August 2013 Cycle

Patient-Centered Outcomes Research Institute

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

Published May 22, 2012
Revised May 20, 2013
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.

Our Mission: 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.

Our History: 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.”

Questions Regarding PCORI Funding Announcements: Please email (pfa@pcori.org), phone (202-627-1884), or contact us online (pcori.org/funding-opportunities/programmatic-inquiry/) if you have any 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 72 hours prior to a Letter of Interest or application deadline.

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1. INTRODUCTION

1.1. Purpose
In this Improving Methods for Conducting Patient-Centered Outcomes Research (PCOR) 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.

1.2. Funds Available
PCORI expects to fund projects totaling up to $8 million in total costs under this PFA, per cycle. 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.

1.3. Budgets and Project Periods
Projects may not exceed three years in duration. Budgets may not exceed $250,000 in direct costs per year. PCORI encourages studies of shorter duration that can deliver findings promptly, including studies that take advantage of research infrastructure already in place. Currently funded clinical comparative effectiveness research (CER) studies may be considered for PCORI funding to support distinctive methodological work. Efficient use of research resources is a criterion that will be considered by merit reviewers and will also be reviewed by PCORI staff. The total amount awarded and the number of awards will depend on the quality, duration, and costs of the applications received.

1.4. Organization Eligibility
Applications may be submitted by:

Any private sector research organization, including any:
- Non-profit organization
- For-profit organization

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.

1.5. Questions Regarding PCORI Funding Announcements
Please email (pfa@pcori.org), phone (202-627-1884), or contact us online (pcori.org/funding-opportunities/programmatic-inquiry/) if you have any 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 72 hours prior to a Letter of Interest or application deadline.

2. OVERVIEW

The Patient-Centered Outcomes Research Institute (PCORI) is entrusted by the public to fund research that will matter to patients and their caregivers. PCORI seeks to change how research is conducted by emphasizing the role of diverse research teams that include varying perspectives. PCORI distinguishes itself by supporting research in which patients, caregivers, practicing clinicians, and the broader stakeholder community are actively engaged in generating the research questions, reviewing the proposals, conducting the research, disseminating the findings, promoting the implementation of the findings, and using the results to understand and address patient and other stakeholder needs.

2.1. 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.

An important proportion of PCORI’s funding is dedicated to four priority areas identified in the National Priorities and Research Agenda. These include research investigating clinical comparative effectiveness between different treatment options, improving healthcare systems, addressing disparities in health, and communications and dissemination research. The fifth priority identified by the Agenda focuses on accelerating PCOR and includes an emphasis on research into the research methods used in the conduct of 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. On July 23, 2012, the Methodology Committee released its first draft report for public comment.

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.

Acknowledgments
This background section borrows from the following article published on behalf of the Methodology Committee: “Getting the Methods Right — The Foundation of Patient-Centered Outcomes Research by Gabriel and Normand. NEJM August 2012” available at www.nejm.org/doi/full/10.1056/NEJMp1207437.

2.2. 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 (eg, 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.

2.3. Sample Questions
The following research topics are examples of the types of questions PCORI might be interested in. Many of these questions 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.


Every day, patients and their caregivers are faced with crucial healthcare decisions while lacking key information that they need. PCORI has addressed this lack of information in its National Priorities and Research Agenda and has issued funding announcements requiring a comparative clinical effectiveness approach that engages patients in collaboration with their clinicians. To support the conduct of meaningful PCOR and to produce valid findings, it is critical to continue developing stronger research methods in a number of areas.

PCORI’s founding legislation established 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.” On July 23, 2012, the Methodology Committee produced its first draft report for public comment. It contains the first set of recommended selected standards for the conduct of PCOR and also highlights gaps in the current evidence that PCORI’s program of methodological research should address.

PCORI is entrusted by the public to fund research that will matter to patients and their caregivers, and it now turns to you to help address methodological gaps in PCOR. We hope that you—researchers and methods experts from across the country, in collaboration with patients and stakeholders where appropriate—will join us in advancing the field. The development of strong methods to support PCOR studies has the potential to transform the ability of patients, their caregivers, and clinicians to seek, find, understand, and use practical information in the decision-making process.
• 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.

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:**
- 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.**

**2.4. Other Programmatic Considerations**

N/A

**2.5. Definition of Patient-Centered Outcomes Research**
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.

- Investigates (or may investigate) optimizing outcomes while addressing burdens to individuals, availability of services, technology, personnel, and other stakeholder perspectives.

3. ELEMENTS OF PCORI-FUNDED RESEARCH

3.1. Technical Requirement and Review Criteria

Now that you understand the research focus and priorities, you will need to determine if your organization, proposed study, and approach meet PCORI’s technical requirements and review criteria for a successful project, which are described below:

1. The application demonstrates the impact on the field of PCOR Methods and justifies the importance of their methodological research questions with specific references to the gaps identified in the draft Methodology Report or from other sources. Applicants are encouraged to refer to the contents of the PCORI revised Methodology Standards in justifying their research question and developing their research plan.

2. The application explains how the proposed methods studied have the potential to improve PCOR methods. Applicants should demonstrate that the proposed research question and project has the potential to provide truly important advances in methods that will support the generation of information that patients need to make decisions.

