PATIENT-CENTERED OUTCOMES RESEARCH INSTITUTE

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About PCORI

- An independent, non-profit organization authorized by Congress.
- Mission is to fund research that will provide patients, their caregivers and clinicians with the evidence-based information needed to make better-informed health care decisions.
- Committed to continuously seeking input from patients and a broad range of stakeholders to guide its work.
PCORI’s Board of Governors Represents the Entire Health Care Community

- Patients/consumers
- Caregivers
- Physicians, nurses and clinicians
- Hospitals and health systems
- Health plans
- Health services researchers
- State and federal health officials
- Pharmaceutical, device, and diagnostic manufacturers
- Private payers
- Employers
PCORI’s Core Duties

- Establish national research priorities
- Establish and carry out a research agenda
- Develop and update methodological standards
- Disseminate research findings
Patient-Centered Outcomes Research Defined

Patient-Centered Outcomes Research (PCOR) helps people and their caregivers communicate and make informed health care decisions, allowing their voices to be heard in assessing the value of health care options. This research answers patient-centered questions such as:

• “Given my personal characteristics, conditions and preferences, what should I expect will happen to me?”

• “What are my options and what are the potential benefits and harms of those options?”

• “What can I do to improve the outcomes that are most important to me?”

• “How can clinicians and the care delivery systems they work in help me make the best decisions about my health and healthcare?”
Establishing PCORI’s First National Priorities for Research and Initial Research Agenda

- 9 Criteria outlined by law
- 5 Draft priorities proposed
- Public input received and evaluated
- Priorities and agenda revised and approved
- First PCORI Funding Announcements issued
- First Review Session
- First Contracts Announced

- Aug-Dec 2011
- Jan-May 2012
- May 2012
- Nov 2012
- Dec 2012
PCORI’s Research Agenda

Five Board-Approved Priority Areas

1. Assessment of Prevention, Diagnosis, and Treatment Options
2. Improving Healthcare Systems
3. Addressing Disparities
4. Communication and Dissemination
5. Infrastructure and Methods
# Criteria for Research Outlined by Law

<table>
<thead>
<tr>
<th>Impact on Health of Individuals and Populations</th>
<th>Addresses Current Gaps in Knowledge/Variation in Care</th>
<th>Patient-Centeredness</th>
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<tbody>
<tr>
<td>Improvability through Research</td>
<td>Impact on Health Care System Performance</td>
<td>Rigorous Research Methods</td>
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<tr>
<td>Inclusiveness of Different Populations</td>
<td>Potential to Influence Decision-Making</td>
<td>Efficient Use of Research Resources</td>
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PCORI Funding Announcements (PFAs)

- Cycle II opened on September 17; Cycle III will on January 15
- Based on first four adopted research priorities
- Remain “broad” with respect to interest in any condition, as well as cross-cutting questions
- Point out interest in patients with rare diseases
- Emphasize outcomes that matter to patients
Patient and Stakeholder Engagement in Patient-Centered Outcomes Research

**Advise Us as to What PCORI Should Study:**
- What questions are most important? (research prioritization)
- What outcomes should be studied? (topic generation)

**Review Proposals and Partner in Research:**
- Review research proposals for impact and patient-centeredness
- Participate in conducting research

**Tell Us How We Are Doing**
- How can we improve on what we are doing and how we are doing it?

**Help Us Share the Findings**
- How do we best communicate important research findings?
2 Complementary Approaches for Developing PCORI’s National Research Agenda

Investigator-Generated Research Just One Part of the Process

- PCORI issues broad funding announcements
- Researchers partner with stakeholders to generate questions
- Researchers, stakeholders apply review criteria in their applications
- Peer review prioritizes applications by level of alignment with criteria

Diverse Research Portfolio answering key questions for patients and clinicians
Patient/Stakeholder-Led Approach Unique to PCORI

PCORI and stakeholders generate and prioritize questions based on review criteria

PCORI issues specific, funding announcements for highest priority topics

Researchers and stakeholders develop responsive proposals

Peer review prioritizes applications by level of alignment with criteria

Diverse Research Portfolio answering key questions for patients and clinicians
Suggest a Patient-Centered Research Question

Every day, patients and people who care for them must make health care decisions. They may have to choose between two or more options for preventing, diagnosing or treating a health condition. Or, they might need to decide between doing, or not doing something. For these situations, the Patient-Centered Outcomes Research Institute (PCORI) was created. PCORI funds research to help patients make the best decisions about their health care.

We at PCORI want to know what health care question or decision you may be facing. We want to hear from you. Your input can help us develop our research agenda.

Whether you are a patient with a health condition, a caregiver for someone else, a health care professional who wants to improve care for your patients, or a researcher, we invite you to submit a question. In addition to questions about options faced by patients, we also are interested in questions that would help to improve health care delivery, address disparities in health care, or improve the communication of research findings (for more information, please see PCORI's National Priorities for Research).

