Patient-Centered Outcomes Research Institute

PCORI Funding Announcement (PFA): Registration & Letter of Intent

September 2012
I. Introduction to PCORI
- About PCORI, National Priorities, and the Research Agenda
- Overview of the PCORI Funding Announcements

II. Letter of Intent Process and Requirements
- Overview of Preliminary Application Requirements
- Overview of the PCORI Online Letter of Intent (LOI) Process
- Overview of Budget Requirements

III. Common FAQs
## Key Dates

<table>
<thead>
<tr>
<th>Action</th>
<th>Cycle I</th>
<th>Cycle II</th>
<th>Cycle III</th>
</tr>
</thead>
<tbody>
<tr>
<td>PFA Release Date</td>
<td>May 22, 2012</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Online System Opening Date</td>
<td>June 1, 2012</td>
<td>September 15, 2012</td>
<td>January 15, 2013</td>
</tr>
<tr>
<td>Informational Webinars</td>
<td>June and July 2012</td>
<td>October – November 2012</td>
<td>February – March 2013</td>
</tr>
<tr>
<td>(Specific dates to be posted on pcori.org)</td>
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<tr>
<td>Application Deadline</td>
<td>July 31, 2012</td>
<td>December 17, 2012</td>
<td>March 31, 2013</td>
</tr>
<tr>
<td>Awards Announced</td>
<td>December 31, 2012</td>
<td>April 2013</td>
<td>August 2013</td>
</tr>
<tr>
<td>Earliest Start Date</td>
<td>January 2013</td>
<td>May 2013</td>
<td>September 2013</td>
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### Important PCORI Websites:

<table>
<thead>
<tr>
<th>Area</th>
<th>URL</th>
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</thead>
<tbody>
<tr>
<td>General Announcements</td>
<td><a href="http://www.pcori.org">www.pcori.org</a></td>
</tr>
<tr>
<td>Contact for any questions</td>
<td><a href="http://www.pcori.org/funding-opportunities/contact">http://www.pcori.org/funding-opportunities/contact</a></td>
</tr>
<tr>
<td>Application Center</td>
<td><a href="http://www.pcori.org/funding-opportunities/funding-announcements/apply/">http://www.pcori.org/funding-opportunities/funding-announcements/apply/</a></td>
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<tr>
<td></td>
<td>• Application Guidelines</td>
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<td>• Glossary of Key Terms</td>
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<td>• Budget Template &amp; Allowable Costs</td>
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<td></td>
<td>• FAQs</td>
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<tr>
<td></td>
<td>• Apply Online</td>
</tr>
<tr>
<td>Apply to be a Reviewer</td>
<td><a href="http://www.pcori.org/get-involved/reviewers/">http://www.pcori.org/get-involved/reviewers/</a></td>
</tr>
<tr>
<td>PFAs</td>
<td><a href="http://www.pcori.org/funding-opportunities/funding-announcements/">http://www.pcori.org/funding-opportunities/funding-announcements/</a></td>
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Apply to be a Reviewer!

PCORI invites all professionals who are interested in Patient-Centered Outcomes Research (PCOR) to apply to be a scientific or a stakeholder reviewer through our website: http://www.pcori.org/get-involved/reviewers/

Sample screen shot of the Reviewer Application page:
About PCORI

PCORI was created by the Patient Protection and Affordable Care Act of 2010.

It is a non-profit, non-governmental organization.

**PCORI’s Mission**

PCORI helps people make informed health care decisions and improves healthcare delivery and outcomes by producing and promoting high integrity, evidence-based information that comes from research guided by patients, caregivers, and the broader healthcare community.
**PCORI’s National Priorities**

<table>
<thead>
<tr>
<th>Purpose</th>
<th>Methodologies</th>
<th>Research Agenda</th>
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<tbody>
<tr>
<td>Provide information to PCORI that informs future iterations of national research priorities for patient-centered outcomes research.</td>
<td>Support identification of research methodologies that advance patient-centered outcomes research</td>
<td>Support the collection of preliminary data to advance the field of patient-centered outcomes research, providing the platform for an evolving PCORI research agenda. PCORI’s initial Research Agenda is as follows:</td>
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<tr>
<td>The National Priorities are:</td>
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<tr>
<td>• Comparative Assessments of Prevention, Diagnosis, and Treatment Options</td>
<td></td>
<td>• Comparisons of Prevention, Diagnosis, and Treatment Options</td>
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<tr>
<td>• Improving Healthcare Systems</td>
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<td>• Improving Healthcare Systems</td>
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<tr>
<td>• Addressing Disparities</td>
<td></td>
<td>• Communication &amp; Dissemination</td>
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<tr>
<td>• Accelerating Patient-Centered and Methodological Research</td>
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<td>• Accelerating Patient-Centered and Methodological Research</td>
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PCORI FUNDING ANNOUNCEMENTS
PCORI’s Four PFA Areas

