December 2013 Funding Cycle

PCORI Funding Announcement:
Improving Methods for Conducting Patient-Centered Outcomes Research

This PCORI Funding Announcement applies to the funding cycle that closes December 16, 2013. Application guidelines, templates, and other resources are available at pcori.org/PFA/methods.
About PCORI

PCORI is committed to transparency and a rigorous stakeholder-driven process that emphasizes patient engagement. PCORI uses a variety of forums and public comment periods to obtain public input to enhance its work. PCORI helps people make informed healthcare 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 was authorized by the Patient Protection and Affordable Care Act of 2010 as a non-profit, nongovernmental organization. PCORI’s purpose, as defined by the law, is to help patients, clinicians, purchasers, and policy makers make better informed health decisions by “advancing the quality and relevance of evidence about how to prevent, diagnose, treat, monitor, and manage diseases, disorders, and other health conditions.”
### Overview

<table>
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<tr>
<th>Published</th>
<th>September 5, 2013</th>
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<tr>
<td>Letter of Intent Due</td>
<td>October 15, 2013 by 5:00 pm ET. October 15, 2013 by 5:00 pm ET. Upon receipt, PCORI program staff will screen Letters of Intent for programmatic fit. An applicant whose Letter of Intent does not meet program areas of interest will not be invited to submit a full application. PCORI encourages prospective applicants to contact us with questions prior to the deadline. See &quot;Contact Us&quot; below for additional details.</td>
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<tr>
<td>Summary</td>
<td>In this PFA we seek studies to address gaps in methodological research relevant to conducting PCOR. Results of these studies will inform future iterations of the Methodology Committee report and its standards. The improvement of existing methods will benefit all stakeholders, including researchers planning investigations, policy makers weighing the value of healthcare interventions; and patients, clinicians, and caregivers facing healthcare decisions.</td>
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<td>Applicant Resources</td>
<td>See pcori.org/PFA/methods</td>
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<td>Key Dates</td>
<td>Online System Opens</td>
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<td>Letter of Intent (LOI) Due</td>
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<td>Applicant Town Hall Session (Event webinar will be archived post event)</td>
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<td>Earliest Start Date</td>
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<tr>
<td>Maximum Budget (Direct Costs)</td>
<td>$750,000 total direct costs</td>
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<td>Maximum Project Period</td>
<td>3 Years</td>
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<td>Funds Available Up To (Direct Costs)</td>
<td>$8 million. Because the nature and scope of the proposed research is expected to vary widely from application to application, it is anticipated that the size and duration of each award will also vary. PCORI reserves the right to change the funds available at any time.</td>
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<td>Eligibility</td>
<td>Applications may be submitted by any private sector research organization, including any non-profit or for-profit organization and any public sector research organization, including any university or college; hospital or healthcare system; laboratory or manufacturer; unit of state or local government. All US applicant organizations must be recognized by the Internal Revenue Service. Foreign organizations and nondomestic components of organizations based in the United States may apply, as long as there is demonstrable benefit to the US healthcare system, and US efforts in the area of patient-centered research can be clearly shown. Organizations may submit multiple applications for funding. Individuals may not apply.</td>
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<tr>
<td>Review Criteria</td>
<td>1. Impact on the field of PCOR methods</td>
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<td>2. Potential for the study to Improve PCOR methods</td>
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<td>3. Technical merit</td>
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<td>4. Patient-centeredness</td>
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<td>5. Patient and stakeholder engagement</td>
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<tr>
<td>Other</td>
<td>Deadlines are at 5:00 PM ET. If deadlines fall on a weekend or a federal holiday, the deadline will be the following Monday or the next day after the federal holiday.</td>
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To propose a project budget that is greater than the direct costs or maximum project period listed for a PFA, submit a request by the LOI deadline using the templates provided above.

