Patient-Centered Outcomes Research Institute

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Board of Governors, PCORI

October 12, 2011
“(c) PURPOSE.—The purpose of the Institute is to assist patients, clinicians, purchasers, and policy-makers in making informed health decisions by advancing the quality and relevance of evidence concerning the manner in which diseases, disorders, and other health conditions can effectively and appropriately be prevented, diagnosed, treated, monitored, and managed through research and

“(h) ENSURING TRANSPARENCY, CREDIBILITY, AND ACCESS.—The Institute shall establish procedures to ensure that the following requirements for ensuring transparency, credibility, and access are met:
The Patient-Centered Outcomes Research Institute (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.
The Need for PCORI

PATIENT-CENTERED OUTCOMES RESEARCH INSTITUTE
The Promise of PCORI

Understanding the choices patients face

Aligning methods and data with patient needs

Providing patients and providers information for better decisions
What Can Patient-Centered Outcomes Research Answer for Patients?

Four questions are at the heart of PCORI’s working definition of “patient-centered outcomes research”

1. “Given my personal characteristics, conditions and preferences, what should I expect will happen to me?”
2. “What are my options and what are the benefits and harms of those options?”
3. “What can I do to improve the outcomes that are most important to me?”
4. “How can the health care system improve my chances of achieving the outcomes I prefer?”
Who is PCORI?

- Patient representatives
- Caregivers
- Physicians, nurses and providers
- Health services researchers
- State and federal health officials
- Pharmaceutical, device, and diagnostic manufacturers
- Private payers

Board of Governors
- 21 members
  - 19 Appointed members plus Directors of NIH & AHRQ

Methodology Committee
- 15 members
PCORI’s Core Duties

• Establish national research priorities
• Establish and carry out a research project agenda
• Develop and update methodological standards
• Provide a peer-review process for primary research
• Disseminate research findings
PCORI Timeline

- **PCORI’s Establishment**
  - September 2010 – January 2011

- **Organizational Development**
  - January 2011 – June 2011

- **Setting Initial National Research Priorities**
  - July 2011 – June 2012

- **Establishing PCOR Agenda, Generating Knowledge, Disseminating Findings, and Updating Priorities**
  - July 2012 -
PCORI’s Establishment

Sep. 2010 - Jan. 2011

- Mar. 2010 – Created by Patient Protection and Affordable Care Act (Subtitle D, Sec. 6301)
- Sep. 2010 – GAO Appoints PCORI Board of Governors
- Nov. 2010 – PCORI Incorporated as Independent Not-For-Profit Entity
- Jan. 2011 – GAO Appoints Methodology Committee
Organizational Development
• Mission Defined
• Governance and Financial Systems Established
• Standing Committees Created
• Public Board Meetings
• Stakeholder Engagement
• Annual Operating Plan and Budget Approved
• Methodology Workgroups Created
• Executive Director Hired
• Website expanded: www.pcori.org
Setting Initial National Research Priorities


- Priorities informed by:
  - Stakeholder Engagement
  - Landscape Reviews
  - Pilot Projects
  - Conference Grants
  - Methodology Committee Report

- Extensive public comment

- To be approved by Board of Governors
July 2012 –

- Full research arsenal
- Informed by national priorities
- Methodological standards defined and updated
- Collaboration with AHRQ, NIH, and others
- Close gap between availability of information and uptake
- Stakeholder engagement throughout
- Extensive public comment
- To be approved by Board of Governors
Patient and Stakeholder Engagement

- Direct engagement around public Board meetings
  o Discussion forums and small-group meetings

- Informational presentations
  o PCORI representatives have presented at 20 meetings since March

- Opportunities for public input
  o Going beyond statutory requirements to solicit feedback throughout

- Expanding website
  o Redesigned site launched in September
Opportunities for Nursing

• Input: Current and Emerging
• Employment
• Funding
• Reviewers
• Advisory Panels
Public Input: PAST Opportunities

• Working Definition of “Patient-Centered Outcomes Research”
  o 45-day input period through Sept. 2

• Initial Topics for Pilot Projects
  o 30-day input period through Aug. 31

• These solicitations for input go beyond PCORI’s statutory requirements

• Demonstrates PCORI’s commitment to patient and stakeholder involvement throughout our work