PCORI Funding Announcements (PFAs) focus on four areas of research addressing currently unmet needs of patients, their caregivers, clinicians, and other healthcare system stakeholders.

- Assessment of Prevention, Diagnosis, and Treatment Options
- Improving Healthcare Systems
- Communication and Dissemination Research
- Addressing Disparities
Projects that address critical decisions that patients, their caregivers, and clinicians face with too little information

In this PFA we seek to fund projects that:

• Address critical decisions that face patients, their caregivers, and clinicians every day and with too little information

• Address consequential decisions now occurring without key evidence about the comparative effectiveness of two or more options

• Benefit patients/caregivers with new knowledge in ways that are clear and important

Available funds: $48 Million
Expected awards: 54 awards
Maximum project period: 3 years
Letters of Intent due: October 15
Applications due: November 30
Initial funding period: Spring 2013
Projects that address critical decisions that face healthcare systems, the patients and caregivers who rely on them, and the clinicians who work within them

In this PFA we seek to fund projects that:

- **Address critical decisions that face healthcare system leaders and policymakers, clinicians, and the patients and caregivers who rely on them**

- **Offer substantial potential that patients/caregivers will benefit from the new knowledge in ways that are important**

**Available funds:** $24 Million  
**Expected awards:** 27 awards  
**Maximum project period:** 3 years  
**Letters of Intent due:** October 15  
**Applications due:** November 30  
**Initial funding period:** Spring 2013
Communication and Dissemination Research

Projects that address critical elements in the communication and dissemination process among patients, their caregivers and clinicians.

In this PFA we seek to fund projects that:

- Address critical knowledge gaps in the communication and dissemination process

- Gaps to consider:
  - The communication and dissemination of research results to patients, their caregivers, and clinicians
  - The communication between patients, caregivers, and clinicians in the service of enabling patients and caregivers to make the best possible decisions in choosing among available options for care and treatment

Available funds: $12 Million
Expected awards: 14 awards
Maximum project period: 3 years
Letters of Intent due: October 15
Applications due: November 30
Initial funding period: Spring 2013
Addressing Disparities

Projects that will inform the choice of strategies to eliminate disparities

In this PFA we seek to fund projects that:

• **Will inform the choice of strategies to eliminate disparities**
  ➢ *We are not interested in studies that describe disparities; instead, we want studies that will identify best options for eliminating disparities*

• **Focus on areas of importance to patients and their caregivers, where there are critical disparities that disadvantage members of a particular group and limit their ability to achieve optimal, patient-centered outcomes**

Available funds: $12 Million
Expected awards: 14 awards
Maximum project period: 3 years
Letters of Intent due: October 15
Applications due: November 30
Initial funding period: Spring 2013
PRELIMINARY CHECK
To be eligible for funding opportunities be sure that:

1. The project is relevant to our working definition of Patient-Centered Outcomes Research.
2. The project falls within the four areas of interest described in the PFAs.
3. Stakeholders are engaged as partners in the research.
4. Applications must be eligible, follow all of the instructions, have submitted the LOI and application on time, and meet human subjects and budget requirements.*

*International researchers are eligible to apply with no additional requirements.
Partnerships and Stakeholders

PCORI requires stakeholder involvement unless the applicant sufficiently explains why such an arrangement is not feasible.

Projects must include stakeholders as partners with significant involvement at all appropriate stages of the project.

Who are stakeholders?

- Patients and caregivers
- Patient and caregiver organizations
- Clinicians and clinician organizations
- Organizational providers
- Purchasers and payers
- Industry
- Researchers
- Policymakers
- Training Institutions
- Any others who can bring insight
REGISTERING FOR PCORI ONLINE
PCORI’s online system was developed to assist in the creation and submission of your Letters of Intent (LOIs) and applications. You must use the PCORI Online system to submit LOIs and applications.