<table>
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<th>Contact Us</th>
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<tbody>
<tr>
<td>Please email (<a href="mailto:pfa@pcori.org">pfa@pcori.org</a>), phone (202-627-1884), or contact us online (<a href="http://www.pcori.org/PFA/inquiry">http://www.pcori.org/PFA/inquiry</a>) if you have questions regarding this PCORI Funding Announcement or would like to schedule a call with program staff.</td>
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PCORI will provide a response within 72 hours. However, PCORI cannot guarantee that all questions will be addressed 72 hours prior to a Letter of Intent or application deadline.
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1. Request for Proposals

Summary
In this PCORI Funding Announcement (PFA), we seek studies to address gaps in methodological research relevant to conducting PCOR. Results of these studies will inform future iterations of the Methodology Committee report and its standards. The improvement of existing methods will benefit all stakeholders, including researchers planning investigations, policy makers weighing the value of healthcare interventions; and patients, clinicians, and caregivers facing healthcare decisions.

Background
The availability of multiple options for treatment, prevention, and diagnosis in health care presents a significant challenge to patients and clinicians trying to make informed care decisions. Deciding between alternative options in health care requires an understanding of how to balance the benefits and risks of each treatment option and understanding how each option may apply differently to patients given their unique personal characteristics. PCORI was created with the promise of enhancing the ability of people who are making decisions about health care to fully understand and weigh these options.

To address this challenge, PCORI seeks to fund proposals emphasizing research into the methods used in the conduct of patient-centered outcomes research (PCOR). PCORI and its Methodology Committee recognize the need to better understand and advance the appropriate and efficient use of these methods. Strong methods will support the generation of research findings that can be trusted to directly improve patients’ healthcare outcomes.

The importance of understanding the methods underlying research findings for all healthcare stakeholders involved in making healthcare decisions can be illustrated in several ways. Firstly, patients’ healthcare issues have become more complex, in part due to an aging population and patients living with multiple conditions. Secondly, the availability of different types of treatment options has increased markedly over the past decades, offering a sometimes bewildering number of options to patients and their clinicians. Other developments, such as the increasing use of research findings by healthcare delivery systems to inform their policies, as well as the advances in personalized medicine, present further methodological challenges to PCOR. Together, these factors contribute to making decisions for patients and their clinicians more complex and underscore the importance of understanding the methods behind the research findings. An understanding of how the research study was designed and conducted is critically important in determining...
whether the research finding should be used by patients and caregivers when healthcare decisions need to be made.

PCORI was created to support research that provides relevant information to patients and clinicians. Research findings that can be trusted must be valid, rigorous, patient-centered methods for research. PCORI’s founding legislation contained a provision to set up a 17-member Methodology Committee, whose charge is “to develop and improve the science and methods of comparative clinical effectiveness research” and to produce “methodological standards for research.” These standards are intended to support the generation of patient-centered health interventions. The draft Methodology Report contains the first set of recommended selected standards for the conduct of PCOR. The report describes the rationale behind creating standards for patient-centeredness; for prioritizing topics for research; for choosing a study design (including the first edition of the translation table); and for designing, conducting, and reporting PCOR. It also highlights gaps in the evidence that PCORI’s program of methodological research should address.

PCORI is releasing this funding announcement to begin addressing the methodological gaps in PCOR identified by the Methodology Committee. Findings from these research studies on methods will inform future iterations of the Methodology Committee report and its standards. The improvement of existing methods will benefit all stakeholders, including researchers; policy makers; and patients, clinicians, and caregivers facing decisions.

Research Areas of Interest

The Improving Methods for Conducting Patient-Centered Outcomes Research program is interested in the following broad topical areas:

- Research in patient-centeredness. This will include research that identifies optimal methods for engaging patients in the research process, and methods for evaluating the impact on research outcomes of patient engagement in the research process. This also includes research that determines methods for assuring study questions, outcomes, and interventions are meaningful to patients and other stakeholders.
- Research in methods for conduct of systematic reviews of patient-centered comparative effectiveness research topics.
- Research in generating, selecting, and prioritizing topics for research as well as research into the inclusion of patients and stakeholders in the peer review process.
- Research that aims to improve the validity and/or efficiency of analytic methods for comparative effectiveness research (e.g., approaches for strengthening causal inference in observational and randomized studies; approaches to identifying and confirming heterogeneity in risk factors, disease prevalence and treatment effects).
- Research that determines the validity and efficiency of data sources commonly used in PCOR. For example, research that seeks to improve the volume, completeness, comprehensiveness, accuracy, and efficiency of use of clinical data collected across healthcare systems, clinical data networks, registries, or payer databases, and the utility of this data for conducting longitudinal studies of patient outcomes; or research that develops and promotes the utility, performance, and efficiency of large clinical data networks or registries for supporting patient-centered
outcomes research for patients with rare diseases.

