Patient-Centered Outcomes Research Institute

Funding Announcement:
Addressing Disparities

Published May 22, 2012

Key Dates			
Action	**Cycle I**	**Cycle II**	**Cycle III****
PFA Release Date	May 22, 2012	N/A	N/A
Online System Opening Date	June 1, 2012	September 15, 2012	January 15, 2013
Letter of Intent* (LOI) Due Date	June 15, 2012	October 15, 2012	February 15, 2013
Informational Webinars (Specific dates to be posted on pcori.org.)	June and July 2012	October – November 2012	February – March 2013
Application Deadline	July 31, 2012	November 30, 2012	March 31, 2013
Merit Review Dates	August – November 2012	December 2012 – March 2013	April – July 2013
Awards Announced	December 31, 2012	April 2013	August 2013
Earliest Start Date	January 2013	May 2013	September 2013

Opportunity Snapshot

A healthcare organization is collecting data for quality improvement and identifies marked disparities in care and outcomes for a variety of conditions. These disparities impact a number of different patient groups in this setting, based on their gender, race/ethnicity, primary language, and other attributes. The organization wants to intervene to remedy the problem, but resources are limited and the leaders are not sure how to proceed to make a wise decision and determine how best to make an impact and change the status quo. They want care to be more equitable—and want to address differences in outcomes. But they need to decide on a plan of action without strong scientific evidence to guide them—or tools to evaluate the effect of their interventions.

Purpose

Every day, healthcare organizations and others are faced with the challenge of how to eliminate disparities in health and health care. After decades of attention to this issue, disparities remain pervasive, leading to preventable suffering and interfering with the ability of individuals and families to live full, healthy lives. We need information to guide decisions about how to eliminate these disparities and ensure that people receive care according to their needs—and that all have the opportunity to achieve the best possible outcomes, in accordance with their wishes.

We at the Patient-Centered Outcomes Research Institute (PCORI) are entrusted by the public to fund research that will matter to patients and their caregivers, and we now turn to you to help us. We have designed five national priorities and a research agenda for the projects we will fund that is focused on producing knowledge that is useful to patients, their caregivers, and clinicians. This knowledge is also expected to be useful to health system leaders, payers, and regulators who make decisions that impact patients. We have not specified the questions or the conditions. We believe that the important gaps in knowledge are pervasive and that, rather than dictate which conditions and questions are more important than others, we have chosen to seek wisdom from around the country in the form of applications for funding in the five priority areas. We also have identified some areas, such as rare conditions, and the needs of patients with multiple chronic conditions that are often neglected to be sure they are covered among our funded projects.

In this PCORI Funding Announcement (PFA), we want studies that will inform the choice of strategies to eliminate disparities. We are not interested in studies that describe disparities; instead, we want studies that will identify best options for eliminating disparities. We have not stated where the studies should be directed, but we have been very clear that they must focus on areas of importance to patients and their caregivers, where there are critical disparities that disadvantage members of a particular group and limit their ability to achieve optimal, patient-centered outcomes.

We are seeking to change how research is done by emphasizing the role of strong research teams that include varying perspectives. PCORI seeks to distinguish itself by supporting research in which patients, caregivers, and practicing clinicians are actively engaged in generating the research questions, conducting the research, and using the results of that research to truly understand and address patient needs. In the end, PCORI will be held accountable for whether this model succeeds in producing knowledge that patients

need and use. We hope that you—patients, caregivers, clinicians, health plans, product manufacturers, policy makers, and researchers from around the country—will join us in producing an unprecedented portfolio of truly patient-centered outcomes research that will transform the ability of patients, their caregivers, and clinicians to seek, find, and use practical information in the decision-making process.

Funds Available

We anticipate that approximately 14 contracts totaling up to $12 million in total costs may be funded under this PFA in this initial funding cycle, assuming receipt of a sufficient number of high quality applications. PCORI anticipates additional funding cycles related to this announcement. However, funds available may vary, and PCORI reserves the right to modify or terminate this announcement at any time.

Budget and Project Periods

Direct project costs are limited to a maximum of $500,000 per year.

Organizational Eligibility

Applications may be submitted by any private sector research organization, including non-profit and for-profit organizations, any public sector research organization, universities, colleges, hospitals, laboratories, healthcare systems, and units of state and local governments. 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. Individuals may not apply. Foreign organizations should consult the PCORI Application Guidelines because there is an extra step for such organizations to register within the PCORI online system.