How to Register for PCORI Online
To apply for PCORI research project funding, you must first register. To do so, please go to http://contracts.pcori.org/.

Click on “Register here” to begin your registration.
PCORI Online System

Enter all required fields to register

*Note that your e-mail address will serve as your login name.
LETTER OF INTENT PROCESS: PCORI ONLINE
Letters of Intent (LOIs)

An LOI must be submitted by 5:00 PM EST October 15, 2012 in order to apply for a PFA

- Descriptive title of proposed research
- Legal name of the applicant organization
- Name, institutional affiliation address, and telephone number of the Principal Investigator
- Names and institutional affiliations of other key personnel and significant contributors
- Participating institutions and organizations
- A brief summary of the proposed research questions and methods
- A paragraph describing the significance of the research project relative to the stated goals of the PFA being applied to
- Identify the area of interest(s) the proposed project will address
- Contact information for an institutional official that PCORI may contact about the application
PCORI Online System Homepage Tabs

- My Tasks: a list of tasks that must be completed in the system
- My Contracts: view details for each of your PCORI contracts
- Profile: view/update your contact information
- Apply for Funding: apply for PCORI contracts
LOI Creation and Submission

Note: Submission of the LOI is required prior to submitting a full application. LOIs will be used to gauge interest and plan our review process. The LOIs will not be used to vet proposals.

- After log in, you will land on a PCORI Online page with the “Apply for Funding” tab.
- To start the submission of your LOI, click on the PFA you would like to apply for:
Create and Submit LOI

LOI Main Page

- Use the left-side navigational links to guide you through LOI creation and submission
- The Validation Summary informs you of the status of each component of your LOI
- On each component page, use the “Save” and “Save and Continue” buttons to save your work and to continue to the next section of the LOI. You must save your information before navigating away, or work will be lost.
- Fields marked with a red asterisk (*) are required

The Validation summary (displayed below) will provide the status of the completeness of each section. Click the “Review and Submit” link to review your entry before submitting.

<table>
<thead>
<tr>
<th>Project Information</th>
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<tbody>
<tr>
<td><strong>Program</strong></td>
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<tr>
<td><strong>Funding Opportunity</strong></td>
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<tr>
<td><strong>Funding Cycle</strong></td>
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<tr>
<th>Validation Summary</th>
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<tr>
<td><strong>Page Name</strong></td>
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<tr>
<td>PI Information</td>
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<tr>
<td>Project Information</td>
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<tr>
<td>Upload</td>
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<tr>
<td>Key Personnel</td>
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<tr>
<td>Additional Information</td>
</tr>
</tbody>
</table>
Create and Submit LOI

Principal Investigator (PI) Contact Information

- Enter/update the PI’s contact information, including name, organization, address, phone, and email
- If Grantee Organization does not exist in the PCORI system, you will be required to enter additional organization information (name, DUNS/EIN #, address, organization type)
Project Information

Enter/update Project Information details, including title, start and end dates, projected amount requested, and technical abstract.

Instructions
If your Letter of Intent/Application includes a projected budget of $500,000 or more (of Direct Costs) during any year of the project, you must fill out a budget template and request permission before submitting your application. The budget template can be found at: http://www.pcori.org/assets/FPA-Budget-Template.xls Requests for permission should be made here: http://www.pcori.org/funding-opportunities/contact.

Program
Improving Healthcare Systems
Funding Opportunity
Improving Healthcare Systems
Funding Cycle
LOIs due October 16, 2012 | Applications due November 30, 2012

Project Details

Project Title

Are Direct Costs requested greater than $500k during any year of the project?
<Select> ▼

Is the Project Length greater than 3 years?
<Select> ▼

Technical Abstract

Limit: 3000 characters
Remaining: 3000

Save  Save and Continue
Create and Submit LOI

Technical Abstract

A technical abstract must be provided, and should be written so that it can be separated from the application and the project still fully understood. It must include:

– **Background:** State the problem or question the research is designed to address
– **Objectives:** Briefly describe the specific aims of the study, including the specific research question(s) and the long-term objectives
– **Methods:** Give a concise description of the study population, sample size, and analytic methods that will be employed
Create and Submit LOI

Key Personnel

- Enter Key Personnel information, including name, contact information, and role
- If Grantee Organization does not exist in the PCORI system, you will be required to enter additional organization information (name, DUNS/EIN #, address, organization type)

Instructions

Add additional key personnel by performing the following actions:

- Click on the "Add" button below.
- Click the "Edit" button to make changes to a key person.
- Click the "Delete" button to remove personnel.
- Click the "Continue" button to be taken to the next section of the LOI.