- Research to support the routine and systematic collection of key patient-reported and patient-centered outcomes. Research on methods to elicit patient preferences in regard to how they value the benefits and harms of alternative interventions.
- Research in methods to enhance the reproducibility, transparency, and replication of PCOR research.

Please note that proposals to develop or expand large clinical data networks to support PCOR are not solicited in this funding announcement.

Sample Research Topics
PCORI is interested in supporting research that has the potential to impact the field of PCOR Methods and has the potential to provide methodological advances that will generate information that patients need to make decisions. Proposed research should be justified with specific references to gaps identified in the draft Methodology Report or published scientific literature. Applicants are further encouraged to refer to PCORI’s Methodology Standards\(^3\) to develop their research question(s) and research plan.

Below are examples of the research topics that PCORI seeks to support. Many of these topics were identified as gaps in need of further research in the draft Methodology Committee Report. The list is not exhaustive, and applicants may submit other questions that can advance the field of PCOR.

   - Development of comprehensive typologies or inventories of methods for achieving effective patient and stakeholder engagement.
   - Research on the most effective methods for engaging patients and stakeholders in the research process, with attention to factors such as clinical condition, care setting, study design, or other relevant factors. Specific examples may include methods for building trust with patients and organizations and for partnering with organizations and communities; methods for engaging patients and stakeholders in all phases of research; methods to translate and scale successful local engagement processes.
   - Research on methods for selecting patients and stakeholders for engagement in the research process. Specific examples may include: methods for engaging patients and stakeholders who are underrepresented or hard to reach, or who are in different settings (such as primary care, long-term care, acute care setting, hospices), and methods to understand the appropriate role of surrogates.
   - Research on methods to balance and reconcile input from various stakeholder groups in design, conduct, and dissemination of PCOR.
   - Research on methods for assuring study questions, outcomes, and interventions are meaningful to patients and other stakeholders.

\(^3\) Available at pcori.org/assets/PCORI-Methodology-Standards.pdf
• Research on issues related to human subjects protections, including but not limited to IRB review of PCOR studies and informed consent.

2. **Research in methods to conduct systematic reviews of patient-centered CER.**

• Research on methods for improving the validity of systematic reviews of CER.
• Research on methods for improving the efficiency of systematic reviews without compromising validity.

3. **Development of methods for generating, selecting, and prioritizing topics for research and for including patients and stakeholders in the peer-review process.**

• Review or development of methods for patient and stakeholder engagement in topic generation.
• Evaluation of the employment of research gap analysis to continue to develop the empirical evidence on its use.
• Development of methods to improve and/or compare research prioritization methods, including Value of Information (VOI) approaches. Given the limited evidence available in the area of prioritization, PCORI is particularly interested in applications on this topic. The evaluation of different stakeholder panel sizes and compositions in prioritization is also of interest.
• Research on the effect of alternative approaches to managing bias and conflict of interest in topic prioritization and peer review of proposals.

4. **Development and refinement of general analytic methods.**

**Methods related to causal inference:**

• Development of innovative ways to identify and recruit new users of interventions for research studies.
• Development of methods to study complex interventions in experimental and observational research.
• Comparison of the validity of different methods for reducing confounding and bias using randomized controlled trials (RCT) and registry studies.
• Development and dissemination of software needed for sensitivity analyses and approaches to evaluating the assumptions underlying complex analyses, such as instrumental variable analyses.
• Development and dissemination of methods for adequate analysis of data in cases where the treatment/exposure varies over time.
• Development of a consensus for the types and quantity of target parameters causal inference should estimate in order to be most informative for a range of decision makers, including patients, providers, payers, and industries/manufacturers.
Methods related to Heterogeneity of Treatment Effect (HTE):

- Development of analytic approaches to help support methods guidance for predictive approaches to HTE, as well as for subgroup analysis with a focus on their use for PCOR.
- Development of methods to help support guidance for HTE analyses in comparative effectiveness trials.
- Development and evaluation of methods for HTE analyses that consider the predicted level of non-adherence to a given healthcare intervention.
- Research on methods to help support the development of guidance on the use of Bayesian methods in HTE analyses and appropriate outcome scale for HTE analysis (e.g., risk difference, risk ratio, log of odds-ratio).
- Research on methods to help support the development of guidance for analyses for HTE in observational studies.
- Review of standards for decision analysis and simulation modeling with respect to HTE analysis.