We will carefully consider your question as we plan which questions to study.

Is your question about a certain disease, behavior or health condition?

If yes, please name the disease, behavior or health condition. If no, leave blank and continue.

What is your question?
Advise Us as to What PCORI Should Study:

What questions are most important? (research prioritization)
What outcomes should be studied? (topic generation)

Tell Us How We Are Doing

How can we improve on what we are doing and how we are doing it?

Review Proposals and Partner in Research

Review research proposals for impact and patient-centeredness
Participate in conducting research

Help Us Share the Findings

How do we best communicate important research findings?
What roles should patients and stakeholders play in research teams?

The engagement of patients and stakeholders should include:

• Participation in formulation of research questions;

• Defining essential characteristics of study participants, comparators, and outcomes;

• Monitoring of study conduct and progress; and

• Dissemination of research results.

Source: PCORI PFA Application Guidelines (Sec. 3.1.3.4) [http://www.pcori.org/assets/PFAguidelines.pdf](http://www.pcori.org/assets/PFAguidelines.pdf)
Be a Reviewer of PCORI Funding Applications

- PCORI invites professional and lay audiences to be reviewers of research applications submitted in response to PCORI funding announcements.

- Reviewers are highly valued members of the PCORI community whose work is essential to helping us support research that will be scientifically rigorous and truly patient-centered.

- Learn more and apply online: [http://www.pcori.org/get-involved/call-for-reviewers/](http://www.pcori.org/get-involved/call-for-reviewers/)
Patient and Stakeholder Reviewers

- Patients and stakeholders will be one-half of review panels
- 350 total applicants
- 242 with prior grant review experience
  - 102 from patient community
  - 140 from stakeholder community
- 58 selected in final vetting
  - Based on balanced criteria
- Goal is to build a database of lay reviewers of PCORI funding applications
Patient and Stakeholder Reviewers
What We Heard From Reviewers

“This is exciting and will lead to positive outcomes.”

“17-year breast cancer survivor and want to see an end to the disease.”

“First time patient’s voice is being formalized.”

“It's about time this is happening in healthcare.”

“Need to find ways to optimize healthcare system.”

“Need for more research to meet current needs of patients.”

“Want to get patients' perspective and find ways to get them involved.”

“Served as a PCORI reviewer and experience was fascinating.”

“Need to get patients’ perspective and find ways to get them involved.”

“I want do my part as a patient, and I will be honored with this opportunity.”

“Stakeholder engagement is essential to relevant and useful research and evaluation: from identification of study questions to dissemination and utilization of findings.”

Source: Patient and Stakeholder Interviews. August 2012
Engagement Workshops

Transforming Patient-Centered Research: Building Partnerships and Promising Models
- October 27-28, 2012
- Washington, DC

What Should PCORI Study? A Call for Topics from Patients and Stakeholders
- December 4, 2012
- Washington, DC

PCORI Methodology Workshop for Prioritizing Specific Research Topics
- December 5, 2012
- Washington, DC
Methodology Report

• The mandate for PCORI’s Methodology Committee is to define methodological standards and a translation table to guide health care stakeholders towards the best methods for patient-centered outcomes research (PCOR).

• Rigorous methods are essential to building trust in research findings.

• This report (which will continue to be revised and improved over time) is the necessary catalyst for scientifically rigorous, patient-centered outcomes research that can inform decision-making.
Methodology Report Timeline

May 10, 2012
- Report delivered to PCORI Board of Governors

May 21, 2012
- Accepted by Board
- Staff instructed to prepare draft report for public comment

June 4, 2012
- Preliminary draft posted on website

July 23, 2012
- 54-day Public Comment Period begins (closed Sept. 14)

Nov. 2012
- Revised report adopted
PCORI Pilot Projects Program

• Allocates **$30 million** in funding over two years for a slate of **50 pilot projects**.

• Supports the collection of preliminary data that can be used to advance the field of patient-centered outcomes research

• Research will address how to engage patients in the research and dissemination process.
PCORI Pilot Project Research Topics

Methods for engaging patients and stakeholders in:

- Informing PCORI’s national priorities
- The research process, along with other stakeholders
- Developing evidence-based decision support tools that account for patient preferences
- Developing patient-centered outcomes instruments
- Researching behaviors, lifestyles, and choices
- Studying patient care team interactions in situations where multiple options exist
- Analytical methods for CER
What Makes PCORI Funding Different?

• Special features include:
  – Patient & stakeholder engagement plan
  – Dissemination and implementation Assessment
  – Reproducible and transparent research plan
  – PCORI criteria outlined by statute
  – References methodology standards
  – User-friendly announcements to encourage broader range of applicants
PCORI’s Next Steps

- Analyze and incorporate comments on draft Methodology Report
- Establish advisory groups and convene workshops
- Issue targeted funding announcements
- Award first round of primary research contracts
Connect with PCORI

Keep Informed about PCORI Funding Announcements and Opportunities to Get Involved
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