



PATIENT-CENTERED OUTCOMES RESEARCH INSTITUTE

Fall 2014 Funding Cycle

PCORI Funding Announcement: Addressing Disparities

Published August 6, 2014

This PCORI Funding Announcement applies to the funding cycle that closes November 4, 2014, at 5:00 p.m. (ET). Application guidelines, templates, and other resources are available at <http://www.pcori.org/fall-2014-disparities/>.



About PCORI

PCORI is committed to transparency and a rigorous stakeholder-driven process that emphasizes patient engagement. PCORI uses a variety of forums and public comment periods to obtain public input to enhance its work. PCORI helps people make informed healthcare decisions and improves healthcare delivery and outcomes by producing and promoting high-integrity, evidence-based information that comes from research guided by patients, caregivers, and the broader healthcare community.

PCORI was authorized by the Patient Protection and Affordable Care Act of 2010 as a nonprofit, 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."

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Published	August 6, 2014																
Letter of Intent Deadline	September 5, 2014, by 5:00 p.m. (ET) Letters of Intent will be screened for responsiveness to this PCORI Funding Announcement (PFA) and fit to program goals. Only those selected will be permitted to submit full applications. Notification of request to submit full application will occur no later than September 19, 2014.																
Summary	In this PFA, we seek to fund comparative effectiveness research (CER) studies that evaluate and compare new and/or enhanced interventions to reduce or eliminate disparities in health and health care. Studies in the Addressing Disparities program should focus on overcoming barriers that may disproportionately affect the outcomes of specific groups of patients, or identify best practices for sharing results and information about patient-centered research across patient groups.																
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Earliest Project Start Date:	July/August 2015																
Maximum Project Budget (Direct Costs)	\$1.5 million																
Maximum Project Period	Three years																
Funds Available up to	\$8 million																
Eligibility	Applications may be submitted by any private sector research organization, including any nonprofit or for-profit organization, and any public sector research organization, including any university or college hospital or healthcare system, laboratory or manufacturer, or unit of local, state, or federal government. The Internal Revenue Service must recognize all US applicant organizations. Nondomestic components of organizations based in the US and foreign organizations 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 are not permitted to apply.																



Review Criteria	<ol style="list-style-type: none">1. Impact of the condition on the health of individuals and populations2. Potential for the study to improve health care and outcomes3. Technical merit4. Patient-centeredness5. Patient and stakeholder engagement
Contact Us	<p>Programmatic Inquires: Please contact the PCORI Helpdesk via email (pfa@pcori.org), phone (202-627-1884), or online (http://www.pcori.org/PFA/inquiry). PCORI will provide a response within three business days. However, we cannot guarantee that all questions will be addressed three business days prior to a Letter of Intent or application deadline.</p> <p>Administrative, Financial, or Technical Inquiries: Please contact the PCORI Helpdesk at pfa@pcori.org. PCORI will provide a response within two business days. Please note that during the week of the application deadline, response times may exceed two business days. One week prior to an application deadline, applicants may also call the PCORI Helpdesk (202-627-1885). Applicants are asked to plan accordingly. It is the applicant’s responsibility to submit the application on or before the application deadline.</p>
Other	*Deadlines are at 5:00 p.m. (ET). If deadlines fall on a weekend or a federal holiday, the deadline will be the following Monday or the next day after the federal holiday.

New or Revised for the Fall 2014 Funding Cycle:

- New section on the Addressing Disparities Program Targeted Populations
 - Note populations of interest
 - Note non-priority areas of funding
- New/updated sections: Non-responsive and Non-priority Research Areas, and Replication and Reproducibility of Research and Data Sharing Plan
- Revised and expanded “Letter of Intent” section and added instructions
- New “LOI Review” section; this is now a competitive screening process. Only Letters of Intent deemed most responsive to this PFA will be invited to submit a full application.
- No longer accepting Greater Than requests to increases to the budget or time (project duration) for studies
- New “IV. Merit Review” section and updated Criterion 3



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I. Introduction

Summary of Program

PCORI invites applications for comparative clinical effectiveness research (CER) designed to evaluate and compare new and/or enhanced interventions to reduce or eliminate disparities in health and health care. Studies should focus on overcoming barriers that may disproportionately affect the outcomes of specific groups of patients, or identify best practices for sharing results and information about patient-centered research across patient groups.

Background

Patients, caregivers, and clinicians often lack the appropriate evidence required to make the best choices regarding prevention, screening, diagnosis, monitoring, or treatment. PCORI seeks to fund studies that provide evidence to help guide decisions about how to eliminate disparities in health and health care and ensure that people receive care according to their needs and have the opportunity to achieve the best possible health outcomes.