Methods related to missing data:

- Development and refinement of methods for missing data in RCTs and observational studies, including registries.
- Development of software to reduce barriers that inhibit the use of more rigorous methods for handling missing data.

5. Development and refinement of design-specific analytic methods.

Methods related to cluster-randomized trials:

- Development of methods for improving the conduct of cluster-randomized trials with specific attention to their application in PCOR.

Methods related to adaptive trials:

- Research to help support methods guidance on adaptive trials specific to PCOR.
- Development of software for adaptive trials that can simulate complex designs.

Methods related to registries:

- Development of innovative ways to reduce loss to follow-up as registries encompass longer time periods and ways to improve follow-up rates and testing these strategies in different types of registries and among different patient populations.
- Development of improved strategies for linking data while maintaining privacy protections and assuring that linked data do not lead to re-identification in de-identified data.
• Development of methods to enable routine, inexpensive nesting of clinical trials into existing registries (also known as “clinical registry trials”).

**Methods related to diagnostic tests:**

• Development of improved methods for measuring the impact of diagnostic testing on patient outcomes, including methods for improving their predictive value, given patient heterogeneity.

**Methods related to devices:**

• Development of improved methods for assessing the impact of devices on patient-centered outcomes.

**Methods related to decision analysis and simulation models:**

• Review of standards for best practices in the development of decision analysis and simulation models for patient-centered comparative effectiveness questions.
• Development of methods to use simulation models to address questions on heterogeneity of treatment effect.

6. **Research that determines the validity and efficiency of data sources commonly used in PCOR.**

• Methods to improve the use of clinical data collected across healthcare systems, clinical data networks, registries, or payer databases and the utility of this data for conducting longitudinal studies of patient outcomes.
• Methods to integrate randomized trials directly into clinical care; methods to enable patients to enter their own data via web and mobile technologies; methods to enable passive collection of certain patient-centered data from mobile technologies.
• Research that develops and promotes the utility, performance, and efficiency of large clinical data networks or registries for supporting PCOR for patients with rare diseases.

7. **Research related to Patient-Centered Outcomes (PCOs) and Patient-Reported Outcomes (PROs).**

• Research on methods for the development, reliability, validity, and utility in clinical care of PCOs.
• Research on methods for assessing measurement properties (based on qualitative and quantitative evaluations), score interpretability, meaningfulness of score changes, and strategies for minimizing and interpreting missing PRO data in PCOR.
• Development of PRO measures for use in product development trials and in comparative effectiveness studies. PCORI highly encourages networks of investigators to collaborate in this area.
• Development of methods to understand the impact and burden of disease, in specific
diseases, from the patient’s point of view. This includes identifying, in collaboration with
patients, which symptoms or other disease characteristics are most important to them and
which benefit-risk trade-offs are acceptable to patients with this condition when receiving
treatments.
• Research on methods to elicit patient preferences in regard to how they value the benefits and
harms of alternative interventions.

8. Research in methods to enhance the reproducibility, transparency, and replication of PCOR.

Applications to this PFA will be considered nonresponsive if the proposed research:

• Conducts a formal cost-effectiveness analysis in the form of dollar-cost per quality-adjusted
life-year (including non-adjusted life-years) to compare two or more alternatives.
• Directly compares the costs of care between two or more alternative approaches as the
criteria for choosing the preferred alternative.

2. What Research Does PCORI Fund?

Research Priorities
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. For more information on PCORI’s research priorities, see our National Priorities and
Research Agenda.4

Definition of PCOR
Patient-centered outcomes research (PCOR) helps people and their caregivers communicate and
make informed healthcare decisions, allowing their voices to be heard in assessing the value of
healthcare options. This research:

• Assesses the benefits and harms of preventive, diagnostic, therapeutic, palliative, or health
delivery system features to inform decision-making, highlighting comparisons of outcomes
that matter to people.
• Is inclusive of an individual’s preferences, autonomy, and needs, focusing on outcomes that
people notice and care about, such as survival, function, symptoms, and health-related
quality of life.
• Incorporates a wide variety of settings and diversity of participants to address individual
differences and barriers to implementation and dissemination.