3. The application demonstrates strong technical merit, including:
   - A clear research plan with rigorous design and analytic methods
   - Key project milestones clearly articulated
   - A strong research team
   - A supportive research environment

4. The application demonstrates patient-centeredness through:
• Research into methods that will support the generation of information that patients need to make decisions.

5. The application demonstrates a commitment to patient and stakeholder engagement through the integration of patients and stakeholders in key elements of the proposed project. PCORI recognizes that for some applications, particularly in the area of analytic methods, a patient and stakeholder plan may not be necessary and applicants should provide a justification for their non-inclusion. For projects where it will be appropriate to meaningfully include patients and relevant stakeholders in the research team, the project should include:

• Participation in formulation of research questions
• Defining essential characteristics of the study, participants, comparators, and outcomes
• Monitoring study conduct and progress
• Dissemination of research results

The specific research questions and the specific populations to which the research is intended to apply, and the specific research settings, will all inform the nature of appropriate patient and stakeholder engagement.

Below we provide additional guidance for proposal development in areas of particular interest to PCORI.

3.2. Additional Guidance and Characteristics

Patient and Stakeholder Involvement
A key goal of patient engagement in research is to support health decisions through generation of evidence relevant to patients, their caregivers, and clinicians. For some methods questions related to patient-centeredness and patient engagement, it will be appropriate to meaningfully include patients and relevant stakeholders in the research team, although the specific members of the team will vary from study to study. However, PCORI recognizes that for some applications in the area of analytic methods, a patient and stakeholder plan may not be necessary. These research proposals should nevertheless clearly identify how the improvement in the particular area of methods chosen is relevant to the patient population and how subsequent health decisions may be supported by more robust evidence through the proposed improvement in methods. In cases where patient and stakeholder engagement is appropriate, research proposals should clearly identify who will be selected to participate and justify the choice of selection. Engagement should include participation in formulation of research questions; defining essential characteristics of study participants, comparators, where appropriate, and outcomes; monitoring of study conduct and progress; and dissemination of research results.

Details of the required plan for patient and stakeholder engagement are in the Application Guidelines.

Dissemination and Implementation Potential
In addition to the elements described above that represent the criteria by which we review proposed projects, PCORI is interested in research that can be rapidly disseminated and implemented into clinical and community settings, facilitating improvements in patients’ and other stakeholders’ decision making about health care. Therefore, applications should include a section that describes the potential for disseminating and
implementing the results of your work in other settings. We also request that you describe possible barriers to dissemination and implementation of your work 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.

PCORI will hold a research methods symposium where applicants will be asked to present their work. Applicants should budget to attend one, two-day meeting in Washington, DC.

**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 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
- Patients with low health literacy/numeracy and limited English proficiency
- 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
- Individuals with low health literacy
- Lesbian, gay, bisexual, transgender (LGBT) persons

**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, data definitions) so that other researchers may replicate the findings in other populations. For large studies—those with direct costs greater than $250,000 in any year—PCORI requires that applicants propose a plan for sharing of de-identified data, so that results may be reproduced by others in 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, as found on the National Institutes of Health (NIH) website:
http://grants.nih.gov/grants/funding/phs398/phs398.html

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.
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<tr>
<th>PCORI Criteria</th>
<th>Brief Description</th>
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<tr>
<td><strong>1. Impact on the field of PCOR Methods</strong></td>
<td>• Refers to the extent that the proposed methods are needed in the field of PCOR. 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?</td>
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<td><strong>2. Potential for the study to improve PCOR Methods</strong></td>
<td>• 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. 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?</td>
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<td><strong>3. Technical merit</strong></td>
<td>Refers to the technical merit of the proposal.</td>
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<td>• 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?</td>
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<td>• Is the research team appropriately trained and experienced to carry out the planned studies?</td>
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<td>• Is the research environment sufficient to support the conduct of the work, and are appropriate resources available?</td>
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<td>• 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?</td>
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<td><strong>4. Patient-centeredness</strong></td>
<td>Refers to the level of patient-centeredness of the proposal.</td>
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<td>• Is the proposed methodological investigation specifically linked to improving PCOR methods, and specifically to the improved study of comparisons and patient-centered outcomes that are relevant and valued by patients, caregivers, and clinicians?</td>
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<td>• For relevant studies, how credible are the application’s 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?</td>
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5. Patient and stakeholder engagement

Refers to the level of engagement of patients and stakeholders in the proposed project.

Where applicable, applications 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 including:

- Participation in formulation of research questions
- Defining essential characteristics of the study, participants, comparators, and outcomes
- Monitoring study conduct and progress
- Dissemination of research results

If the project has not included patient and stakeholder engagement (for example, in the area of analytic methods), has the application justified their non-inclusion?

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4. APPLICATION AND SUBMISSION GUIDELINES

4.1. Submission Procedures
To apply with PCORI, you must register with the PCORI Online System and submit both a timely and required Letter of Intent (LOI) and a timely application for each cycle that you are applying. To learn more about completing your application, please see the PCORI Application Guidelines.

4.2. Funding and Project Period Limits
This is a standing announcement. Applicants must submit an LOI and application to PCORI, in accordance with the published dates and times listed in the PCORI Funding Center.