PCORI is entrusted by the public to fund research that will matter to patients, their caregivers, and other stakeholders (defined as clinicians and clinician societies, hospitals, and health systems; payers [insurance]; purchasers [business]; industry; researchers; policy makers; and training institutions). 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 research questions, reviewing research proposals, conducting research, disseminating research findings, promoting the implementation of research findings, and using the results to understand and address patient and other stakeholder needs.

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 in care and outcomes remain pervasive, leading to preventable suffering and interfering with the ability of individuals and families to live full, healthy lives.

Disparities in health and health care persist, based on race/ethnicity, gender, geographic location, socioeconomic status, disability, 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 multifactorial, complex, and context specific. The health disparities literature has largely been devoted to describing disparities and identifying the potential sources and drivers of those disparities. Despite the heterogeneity of populations being studied, research has identified consistent disparities in access, healthcare quality, and health outcomes for a variety of conditions across multiple settings.

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 underserved and vulnerable patient populations.



However, there have not been many studies comparing interventions at these different levels for improving health outcomes.

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 or, conversely, they may further exacerbate disparities. It is important to delineate when generic quality improvement can improve outcomes versus when a more targeted approach, with a focus on reducing disparities, is needed. Some studies have started to examine how redesigning the healthcare system may reduce disparities in care and advance health equity. For example, preliminary data show that the patient-centered medical home model of care delivery may eliminate disparities in prevention, diagnosis, and treatment for a variety of conditions, even in the most vulnerable patient populations, by providing comprehensive, coordinated, and accessible care. Accountable care organizations may also provide a promising model for reducing disparities. Comparative effectiveness studies examining how different care delivery models can reduce disparities are needed (e.g., comparing different models of how patient-centered medical homes and accountable care organizations are structured and operate).¹

Other system-level research has examined performance incentive models such as pay-for-performance and pay-for-reporting programs, the role of public reporting, and the use of health information technology (HIT) in reducing disparities. Multiple studies show that vulnerable patient populations are more likely to receive care in poorer performing inpatient and outpatient settings, raising concerns about performance- or incentive-based payments. PCORI is interested in comparative effectiveness studies examining which system-level interventions are most effective in reducing disparities in care.

Research of Interest

PCORI's Addressing Disparities program seeks to fund investigator-initiated research that:

- Compares evidence-based interventions to reduce or eliminate disparities in patient-centered outcomes (PCOs), including health, health care, and patient-reported outcomes. For example, by accounting for possible differences at the patient, provider, or systems level, we are interested in research to determine what interventions can be most effective for eliminating disparities in outcomes.
- Identifies and compares promising practices that address contextual factors (e.g., socioeconomic, demographic, or community) and their impact on patient-centered health outcomes.
- Compares benefits and risks of treatment, diagnostic, prevention, or service options with attention to eliminating disparities.
- Compares and identifies best practices for tailoring evidence-based interventions to patient

¹ See Cooper LA, Marsteller JA, Noronha GJ, Flynn SJ, Carson KA, Boonyasai RT, Anderson CA, Aboumatar HJ, Roter DL, Dietz KB, Miller ER 3rd, Prokopowicz GP, Dalcin AT, Charleston JB, Simmons M, Huizinga MM. A multi-level system quality improvement intervention to reduce racial disparities in hypertension care and control: study protocol. *Implement Sci.* 2013 Jun 4;8:60; Brown AF. Patient, system and clinician level interventions to address disparities in diabetes care. *Curr Diabetes Rev.* 2007 Nov; 3(4):244-8.



populations at risk for disparities.

- Focuses on one or more of the following target populations: racial/ethnic groups, individuals with low socioeconomic status, individuals with limited English proficiency, lesbian, gay, bisexual, and transgender (LGBT), residents of rural areas, and individuals with disabilities.

Addressing Disparities Targeted Populations

PCORI's Addressing Disparities program 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 clinical effectiveness research may be examined. PCORI recognizes that some proposed studies may represent important PCOR opportunities even in the absence of a broadly diverse study population. However, the burden is on the applicant in such cases to justify the importance of the study in the absence of diversity. Alternatively, PCORI's Addressing Disparities program is interested in studies focusing on previously understudied populations for whom effectiveness information is particularly needed, such as hard-to-reach populations or patients with disabilities. 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's Addressing Disparities program focuses on the following list of populations to guide our efforts in research and engagement, which includes:

- Racial and ethnic minority groups
- Low-income groups
- Residents of rural areas
- Individuals with special healthcare needs, including individuals with disabilities
- Patients with low health literacy/numeracy and/or limited English proficiency
- LGBT persons

The following areas are not considered priority areas for funding:

The Addressing Disparities program has funded a large number of projects that focus on self-management techniques, community health workers/navigators, and cultural/language tailoring of interventions. Applications that aim to study these types of interventions will undergo substantial scrutiny to ensure that the studies do not significantly overlap with previously funded studies or concurrent proposals, or that they fill a gap within the program's portfolio.