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Addressing Disparities

If you are interested in applying for an award under this program, follow PCORI's five-step process.

- ✓ **Review the Program Detail:** Get familiar with the program announcement and PCORI's areas of interest. Look at the example questions.
- ✓ **Consider the Requirements:** Consider the applicant eligibility requirements and PCORI's specific requirements to see if your organization, your interests, and your project fit within this program.
- ✓ **Develop Your Application:** Design the project. Determine and document who will be involved, the research strategy, and the budget needs. To see the Application Guidelines, go to http://www.pcori.org/assets/PFAguidelines.pdf.
- ✓ **Know the Review Criteria:** Understand the PCORI merit-review assessment criteria. The criteria are provided at the end of this document.
- ✓ **Submit Your Application:** Compile and submit your application. To see the Application Guidelines go to http://www.pcori.org/assets/PFAguidelines.pdf. You can register for the online system and submit a Letter of Intent (LOI) or an application beginning June 1, 2012. A link to the online system will be available on the PCORI Funding Announcements (PFAs) web page at http://www.pcori.org/funding-opportunities/pfa/.

Step 1: Review the Program Detail

Overview

We seek comparative outcome studies that evaluate new and alternative interventions to reduce or eliminate disparities in health and health care outcomes, to overcome barriers that may disproportionately affect the outcomes of specific groups of patients, or to identify best practices for sharing results and information about patient-centered research across patient groups. The research must address critical gaps in knowledge. PCORI seeks studies that will provide information of value to patients, their caregivers, and clinicians.

Research Areas of Interest

We are interested in the following broad topical areas:

- Research that compares interventions to reduce or eliminate disparities in patient-centered outcomes, including health, health care, and patient-reported outcomes. For example, by accounting for possible differences at the patient, provider, or systems level, determine what interventions can be most effective for eliminating disparities in outcomes.
- Research that identifies and compares promising practices that address contextual factors such as socioeconomic, demographic, or community factors and their impact on patient-centered health outcomes.
- Research that compares benefits and risks of treatment, diagnostic, prevention, or service options across different patient populations, with attention to eliminating disparities.
- Research that compares strategies to overcome patient, provider, or systems level barriers (e.g., language, culture, transportation, homelessness, unemployment, lack of family/caregiver support) that may adversely affect patients and are relevant to their choices for preventive, diagnostic, and treatment strategies—as well as patient-centered outcomes.
- Research that compares and identifies best practices within various patient populations for information sharing about treatment outcomes and patient-centered research.

> *What I'm saying is it doesn't say where the research clients are coming from. If you don't go into the inner cities or the places that don't have health care reform or don't have health care at all, you are not going to get a true outlook of everything.*
>
> *—Parents, pediatric patient*
>
> *The things that we see constantly, the diabetes, the hypertension, the cholesterol, the obesity, may not necessarily be such a big issue in a small town in Vermont. They may have different needs. The fact that they're going to try to look at these different populations and say what we need to do here may be different than somewhere else.*
>
> *—Primary care physician*
>
> *I think some of the biggest barriers are, number one, the economic barriers and, number two, educational barriers. So I have patients who live on a $700 Social Security check each month. I mean they can't join the YMCA at $84 a month and go work out there when that's all their income is. They can't even buy good food sometimes. They can't buy fresh fruits and vegetables— you know, they're living on bad foods, bad diet, no exercise—I mean, it's an economic inequality. It's a disparity that's severe; it's costing them health.*
>
> *—Primary care physician*

Strategies may focus on patient populations with a single condition or involve patients with a range of conditions. Strategies addressing care for patients with rare conditions are of interest. Rare diseases are defined as life-threatening or chronically debilitating diseases that are of such low prevalence in populations that special efforts, such as combining data across large populations, may be needed to address them. The term *low prevalence* is defined as meaning conditions that affect fewer than 200,000 individuals in the United States or have a prevalence of less than 1 in 1,500 persons.

Background

Disparities in health status and health care persist in this country, based on race/ethnicity, gender, geographic location, socioeconomic status, and other factors. These disparities contribute to poor quality care and poor overall health outcomes for specific populations. Solutions that can reduce persistent disparities have been understudied and are likely to be both complex and context specific. The health

disparities literature has largely been devoted to describing disparities and identifying sources of those disparities. Despite the heterogeneity of populations being studied, research has identified consistent disparities in access, health care quality, and health outcomes for a variety of conditions. Hypotheses regarding the factors that cause disparities include the role of poverty and poor education on health outcomes, bias in treatment, cultural differences, differences in patient preferences and response to treatment, and the role of chronic stress as a result of discrimination and its impact on health outcomes. While research has not identified the specific causal pathways that lead to disparities, there are emerging efforts to develop and test interventions that reduce disparities and promote health equity.