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4 Available at http://www.pcori.org/what-we-do/priorities-agenda.
• Investigates (or may investigate) optimizing outcomes while addressing burdens to individuals, availability of services, technology, personnel, and other stakeholder perspectives.

Review Criteria

Criterion 1. Impact of the field of PCOR methods
Refers to the extent that the proposed methods are needed in the field of PCOR. The proposal addresses the following questions:

 How often would these methods be used, and how many PCOR studies would benefit from these improved methods?
 Do existing methods weaken the validity of PCOR studies, and would improved methods therefore increase the validity of PCOR findings?

Criterion 2. Potential for the study to improve PCOR methods
Refers to the potential of the proposed methodological investigation and its results to change methodological practices in ways that improve PCOR and the decisions made by patients. The proposal addresses the following questions:

 Does the research question address a critical gap in current methodological understanding as noted in the Methodology Committee Report or in other sources?
 Is the proposed approach feasible and likely to result in new standards or in the improvement of existing standards?

Criterion 3. Technical merit
Refers to the technical merit of the proposal. The proposal addresses the following questions:

 Is there a clear research plan with rigorous methods and key milestones clearly articulated?
 Do the study methods reflect state-of-the-art thinking and practice in the methodological area, so that results are likely to be accepted and heeded?
 Is the research team appropriately trained and experienced to carry out the planned studies?
 Is the research environment sufficient to support the conduct of the work, and are appropriate resources available?
 Will the proposed methods help support the inclusion and study of diverse populations with respect to age, gender, race, ethnicity, geography, or clinical status, or, alternatively, do the methods support the inclusion of previously understudied populations in PCOR?
**Criterion 4. Patient-centeredness**
Refers to the level of patient-centeredness of the proposal. The proposal addresses the following questions:

- Is the research focused on questions that affect outcomes of specific interest to patients and their caregivers?
- Does the research address one or more of the key questions mentioned in PCORI’s definition of patient-centered outcomes research?
- How credible are claims that engaged patients and stakeholders will exert meaningful influence on the design and conduct of the research, to ensure patient-centeredness of the questions and outcomes addressed?

**Criterion 5: Patient and stakeholder engagement**
Where applicable, proposals need to demonstrate patient and stakeholder engagement through the integration of patients and stakeholders in the development of the research plan and in key elements of the proposed project. The proposal addresses the following questions:

- Does the proposal describe how patients and stakeholders were or will be identified and engaged in the research?
- Are the roles of patients and key stakeholders significant in formulating the study’s research questions, hypotheses and design and in the study’s conduct and dissemination of results?
- Are the roles proposed for patients and stakeholders in any planned dissemination or implementation plans meaningful and likely to be effective?
- If engagement is not applicable to the proposed research, does the application justify why it is not?
Criterion 5: Patient and stakeholder engagement

Where applicable, proposals need to demonstrate patient and stakeholder engagement through the integration of patients and stakeholders in the development of the research plan and in key elements of the proposed project. The proposal addresses the following questions:

- Does the proposal describe how patients and stakeholders were or will be identified and engaged in the research and in formulation of research questions?
- What are the roles of patients and key stakeholders in formulating the study’s hypotheses and design and in the study’s conduct and dissemination of results, including defining essential characteristics of the study, participants, comparators, and outcomes?
- What roles do patients and stakeholders have in monitoring study conduct and progress?
- What roles do patients and stakeholders have in any planned dissemination or implementation plans?
- If the project has not included patient and stakeholder engagement (for example, in the area of analytic methods), has the application explained why it is not applicable and justified their non-inclusion?

Dissemination and Implementation Potential

PCORI is interested in research that can be rapidly disseminated and implemented in clinical and community practice, facilitating improvements in patients’ and other stakeholders’ decision-making about health care. Therefore, applications should include a section that describes the potential for disseminating your findings and facilitating their widespread use in practice. We also request that you describe possible barriers to dissemination and implementation the results in other settings. Please note, we are asking you to describe the potential for dissemination and implementation. PCORI does not expect you to undertake this dissemination and implementation work at this juncture. For projects that produce important findings, PCORI will consider subsequent applications that support dissemination and implementation efforts through separate funding announcements.

