Patient-Centered Outcomes Research Institute

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

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Improving Methods for Conducting Patient-Centered Outcomes Research

Opportunity Snapshot

Every day, patients and their caregivers are faced with crucial healthcare decisions while lacking key information that they need. The Patient-Centered Outcomes Research Institute (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 patient-centered outcomes research (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 now turn to you to help us 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.

Program Overview

Under this PFA, Improving Methods for Conducting Patient-Centered Outcomes Research, PCORI seeks 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.

Research Areas of Interest

We are 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 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 in methods to enhance the reproducibility, transparency, and replication of PCOR research.
- Research that evaluates and compares strategies for training researchers, patients, and other stakeholders in the methods of patient-centered outcomes research.

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

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 to understand 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 could provide 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 patient-centered outcomes research. 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 patient-centered outcomes research. 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.

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

Example 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.

1. **Development of methods for patient-centeredness.**
    - 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 comparative effectiveness research.**
    - Research on methods for improving the validity of systematic reviews of comparative effectiveness research.
    - 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, 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 sub-group 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 (eg, 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 patient-centered outcomes research 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 patient-centered outcomes.

- 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.

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

9. **Research that evaluates and compares strategies for training researchers, patients, and other stakeholders in the methods of patient-centered outcomes research.**

Funding and Project Period Limits

PCORI expects to fund projects totaling up to $12 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.

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 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.

Applicants wishing to propose studies that they believe will require more funding or longer duration may contact PCORI before the required deadline for the LOI to request permission to increase the budget beyond $250,000 in direct costs in any project year or to extend the study duration beyond three years. PCORI does not guarantee that permission will be granted, and applicants should expect that the deliberative process may result in delaying the submission for one or more cycles.

Elements of PCORI Funded Research

Now that you understand the research focus and priorities, you will need to determine if your organization and approach meet PCORI's other eligibility requirements. To do that, please consider the following important issues.

Key Elements

Successful applicants for PCORI funds must:

1. **Justify 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. **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. **Propose to use PCORI resources efficiently in producing new knowledge.** We aim to stretch our resources as far as possible because we recognize the vast information needs of patients. Methodological studies that can be conducted as part of already existing larger studies are of interest.

4. **Provide a justification of how the research may be scalable and generalizable.**

5. **Use rigorous methods in developing the study design.** Research methods may include randomization (for example, in patient engagement studies), simulation, re-analysis of existing datasets, as well as theoretical and conceptual work. We also welcome systematic reviews in areas that are in need of these. Regardless of the particular methods employed, proposals are expected to use rigorous methodology and to explicitly justify the choice of their approach. For example, systematic reviews should follow standards published by the Agency for Healthcare Research and Quality (AHRQ) or the Institute of Medicine (IOM).

Please note that your application will be scored against the seven PCORI review criteria found in this document. These are based on the existing PCORI review criteria developed for non-methodological announcements, but have been adapted for a review of applications for methodological research.

PFA applications will be required to comply with standards adopted by PCORI's Board of Governors that have been approved by the Board at least six months prior to the PFA application due date. This time period, combined with the public comment period (45–60 days prior to adoption, as stated in PCORI's enabling legislation), will erase any knowledge advantage and maintain Methodology Committee application eligibility.

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 Assessment

PCORI is interested in funding studies that produce findings that can be readily disseminated and implemented—and are highly likely to be valued by patients and caregivers. To that end, it is important that potential facilitators and barriers to dissemination and incorporation into practice be assessed and anticipated.

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.

Reproducibility and Transparency of Research

The ability to replicate potentially important findings from PCORI-funded studies in other datasets and populations is essential to building confidence in the accuracy of these findings. PCORI will support policies to promote sharing of study documentation (eg, 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 dataset.

Inclusiveness of Different Populations

PCORI seeks to fund outcomes research that includes diverse populations with respect to age, gender, race, ethnicity, geography, or clinical status. PCORI is also 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. Applicants should keep in mind the need for efficient analytic methods to support analysis of diverse populations and to address potential treatment heterogeneity. PCORI is interested in the following populations: 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 needs, including individuals with disabilities; individuals with multiple chronic diseases; individuals with rare diseases; individuals whose genetic makeup may require differing therapies.

Protection of Human Subjects

PCORI adheres to, 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) Web site: www.grants.nih.gov/grants/funding/phs398/phs398.doc.