Strategies to reduce disparities and promote health equity generally target a range of patient-level, provider-level, and system-level factors. There is widespread recognition that community and other contextual factors impact health outcomes for vulnerable patient populations. However, there have not been a lot of studies comparing interventions at this level for improving health outcomes. Patient- and provider-level interventions are largely based on strategies to improve knowledge and facilitate behavior change, while system-level interventions seek to address the way in which health care is delivered, organized, or financed.

Effective, patient-level approaches to reducing disparities in health and in health care quality are needed. Interventions that leverage the strengths and cultural practices or beliefs of different communities have demonstrated positive trends toward improving health outcomes, as well as measures of patient knowledge, self-efficacy, and experience of care. Targeted strategies directed to patient populations that experience disparities demonstrate a consistent trend toward improving outcomes, even in the most challenging clinical contexts. Studies show that some cultural competence interventions directed to physicians improve provider knowledge, attitudes, and skills, as well as patient outcomes, including patient satisfaction. The current gaps in knowledge regarding patient-level and provider-level interventions to promote health equity relate to which interventions work best. In recent years, several curricula on cultural competency have been developed for physician training, yet there is little knowledge regarding the best types of training, how their effectiveness can be assessed, and what outcomes should be expected as a result of training. Patient education is often used as a method for improving patient-centered outcomes. However, there is a need to determine best methods for patient education; how to develop interventions that truly promote patient engagement and self-efficacy; how to adjust training for differences in language, literacy, and numeracy; and what are reasonable outcomes to expect from patient education.

In addition to patient- and provider-level interventions, systems-level interventions have been developed to promote health equity, and the research on these efforts shows very promising results. For example, when community health workers or patient navigators are integrated into the healthcare delivery team, beneficial effects are seen in patient knowledge and behavior and in rates of health services utilization for patients with a variety of conditions that range from asthma to cancer. Among the most effective strategies in reducing disparities described in the literature are those that combine a variety of interventions to improve health care quality. Research has demonstrated that general system-level quality improvement approaches that are designed to improve outcomes for everyone may have a disproportionately positive effect on underserved populations. Other studies have investigated not only systems-level interventions, but the role of entirely different systems of care for promoting health equity. Preliminary data show that

the medical home, by providing comprehensive, coordinated and accessible care, can eliminate disparities in prevention, diagnosis, and treatment for a variety of conditions, even in the most vulnerable patient populations. Other systems-level research includes pay-for-performance and pay-for-reporting programs and health information technology (HIT) as potential approaches to reducing disparities. With studies showing that vulnerable patient populations are more likely to receive care in poorer performing inpatient and outpatient settings, some have raised concerns that performance-based payments may exacerbate disparities by funneling payments away from settings that provide care to large numbers of vulnerable patient groups. Likewise, it has been theorized that HIT, by improving care coordination, could reduce disparities, but an emerging digital divide among providers has raised questions as to whether this innovation could exacerbate disparities or be an effective approach for promoting health equity.

Here too, the current gaps in knowledge regarding systems-level interventions to promote health equity relate to which interventions in how health care is delivered, organized, and financed work best for promoting health care equity. Recent research on racial and ethnic disparities in care show that patients of color are more likely to use poorer performing providers, which drives much of the disparate outcomes experienced by these groups. What are the best systems-level interventions for improving overall performance and promoting healthcare equity? What are the promising models for health care delivery that promote health equity? While the preliminary data on the medical home is very promising for improving care and promoting health equity for minority populations, can the same findings be replicated for other vulnerable populations, such as those living in rural areas? What are the best pay-for-performance models available for achieving improved outcomes? Should standards be set around “pay for improvement” or “pay for an absolute level of performance”? How could payments be adjusted to account for achieving high levels of performance among more vulnerable, “hard-to-reach” populations?

Definition of Patient-Centered Outcomes Research

PCORI has defined patient-centered outcomes research, posted the definition for public comment, and incorporated these comments into the revised definition. Applications for research projects to PCORI must align with this definition, which is provided here and available at www.pcori.org/what-we-do/pcor/.