Sample Research Questions

The following questions are examples of the types of questions that your research may help answer. This list is by no means exhaustive. **All questions must have a comparative component.**

- Compare which characteristics of the patient-centered medical care are most critical to implement in order to improve PCOs, reduce disparities, and promote health equity.
- Compare best options, materials, and venues for patient education materials that take into consideration patient and caregiver culture, beliefs, literacy, and numeracy, to reduce disparities and improve outcomes.
- How do the practices of the top-performing facilities that primarily serve racial or ethnic minority



groups, low-income populations, or other groups at risk for experiencing disparities compare with lower-performing facilities? Which of the promising practices are replicable?

- Given that effective interventions to improve care in vulnerable populations often require a multipronged approach, compare what options work best under different circumstances.

Certain physiological measurements, such as blood pressure and serum cholesterol, are strongly linked to complications or other outcomes that patients care about. Therefore, an application to PCORI that proposes a study comparing two approaches to helping people control their blood pressure would be well-aligned with PCORI's focus on patient-centeredness, assuming that the study would also compare the two approaches' effects on any other relevant outcomes that are important to patients, such as treatment-related symptoms (side effects).

To be competitive for a PCORI contract, an application must make the case that its proposed research question(s) and outcomes will matter to patients and/or other stakeholders.

Evidence to Action Networks

PCORI is interested in ensuring communication and engagement between awardees with similar needs and interests and end users to help refine and improve the research and facilitate dissemination of research findings that will help patients and the public to make better and informed healthcare decisions. To meet this goal, PCORI has set up Evidence to Action Networks, where PCORI facilitates engagement among awardees and cross-learning between projects and teams comprising researchers, patients, caregivers, and other stakeholders. In addition, PCORI facilitates exchanges between awardees and end users (e.g., patients, caregivers, and other stakeholders such as payers, employers and purchasers, clinicians, professional societies, policy makers, and training institutions) for dissemination and implementation of important research findings.

Awardees are encouraged to participate in these Evidence to Action Networks as they become available.

II. Guidance for Proposing Research

Research Priorities

PCORI funds patient-centered outcomes research (PCOR), a type of comparative CER. The studies PCORI supports must include the perspectives of patients and other healthcare stakeholders. To be considered responsive, applications must describe research that:

- *Compares at least two alternative approaches, both of which are viable alternatives.* The types of interventions tested can include specific drugs, devices, and procedures, as well as other types of alternatives, such as medical and assistive devices and technologies, diagnostic testing, behavioral change, and a wide variety of strategies for improving delivery systems, but the studies must be comparative. "Usual care" (or no specific intervention) may be an appropriate comparator if this is a realistic choice faced by patients and other stakeholders, but the clinical characteristics must be specified. Applications proposing to use usual care as the comparator must justify the choice to use usual care (e.g., usual care is guidelines-based) and should clearly



describe the components of usual care that will be used or measured in the research. A clear description of usual care is necessary to enhance the reproducibility of the research in other settings.

- *Compares two or more clinical strategies that each have established efficacy.* It may be appropriate to include as a comparator a generally accepted practice that occurs with insufficient evidence of efficacy. Applications should evaluate the comparison of two or more clinical interventions. PCORI would like the efficacy of each intervention to be known prior to the initiation of the proposed project, which may include pilot data as appropriate. PCORI is also concerned about commonly accepted practices that occur with insufficient evidence of efficacy. The application must provide information about efficacy of the clinical interventions that will be compared. Projects that aim to develop new or novel interventions, which lack evidence, will be considered out of scope.
- *Studies the benefits and harms of interventions and strategies delivered in real-world clinical settings.* PCORI is interested in innovative studies that provide practical information that can help patients and other stakeholders make informed decisions about their health care and health outcomes.
- *Is based on health outcomes that are meaningful to the patient population under study and are likely to guide the decisions regarding care made by patients, caregivers, and providers.* While most PCOs directly impact the patient's quality of life, certain physiological measurements, such as blood pressure and serum cholesterol, are strongly linked to complications or other outcomes that patients care about and are more knowledgeable of because of increased awareness.