Populations Studied

PCORI seeks to fund research that includes diverse populations with respect to age, gender, race, ethnicity, geography, or clinical status, so that possible differences in comparative effectiveness may be examined. PCORI recognizes that some proposed studies may represent important PCOR opportunities even in the absence of a broadly diverse study population. However, the burden is on the applicant in such cases to justify the importance of the study given the absence of diversity. Alternatively, PCORI is interested in the inclusion of previously understudied populations for whom effectiveness information is particularly needed, such as “hard-to-reach” populations or patients with multiple conditions. Thus, comparisons should examine the impact of the strategies in various subpopulations with attention to the possibilities that the effects of the strategy might differ across various populations. Populations of interest include those that are less frequently studied. PCORI has developed the following list of priority populations to guide our efforts in research and engagement, which includes:
• Racial and ethnic minority groups
• Low-income groups
• Women
• Children (age 0–17)
• Older adults (age 65 and older)
• Residents of rural areas
• Individuals with special healthcare needs, including individuals with disabilities
• Individuals with multiple chronic diseases
• Individuals with rare diseases
• Individuals whose genetic make-up affects their medical outcomes
• Patients with low health literacy/numeracy and/or limited English proficiency
• Lesbian, gay, bisexual and transsexual (LGBT) persons.

3. How to Submit a Proposal

PCORI Online System
To submit a proposal, you must register with the PCORI Online System and submit both a Letter of Intent and an application for each cycle in which you are applying. See the PCORI Funding Center for applicant resources, including application guidelines and templates.

Additional Guidelines
Submission Dates
This is a standing announcement. Applications must be submitted in accordance with the published dates and times listed in the Overview of this document and in the PCORI Funding Center.

Organizational Eligibility
Applications may be submitted by any private sector research organization, including any non-profit or for-profit organization, and any public sector research organization, including any: university or college; hospital or healthcare system; laboratory or manufacturer; or unit of state or local government. All US applicant organizations must be recognized by the Internal Revenue Service. Foreign organizations and nondomestic components of organizations based in the United States may apply, as long as there is demonstrable benefit to the US healthcare system, and US efforts in the area of patient-centered research can be clearly shown. Organizations may submit multiple applications for funding. Individuals may not apply.

Reproducibility and Transparency of Research
The ability to replicate potentially important findings from PCORI-funded studies in other data sets and populations is essential to building confidence in the accuracy of these findings. PCORI will support policies to promote sharing of study documentation (e.g., study protocol, programming code, and data definitions) so

5 Available at https://pcori.fluxx.io/user_sessions/new
6 Available at pcori.org/apply
7 Available at pcori.org/apply
that other researchers may replicate the findings in other populations. For large studies—those with total
direct costs greater than $750,000 and those with durations of more than three years—PCORI requires that
applicants propose a plan for sharing of de-identified data, so that others may analyze the same data set.

Protection of Human Subjects
PCORI adopts, by reference, the Human Subjects requirements of 45 CFR Part 46. If the proposed research will
involve human subjects, refer to the Supplemental Instructions for Preparing the Protection of Human Subjects
Section of the Research Plan in Part II of the Instructions for the PHS 398 Form provided by the National
Institutes of Health.8 Note: PCORI requires engagement in the research by patients and/or other
stakeholders, as research partners. Research subjects protection requirements do not apply to co-
investigators, members of the research team, or research partners.

Applicant Resources

PCORI Funding Center: pcori.org/PFA/methods
PCORI Online System https://pcori.fluxx.io/user_sessions/new
PCORI Funding Awards General: pcori.org/pfaawards
Past Awards by Priority Area: pcori.org/pfaawards/?viewby=priority
PCORI Methodology Standards pcori.org/assets/PCORI-Methodology-Standards.pdf
Contact Us
Please contact us if you have questions regarding this PCORI Funding Announcement or would like to schedule a call with
program staff. PCORI will provide a response within 72 hours. However, PCORI cannot guarantee that all questions will be
addressed during the 72 hours prior to a Letter of Intent or application deadline.
Email: pfa@pcori.org
Phone: 202-627-1884
Online: pcori.org/PFA/inquiry

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8 Available at http://grants.nih.gov/grants/funding/phs398/phs398.html