Application Development and Submission Overview

Application Development

There are five steps to developing a PCORI application:

- **Step 1: Inform PCORI with the Letter of Intent:** submit a required Letter of Intent (LOI) by the deadline.
- **Step 2: Design the research plan:** As part of your application, you must state the specific aims of the project, the research question(s) to be studied, and how you will answer that question. In addition, applicants must:
    - Explain how the research plan aligns with PCORI review criteria.
    - Describe plans for dissemination and implementation.
    - Describe plans for supporting replication and reproducibility of research and data sharing.
- **Step 3: Document the people and places:** Determine and document who will be on the research team, what their roles will be, and where the research will be conducted. Describe plans for engaging patients and other relevant stakeholders as part of the research team in the research project.
- **Step 4: Develop the budget:** Determine, list, and justify the costs associated with the project.
- **Step 5: Submit the application:** Compile and submit your application using PCORI Online.

For further guidance and resources, visit the PCORI Application Center (www.pcori.org/funding-opportunities/funding-announcements/application-center/).

Review Criteria

The PCORI review process for each complete, submitted application includes the three components listed below. This process typically takes about six months.

- Completeness, Compliance, and Eligibility Check
- Merit Review
- Business Review

Carefully read and thoroughly understand the PCORI review criteria before applying.

PCORI Criteria	Brief Description
RESEARCH STRATEGY: Background and Significance	
1. Impact	Refers to the extent that the proposed methods are needed in the field of Patient-Centered Outcomes Research (PCOR). How often would these methods be used, and how many PCOR studies would benefit from these improved methods? Do existing

PCORI Criteria	Brief Description
RESEARCH STRATEGY: Background and Significance	
	methods weaken the validity of PCOR studies, and would improve methods therefore increase the validity of PCOR findings?
2. Innovation and potential for improvement	Refers to the potential of the proposed methodological investigation and its results to change methodological practices in ways that improve PCOR and the healthcare decisions made by patients. Is the research novel or innovative in its methods or approach? 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?
RESEARCH STRATEGY: Relevance to Patients	
3. Patient-centeredness	Is the proposed methodological investigation specifically linked to improving Patient-Centered Outcomes Research (PCOR), and specifically to the improved study of comparisons and patient-centered outcomes that are relevant and valued by patients, caregivers and clinicians?
RESEARCH STRATEGY: Approach	
4. Rigorous research methods	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?
RESEARCH STRATEGY: Inclusiveness of Different Populations	
5. Inclusiveness of different populations	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, does it support the inclusion of previously understudied populations in PCOR?
PEOPLE AND PLACES	
6. Research Team and Environment	The research team must be appropriately trained and experienced to carry out the planned studies. Does the study team have complementary and integrated research expertise in implementing the study? If the research is on patient and stakeholder engagement and patient-centeredness, are relevant patients and other key stakeholders (eg, caregivers, clinicians, health system, community, or policy makers) appropriately included on the team? Will the research environment contribute to the probability of success? Are features of the research environment, such as health system or community involvement or collaborative arrangements, described? Are institutional and community investment in the success of the research described? For pure analytic studies, the patient and stakeholder involvement in the team may not apply. PCORI encourages submissions from underrepresented minority investigators.

PCORI Criteria	Brief Description
RESEARCH STRATEGY: Background and Significance	
BUDGET	
7. Efficient use of research resources	Does the budget appear to be reasonable in relation to the potential contribution of the research? Does the justification address the efficiency with which PCORI resources would be used? Are there opportunities to make the study more efficient? Are there additional benefits to a PCORI investment in this study through the creation of common data or infrastructure that could support future research?

Organizational 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.

Submission Procedures

To apply with PCORI, you must register with PCORI's online system and submit both a timely Letter of Intent and a timely application. To learn more about completing your application, please see the PCORI Application Guidelines (www.pcori.org/assets/PFAguidelines.pdf).

Submission Deadlines

This is a standing announcement, with three application deadlines per year. Applicants must submit a Letter of Intent and application to PCORI, in accordance with the published dates and times listed in the Application Center (www.pcori.org/funding-opportunities/funding-announcements/application-center/#anchor).

About PCORI

The Patient-Centered Outcomes Research Institute (PCORI) is an independent organization created to help people make informed healthcare decisions and improve healthcare delivery. PCORI will commission research that is guided by patients, caregivers, and the broader healthcare community and will produce high-integrity, evidence-based information.

PCORI is committed to transparency and a rigorous stakeholder-driven process that emphasizes patient engagement. PCORI will use a variety of forums and public comment periods to obtain public input throughout 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."

The statutory language defining PCORI is broad and authorizes research that will support a strong patient-centered orientation, inform better choices among alternative treatment and prevention strategies, and direct attention to individual and system differences that may influence strategies and outcomes. PCORI was designed to produce knowledge through the analysis and synthesis of existing research or the support of new research.