• Rare for researchers and the public to get the chance to preview and influence what a call for applications may contain

• This transparency and access will be typical of PCORI

• Webform, email and mail feedback options provided through http://pcori.org/provideinput.html
Public Input: Current/Emerging

- Defining Research Priorities
- Public Comment Periods at Face to Face meeting
  - Live
  - Via Webinar
  - In writing
  
http://www.pcori.org/

http://www.pcori.org/provide-input/
Proposed Timeline for National Priorities

- Develop Candidate Framework: Currently Underway
- Engage Stakeholders: September-November
- Public Comment: December-February
- Finalize National Priorities: March
Employment

PCORI is an equal opportunity / affirmative action employer committed to cultural diversity in the workplace

• Expecting a staff of 40

• Current Openings
  • Director of Communications
  • Director of Finance
  • Director of Patient Engagement
  • Director of Stakeholder Engagement
  • PCORI Scientist
PCORI’s Long-Term Home
1828 L Street, DC

- $48 per sq. foot
- Attractive, not extravagant
- 13,000 sq feet
- Close to Metro
- Green building
- Move-in: February
Hot off the press!!!
http://www.pcori.org/funding-opportunities/

Existing Calls: “Contracts”

- Review and Synthesis of Evidence for Eliciting the Patient’s Perspective in Patient-Centered Outcomes Research (Literature Review) (Deadline to provide notice of intent to respond to solicitation: Sept. 15, 2011)

- Expert Stakeholder Interviews to Identify Evidence for Eliciting the Patient’s Perspective in Patient-Centered Outcomes Research (Interviews) (Deadline to provide notice of intent to respond to solicitation: Sept. 15, 2011)

- Methods for Setting Priorities in Research (White Papers) (Deadline to provide notice of intent to respond to solicitation: Sept. 15, 2011)
PCORI Pilot Projects Grants Program

Purpose:

• **National Priorities** – provide information to PCORI that informs future iterations of national research priorities for patient-centered outcomes research.

• **Research Agenda** – support the collection of preliminary data to advance the field of patient-centered outcomes research, providing the platform for an evolving PCORI research agenda.

• **Methodologies** – support identification of research methodologies that advance patient-centered outcomes research
Applicants must address at least one eight areas of interest, six of which speak directly to patient engagement:

- Stakeholder involvement is required unless the application can sufficiently explain why it is not feasible.
- Expect to commit approximately $13 million in FY 2012 to support approximately 40 projects.
- Applicants can propose project periods of up to two years. Second year funding is subject to noncompetitive review by PCORI staff.
- Direct costs are limited to $250,000 per year with an additional 40% of salary and fringe allowable as indirect costs.
- Letters of intent are due on Nov. 1 with applications due on Dec. 1.
- NIH will conduct the merit review process with all other aspects of grant awards and grants management handled by PCORI.
Pilot Projects

• Request for applications (RFA) released September 28, 2011

• Eight (8) initial topics identified for the pilot projects, focusing on developing, testing or evaluating approaches that:
  o inform the national priorities
  o bring together different stakeholders in all stages of a research process
  o translate research into practice
  o identify gaps in evidence that most affect vulnerable populations
  o identify predictors of patient outcomes
  o elucidate behaviors, lifestyles, and choices within patient control that may influence their outcomes
  o study patient-clinician interaction
  o assess strategies that respect patient autonomy and promote informed decision-making, incorporating the best healthcare knowledge into the application of care
### Areas of Interest

- **Developing, testing, refining, and/or evaluating new or existing methods** (qualitative and quantitative) and approaches that can inform the process of establishing and updating national priorities for the conduct of patient-centered outcomes research (PCOR). This may include research prioritization approaches (such as Value of Information (VOI), burden of illness, peer review/expert opinion/Delphi approaches) or methods for incorporating the perspectives of patients or other stakeholders into the development of national priorities.

- Developing, testing, refining, and/or evaluating **patient-centered approaches**, including decision-support tools, for translating evidence-based care into health care practice in ways that account for individual patient preferences for various outcomes. This may include developing or comparing conceptual models of translation or dissemination of CER research findings from the patient perspective.