Definition of Senior/Key Personnel – Individuals who contribute to the scientific development or execution of the project in a substantive and measurable way. The contribution is independent of financial compensation.

Please note that "Organization and DUNS #" is a required field for key personnel. If a DUNS # needs to be requested at this time, you may omit the key personnel for the purpose of submitting the LOI timely. Then later at the application stage, add the key personnel once the DUNS # is established.

Primary Contact/PI

<table>
<thead>
<tr>
<th>Name</th>
<th>Maceray, Muireann</th>
</tr>
</thead>
<tbody>
<tr>
<td>Organization</td>
<td></td>
</tr>
</tbody>
</table>

Personnel List

Add

Continue

Once the Key Personnel list is created, use it to view Key Personnel information and add, edit, or delete any entries.
Additional Project Information

You will be required to answer the following questions related to your project:

– What diseases or conditions does your proposal address? *Choose all that apply.*
– Does your proposal include a vulnerable and/or underserved population? *Yes/No.*
– What specific area of the PCORI priorities does your application address? (See [www.pcori.org/priorities](http://www.pcori.org/priorities) for a list of PCORI priorities.) *Select from list.*
– What study design does your research utilize? *Choose all that apply.*
– Does your application include any of these specific analytic methods? *Choose all that apply.*
– Are you interested in becoming a PCORI Reviewer? *Yes/No.*
– Etc. - *complete list of questions can be found on the Additional Information Page*
Create and Submit LOI

Review and Submit

– Click “View PDF” to view the full LOI as a PDF
– “Validation Status” informs you of the completion of each section. When all sections are complete, click the “Submit” button

Submission

View Full Submission

View PDF

Project Information

Program: Improving Healthcare Systems
Funding Opportunity: Improving Healthcare Systems
Funding Cycle: LOIs due October 15, 2012 | Applications due November 30, 2012

Validation Status

<table>
<thead>
<tr>
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<th>Status</th>
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<tbody>
<tr>
<td>PI Information</td>
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<tr>
<td>Project Information</td>
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</tr>
<tr>
<td>Key Personnel</td>
<td>✓ Complete</td>
</tr>
<tr>
<td>Additional Information</td>
<td>✓ Complete</td>
</tr>
</tbody>
</table>
## Budget Requirements

### Human Subjects
- PCORI adopts the human subjects requirements of HHS
- IRB approval must be received prior to award

### Allowable Costs
- Salaries (PI salary cap is $200,000 per full year) plus fringe
- Consultant fees
- Equipment
- Supplies
- Project-related travel
- Consortium/Contractual direct costs

### Indirect Costs
- Limited to 40% of direct costs and other allowable costs excluding equipment.
- Indirect costs for subcontracts may not exceed $25,000

### Direct Costs
- Maximum of $500,000 year.
- If greater than $500K, you must fill out the formal request in PCORI Online
PCORI requires that budgets exceeding $500,000 per annum seek pre-approval prior to submitting an application.

To seek approval:

- Please respond to the applicable “Over 500K” question field in the application.
- Include a clear explanation of why your budget exceeds the limit.

PCORI will convene to discuss these proposals and provide approval prior to the application deadline.
FREQUENTLY ASKED QUESTIONS
May I speak to a scientist regarding the suitability of my application?

PCORI will consider studies that are comparative and that include patient-centered outcomes. We encourage you to carefully read the PCORI Funding Announcements (PFAs) and other background material on our website to understand our goals and the PFA you are considering.

PCORI encourages open communication while ensuring each applicant has equal access to information. We implemented an online inquiry system where questions will be answered as soon as possible. All information is made equally available to all interested parties on the FAQ webpage.

Please visit the PCORI website to view the FAQs:

http://www.pcori.org/funding-opportunities/funding-announcements/faq/
Thank you for taking this training. PCORI will provide additional application webinars throughout the fall – details forthcoming and will be posted at www.pcori.org