Patient-Centered Outcomes Research (PCOR) helps people and their caregivers communicate and make informed health care decisions, allowing their voices to be heard in assessing the value of health care options. This research answers patient-centered questions such as:

1. “Given my personal characteristics, conditions and preferences, what should I expect will happen to me?”
2. “What are my options and what are the potential benefits and harms of those options?”
3. “What can I do to improve the outcomes that are most important to me?”
4. “How can clinicians and the care delivery systems they work in help me make the best decisions about my health and healthcare?”

To answer these questions, PCOR:

- Assesses the benefits and harms of preventive, diagnostic, therapeutic, palliative, or health delivery system interventions 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 questions are meant as examples of the types of questions that your research may help answer. The list is by no means exhaustive.

- If the medical home is a promising model for promoting health equity, what characteristics are most critical to implement to improve outcomes?
- How does the availability of a patient navigator for patients and/or caregivers improve patients' health outcomes compared to usual strategies? Under what circumstances, or for what conditions, are patient navigators most effective?
- What are the best options, materials, and venues for patient education materials that take into consideration patient and caregiver culture, beliefs, literacy, and numeracy?
- How do outcomes of patients whose care entails a community health worker compare with those whose care does not? What is the optimal role for a community health worker in different care settings?
- How do the practices of the top-performing facilities that primarily serve racial or ethnic minority or low-income populations compare with lower-performing facilities?
- How do patient outcomes for patients whose provider has received cultural competence training compare with patients whose providers have not?
- What are the best methods for developing cultural competency curricula that lead to measureable changes in provider knowledge, attitudes, and practices?
- Does enhanced primary care access (extended hours, open access) improve patient outcomes for different target patient populations compared to usual access?
- Given that effective interventions to improve care in vulnerable populations often require a multipronged approach, under what circumstances do different options for interventions work best?
- Does generic quality improvement work always have a disproportionate impact on vulnerable patient populations? How can quality improvement efforts be tailored to ensure they promote health equity?

Deadlines and Submission

This is a standing announcement, with three application deadlines per year. For this initial round, applicants must submit a Letter of Intent to PCORI no later than 5:00 PM EST on the due date shown in the Key Dates table via PCORI's online system (www.pcori.org). Full applications must be submitted to PCORI no later than 5:00 PM EST on the due date shown in the Key Dates table via the PCORI online system.

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*Letter of Intent is required to submit an application. **Subsequent cycles are also expected. Check PCORI's website for future submission dates. Details within these announcements may change. Please check the date of the PFA you are reviewing and the PCORI website (www.pcori.org/funding-opportunities) to be sure you have the most recent version.			

Funding and Project Period Limits

We expect to fund approximately 14 projects totaling up to $12 million in total costs under this PFA. 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 $500,000 in direct costs per year. It is expected that, within these limitations, project budgets and duration will vary substantially, depending on the study design, needs for recruitment and/or primary data collection, required length of follow-up, and analytic complexity. To that end, PCORI will reserve a portion of funding for smaller (less than $500,000 in total costs) and intermediate sized projects (less than $1 million in total costs). PCORI encourages studies that can deliver findings promptly, including studies that take advantage of research infrastructure already

in place and of longitudinal studies already underway. Currently funded comparative clinical effectiveness research (CER) studies may be considered for PCORI funding to support distinctive work related to extending follow-up, adding additional outcomes, or examining outcomes in key patient subgroups. 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 prospective randomized trials or other complex studies that they believe will require more funding or longer duration may contact PCORI before the required deadline for the Letter of Intent to request permission to increase the budget beyond $500,000 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.

Step 2: Consider the Requirements

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.

Organizational Eligibility

Applications may be submitted by any private sector research organization, including non-profit and for-profit organizations, or any public sector research organization, universities, colleges, hospitals, laboratories, healthcare systems, and units of state and local governments. 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. Individuals may not apply. Foreign organizations should consult the PCORI Application Guidelines because there is an extra step for such organizations to register within the PCORI online system.

Characteristics of PCORI-Funded Research

Successful applicants for PCORI funds must:

1. Have a research team that includes patients and/or caregivers, as well as clinicians, health system managers, or other potential end-users of the study findings, along with researchers—each contributing the expertise that they have and participating actively in the design and implementation of the study and the dissemination of its results. A key concept here is ensuring that the research remains true to the interests of those who would use it.

2. Be familiar with the four questions of our patient-centered outcomes research definition. These questions articulate the needs of people as they make health care decisions. Applicants must clearly explain how their proposed research aligns with one or more of these questions.

