additional projects have been funded.
Treatments or Interventions Represented

**Projects may include more than one treatment or intervention.**

**As of 8/30/2014. Additional projects have been funded.**
Accelerating PCOR and Methodological Research

- Addresses gaps in methodological research relevant to conducting PCOR
  - Development of methods for patient and other stakeholder engagement in research
  - Development and refinement of general analytic methods and design specific methods
  - Patient-centered outcomes (PCOs) and patient-reported outcomes (PROs)
  - Development of methods to support data research networks

- Recently awarded PROMIS related projects: 8 projects (~$5.5 million)
## Additional Funding Opportunities

<table>
<thead>
<tr>
<th>Topic</th>
<th>Funding Total</th>
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<tr>
<td>Large Pragmatic Studies to Evaluate Patient-Centered Outcomes</td>
<td>$90 million</td>
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<tr>
<td>Clinical Trial of a Multifactorial Fall Injury Prevention Strategy in Older Persons (Administered by NIA)</td>
<td>$30 million</td>
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<tr>
<td>Effectiveness of Transitional Care</td>
<td>$15 Million</td>
</tr>
<tr>
<td>Obesity Treatment Options Set in Primary Care for Underserved Populations</td>
<td>$20 Million</td>
</tr>
<tr>
<td>PCOR Treatment Options in Uterine Fibroids (Administered by AHRQ)</td>
<td>$20 Million</td>
</tr>
<tr>
<td>Treatment Options for African Americans and Hispanics/Latinos with Uncontrolled Asthma</td>
<td>$17 Million</td>
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Large Pragmatic Studies to Evaluate Patient-Centered Outcomes

Seeks to fund investigator-initiated research that compares two or more alternatives for:

- Addressing prevention, diagnosis, treatment, or management of a disease or symptom
- Improving health care system–level approaches to managing care; or
- Eliminating health or healthcare disparities.
- Research topics of particular interest identified by stakeholders, or questions included in IOM’s Top 100 Topics for CER or AHRQ’s Future Research Needs.

Opportunity Snapshot

- Number of Anticipated Awards per Funding Cycle: Six to Nine
- Funds Available per Cycle: $90 Million
- Maximum Project Duration: 5 Years
- Maximum Direct Costs Per Project: $10 Million
Priority Topics for Large Pragmatic Studies relevant to Psychology

- Treatment strategies for: **autism spectrum disorder** in children and adolescents, **opioid substance abuse**
- Active involvement by patients and caregivers in the **management of chronic mental illness**
- Integration of mental and behavioral health services into the primary care of the general population and of persons at risk for disparities in health care and outcomes
- Enhancing patients’ **adherence to medication regimens**
- Treatment/prevention strategies for: **multiple sclerosis, chronic back pain, cardiovascular disease, migraine headache, osteoarthritis, tobacco use**

**Full list of priority topics:**
The National Patient-Centered Clinical Research Network (PCORnet)

11 Clinical Data Research Networks (CDRNs)
Health 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

Coordinating Center
Provides technical and logistical assistance under the direction of a steering committee and PCORI staff
PCORI and Federal Health Agencies

- PCORI Board of Governors and Methodology Committee representation
- AHRQ legislative mandate for dissemination and implementation of findings
- Co-funding
Supporting Engagement as a Tool to Advance Research

pcori.org/engagement
Taking Patient-Centeredness Seriously

Patient Engagement

Understanding the choices patients face

Patient-Driven Research

Aligning research questions and methods with patient needs

Dissemination

Providing patients and providers with information for better decisions

Patient-Centered Outcomes Research Institute
Research Must Engage Stakeholders at Every Step

- Planning the study
- Conducting the study
- Disseminating study results
- PCORI Engagement Principles

**PCORI Engagement Rubric**

A four-part rubric developed to help guide applicants, reviewers, awardees, and program officers on ways to engage patients and families in conducting research.
Approaches to Engagement (n=58)
Engagement Across the Stages of the Research Process \((n=58)\)
Eugene Washington PCORI Engagement Awards

- Provide “wrap-around” support and enhance impact of PCORI’s research initiatives
- Three award types: Knowledge, Training and Development, Dissemination and Implementation
- Awards of up to $250,000

Objectives

- Engage new groups not previously involved with PCORI
- Develop new mechanisms for disseminating research findings
- Promote “research done differently” by supporting engagement and partnering in conduct and use of CER
Pipeline to Proposal Awards

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
PCORI and APA
Psychologists are Critical for Achieving PCORI’s Vision

- Investigating research questions that matter to patients
- Creating new partnerships
- Enhancing methods for PCOR
- Improving patient-centered outcomes measurement
- Serving as merit reviewers
- Participating in other PCORI events
PCORI invites professional and lay audiences to be reviewers of research applications

Help us support research that will be both scientifically rigorous and truly patient-centered

Learn more and apply online: [www.pcori.org/get-involved/reviewers/](http://www.pcori.org/get-involved/reviewers/)
Have a Question?

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Research/Programmatic Questions
sciencequestions@pcori.org | (202) 627-1884

Administrative/Financial/Technical Questions
pfa@pcori.org