- Developing, refining, testing, and/or evaluating methods to **identify gaps in CE knowledge** such as tools for the ongoing collection and assessment of gaps as perceived by patients and providers. Of special interest are gaps that are particularly relevant to vulnerable populations, including but not limited to, low-income populations; minorities; children; elderly; women; people with disabilities, chronic, rare and/or multiple medical conditions.
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<th>Areas of Interest</th>
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<td><strong>Identifying, testing, and/or evaluating patient-centered outcomes instruments.</strong> This may include predictive tools (eg: instruments that measure or predict outcomes of interest to patients) or identifying standards for measurement properties of patient-reported outcomes for use in comparative effectiveness research, across a variety of interventions and patient populations.</td>
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<td><strong>Identifying, testing, and evaluating methods that can be used to assess the patient perspective when researching behaviors, lifestyles, and choices within the patient’s control that may influence their outcomes.</strong></td>
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<td><strong>Advancing analytical methods for CER.</strong> Examples include but are not limited to the incorporation of mixed methods research designs (qualitative/quantitative), identifying existing methodology to statistically accommodate irregularly spaced multivariate longitudinal data, the use of instrumental variables; and potential solutions for assessing treatment heterogeneity in observational and randomized CER studies.</td>
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# Key Dates and Link to Details

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<tr>
<th>Date</th>
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<tr>
<td>October 18, 2011</td>
<td>Webinar for interested applicants</td>
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<td>November 1, 2011</td>
<td>Letters of Intent are required and must be received on or before this date</td>
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<td>December 1, 2011</td>
<td>Grant applications must be received on or before this date</td>
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<td>December 2011</td>
<td>Completeness/Compliance/Eligibility</td>
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<td>February 2012</td>
<td>Merit Review</td>
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<td>March 2012</td>
<td>Reviewed Projects provided to PCORI Board for Selection</td>
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<tr>
<td>May 2012</td>
<td>Award notification &amp; funding</td>
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Announcement and Application Materials: [pcori.org/funding-opportunities/](http://pcori.org/funding-opportunities/)
Webinar & Inquiry Process

- Webinar for Applicants: October 12, 2011 at 2PM EST.

- Policy for responding to inquiries:
  - A set of FAQs will be developed and issued along with the PFA with frequent updates posted on the PCORI website. Questions and answers will be framed in terms of general applicability.
  - Inquiries should be directed to the PCORI website at pcori.org. PCORI staff and appropriate consultants will receive, triage, route, and ensure answers are provided and shared generally through the website.
Another Opportunity

- PCORI Reviewers
  - Plan to bring on potentially up to 1000 reviewers
- Traditional and Nontraditional
  - Process for identification
    - NIH & AHRQ
    - Self Nomination
    - Referrals
PCORI Advisory Panels

- Advisory Panels will provide advice and make recommendations to PCORI, and help inform decisions of the Board of Governors, the Methodology Committee and Institute staff.

- Advisory Panel members can advise in shaping priorities, developing the research agenda, refining research questions and informing study design.

- Stakeholder-specific panels will be populated by individuals with similar experience and expertise, be they patients, consumers, caregivers, providers, policy makers, or industry representatives.

- Multi-Disciplinary panels will be populated by individuals representing a “mix” of patients, caregivers and professionals, perhaps with a disease-specific focus, or an outcome-specific focus, or a life circumstance in common.
PCORI Advisory Panel
Charter Template - DRAFT

Subject Matter:
- Questions to be asked.
- Problems to be addressed.
- Topics to be discussed.

Duration:
- Charter Start Date: __________
- Charter End Date: __________
- (Not to exceed 2 yrs duration)

Membership Type:
- □ Individual Discipline
- □ Multi-Disciplinary
- (Check One)

Experience:
- □ Active Patient
- □ Former Patient
- □ Chronic Patient
- □ Caregiver
- □ Consumer
- □ Clinicians
- □ Other Professionals
- □ Policy Makers
- □ Advocates
- (Check All That Apply)

Membership Roster:
1. 7.
2. 8.
3. 9.
4. 10.
5. 11.

Content:
- In Scope:
- Out of Scope:

Meeting Frequency / Schedule:

Stage I Board Approval (Required): _______(date)
Stage II Board Approval (at Board Discretion): _______(date)
Thank You

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