3. Demonstrate that the proposed research question and project has the potential to provide truly important information that patients need to make decisions but that is not currently available. Think about what kind of information patients, clinicians, or health systems need to effect interventions and changes that will bring us closer to the elimination of these disparities—and for an effort that makes it feasible to be adopted widely. What information would make the biggest difference to those who seek this change?

4. 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. We are looking for approaches that are highly efficient without sacrificing methodological rigor. We are also interested in the potential for findings to be applied in multiple areas, independent of the disease studied.

5. Make clear how you are accounting for individual differences among patients and patient groups. Average results are useful, but we are also very interested in providing evidence that can be tailored to patient subgroups and individuals based on their clinical and demographic characteristics. We want products of the research that are scalable and generalizable—and can be customized for sites. We recognize that there are challenges in seeking evidence at these levels, but we hope that many applications will seek to provide insights about how individual patients may make use of the products of the research.

PCORI is interested in research that can be rapidly disseminated and implemented into clinical and community settings, yielding prompt improvements in patients' decisions and the outcomes experienced. To that end, projects of shorter duration and projects that take advantage of existing research infrastructure and data are of great interest. Applications must include a dissemination and implementation plan that discusses prospects for dissemination and considers possible barriers as well. For projects that produce important findings deserving dissemination, PCORI will consider subsequent applications that evaluate additional dissemination and implementation efforts.

A variety of study designs and analytic methods may contribute valid new knowledge. These include evidence syntheses, randomized comparisons at either the individual or cluster level, or various observational approaches (eg, quasi-experimental studies). Qualitative methods may also be employed, either in mixed methods approaches or, potentially, as qualitative comparative studies. Evidence syntheses should follow rigorous standards accepted in the field, such as those published by the Agency for Healthcare Research and Quality (AHRQ) or the Institute of Medicine (IOM). Issues of possible heterogeneity of treatment effects must be considered and discussed. Any planned analyses of subpopulations should be discussed. Inclusion of previously understudied population groups, including the elderly, children (if appropriate), and vulnerable populations, is particularly important. Randomized evaluations must be generalizable either by virtue of considering entire populations or by efficiently recruiting highly representative study populations rather than selected volunteers. Observational comparisons must employ study designs and analytic methods that convincingly protect against selection bias and other threats to validity. Applicants should specifically discuss the need to measure factors such as differential adherence to chosen treatments that could create apparent differences in effectiveness in

clinical populations. Regardless of the particular methods employed, proposals are expected to use rigorous methodology. Applicants are encouraged to refer to the contents of the PCORI draft Methodology Report, to be posted on June 4, 2012 at http://www.pcori.org/what-we-do/methodology, in developing their research plan. Because the draft report will not have been finalized with the benefit of public comment before the July 31, 2012 application deadline, adherence to the Report's standards will not be a required element of applications for this funding cycle. Adherence to the finalized Methodology standards will be required in future funding cycles.

Comparisons must be to relevant alternatives, which may include other interventions or clinical strategies designed to treat the same need, or to "usual care," or in some instances to no therapy. The research will ideally provide information about the range of outcomes that are experienced by and important to patients. These outcomes may include quality of life, ability to participate in desired activities, degree of suffering from pain or other symptoms, ability to live independently, and satisfaction with health care.

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 (eg, the elderly; children, if appropriate; patients with multiple chronic conditions; patients with rare conditions) and other vulnerable populations, including those of low socioeconomic status, low literacy and/or numeracy, and patients groups known to experience disparities in health care and outcomes, such as racial/ethnic minorities. Alternatively, the study may focus primarily on comparative effectiveness of strategies for prevention, treatment, screening, diagnosis, or management in one or more of these populations of interest.

Please note that your application will be scored against the eight PCORI review criteria found at *the* end of this document.

Patient and Stakeholder Involvement

A key goal of patient engagement in research is to present information that best supports health decisions through generation of evidence relevant to patients, their caregivers, and clinicians. Patients and other key stakeholders should be meaningfully involved in the research team. The specific members of the team will vary from study to study.

Research proposals should clearly identify the relevant patient population and the health decisions that will be affected by the research. Persons representative of the population of interest, referred to here as patients, their caregivers, and clinicians, should be engaged in all phases of the research process. Patients may include individuals who have or had the condition or who are at risk of the condition under study; it may include patient surrogates or caregivers as well. Clinicians who face these decisions in collaboration with their patients are also relevant team members. Engagement should include participation in formulation of research questions; defining essential characteristics of study participants, comparators, 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 (http://www.pcori.org/assets/PFAguidelines.pdf).

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. Applicants must provide a dissemination and implementation assessment as described in the PCORI Application Guidelines (http://www.pcori.org/assets/PFAguidelines.pdf).

Reproducible and Transparent 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. To that end, we 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 $500,000 in any year—we will also require that applicants propose a plan for sharing of de-identified data, so that results may be reproduced by others in the same dataset. Whether data sharing is ultimately requested will depend on study findings and the availability of funds to support the process. Details of both requirements are in the Application Guidelines (http://www.pcori.org/assets/PFAguidelines.pdf).

Inclusiveness of Different Populations

PCORI seeks to fund research that includes diverse populations with respect to age, gender, race, ethnicity, geography, or clinical status. 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.

Protection of Human Subjects

PCORI adopts, by reference, the Human Subjects requirements of 45 CFR Part 46.

Step 3: Develop Your Application

There are three main parts of designing your project: (1) defining your research question and research strategy, including the study population and analytic approach; (2) describing the people who will comprise your research team and the institutions, organizations, and locations that will be involved; and (3) determining the budget. To better understand each of these steps and to find and complete the application forms, please see the PCORI Application Guidelines (http://www.pcori.org/assets/PFAguidelines.pdf).

Step 4: Know the Review Criteria

It is PCORI's goal to make its funding decisions in a way that best supports our mission of improving patient-centered outcomes and in the most fair and transparent way possible. Below is an overview of PCORI's review and decision-making process.

The PCORI review process includes four stages:

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

You should carefully read and thoroughly understand the PCORI review criteria, at the end of this document, before applying.

Step 5: Submit Your Application

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 the application process, go to the Application Guidelines at http://www.pcori.org/assets/PFAguidelines.pdf.

PCORI Review Criteria

PCORI Criteria	Brief Description
RESEARCH STRATEGY: Background and Significance	
1. Impact of the condition on the health of individuals and populations	Refers to the current impact of the condition on the health of individuals and populations. Is the condition or disease associated with a significant burden in the US population, in terms of prevalence, mortality, morbidity, individual suffering, or loss of productivity? A particular emphasis is on patients with chronic conditions, including those patients with multiple chronic conditions.
2. Innovation and potential for improvement	Refers to the potential that the proposed research may lead to meaningful improvement in patient health, well-being, or quality of care. Is the research novel or innovative in its methods or approach, in the population being studied, or in the intervention being evaluated, in ways that make it likely to change practice? Does the research question address a critical gap in current knowledge as noted in systematic reviews, guidelines development efforts, or previous research prioritizations? Has it been identified as important by patient, caregiver, or clinician groups? Do wide variations in practice patterns suggest current clinical uncertainty? Do preliminary studies indicate potential for a sizeable benefit of the intervention relative to current practice? How likely is it that positive findings could be disseminated quickly to effect changes in current practice?
3. Impact on health care performance	Refers to the potential that the proposed research could lead to improvements in the efficiency of care for individual patients or for a population of patients. Does the research promise potential improvements in convenience or elimination of wasted

PCORI Criteria	Brief Description
RESEARCH STRATEGY: Background and Significance	
	resources, while maintaining or improving patient outcomes?
RESEARCH STRATEGY: Relevance to Patients	
4. Patient-centeredness	Is the proposed research focused on questions and 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? Is the absence of any particularly important outcomes discussed?
RESEARCH STRATEGY: Approach	
5. Rigorous research methods	Refers to the use of appropriate and rigorous research methods to generate patient-centered evidence, including appropriate choice of study design and of analytic methods. How likely is it that the proposed study population, study design, and available sample size will yield unbiased, generalizable information with sufficient precision to be useful and reliable for patients, their caregivers, and clinicians
RESEARCH STRATEGY: Inclusiveness of Different Populations	
6. Inclusiveness of different populations	Does the proposed study include a diverse population with respect to age, gender, race, ethnicity, geography, or clinical status? Alternatively, does it include a previously understudied population for whom effectiveness information is particularly needed? Does the study have other characteristics that will provide insight into a more personalized approach to decision-making based on a patient's unique biological, clinical, or sociodemographic characteristics.
PEOPLE AND PLACES	
7. 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? Are relevant patients and other key users of the study information (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?
BUDGET	
8. 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?

About PCORI

The Patient-Centered Outcomes Research Institute (PCORI) is an independent organization created to help people make informed health care decisions and improve health care delivery. PCORI will commission research that is guided by patients, caregivers, and the broader health care 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 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.

Our History: PCORI was created 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.