Non-responsiveness

Applications will be considered non-responsive if the proposed research:

- Conducts a formal cost-effectiveness analysis in the form of dollar-cost per quality-adjusted life-year to compare two or more alternatives.
- Measures the relative costs of care of two or more alternative approaches as the primary criteria for choosing the preferred alternative.

Proposals that include studies of these issues may measure and report utilization of any or all health services, but may not employ direct measurements of costs of care.

PCORI does have an interest, however, in studies that address questions about conditions that lead to high costs to the individual or to society. This is included in our review criterion on impact of the condition on the health of individuals and populations. Thus, PCORI is also interested in studies that:

- Examine the effect of costs on patients, such as patients' out-of-pocket costs, hardship or lost opportunity, or costs as a determinant of or barrier to access to care;
- Address cost-related issues such as the resources needed to replicate or disseminate a successful intervention; or
- Evaluate interventions to reduce health system waste or increase health system efficiency.



Proposals that include studies of these issues without utilizing a formal cost-effectiveness analysis or comparing the costs of alternatives are considered responsive.

PCORI discourages proposals in the following categories and is likely to deem them nonresponsive:

- Study of the natural history of disease
- Instrument development
- Pharmacodynamics
- Fundamental science or study of biological mechanisms
- Developing and evaluating new decision aids or clinical prognostication tools
- Establishing efficacy for a new clinical strategy
- Pilot studies intended to inform larger efforts
- Comparisons of patient characteristics rather than clinical strategy options

Features of Patient-Centered Outcomes Research (PCOR)

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, or palliative care to inform decision making, highlighting the choices 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, functioning, 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.
- Directly compares clinical interventions that are generally available in the clinical settings.
- Obtains the perspectives of stakeholders to address the burdens to individuals, availability of services, and requirements for technology and personnel.

Leveraging Existing Resources

Investigators are encouraged to propose studies that leverage existing resources, such as adding PCOR to an existing large clinical trial or analyzing existing large databases that contain valuable, relevant information that may be used to answer important comparative effectiveness research questions. PCORI is also interested in seeking proposals for meta-analyses that use individual participant data.

Preliminary Data and Use of Accepted Measures

PCORI encourages investigators to design their research using valid PCOs measures, and to include preliminary data that support the proposed measures. Investigators are encouraged to consider those measures described in the [Patient Reported Outcomes Measurement Information System \(PROMIS\)](#).

Documentation of Assumptions

PCORI specifically seeks studies that are sufficiently powered to detect clinically meaningful effects. To that end, applicants must justify the proposed sample sizes by explaining the assumptions used in all



study power calculations. The application should clearly state all the necessary assumptions (i.e., the primary outcome measure, the estimated difference in the mean value of this measure between study arms, standard deviation of the measure, type I error rate, and any other assumptions). All such estimates must be justified by referring to prior published research or preliminary data.

Studies in Rare Diseases

PCORI is interested in the investigation of strategies that address care for patients with rare conditions. 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 conditions that affect fewer than 200,000 individuals in the US or have a prevalence of less than 1 in 1,500 persons.

Methodological Considerations

Regardless of study design, proposals must adhere to all relevant [PCORI Methodology Standards](#). These include 47 individual standards that fall into 11 categories. The first five categories are cross-cutting and are relevant to most PCOR studies. Researchers should refer to all of these standards when planning and conducting their research projects. These categories are:

- Standards for Formulating Research Questions
- Standards Associated with Patient-Centeredness
- Standards on Data Integrity and Rigorous Analyses
- Standards for Preventing and Handling Missing Data
- Standards for Heterogeneity of Treatment Effect (HTE)

Six other categories of standards will be applicable to particular study designs and methods. The standards in each of these categories should be used for guidance when they are relevant to a particular study. These categories are:

- Standards for Data Registries
- Standards for Data Networks as Research-facilitating Infrastructures
- Standards for Causal Inference Methods
- Standards for Adaptive and Bayesian Trial Designs
- Standards for Studies of Diagnostic Tests
- Standards for Systematic Reviews

Most of these should be considered “minimal” standards. Additional best practices, including relevant guidelines for the conduct of clinical trials developed by other organizations, should be addressed in the application for PCORI funding.

All applicants should specifically discuss their capacity to measure factors such as differential adherence



to chosen treatments (or participation in intervention programs) that could create or explain apparent differences in the effectiveness of the alternative interventions being compared in clinical populations.

Patient and Stakeholder Engagement

PCORI encourages all applicants to clearly describe the patient and stakeholder engagement in their research proposals. PCORI understands that patient and stakeholder engagement in research can take many forms; it is not seeking one particular type or method of engagement. Rather, applicants should communicate how patients (those with lived experience), family members, caregivers, and the organizations that represent them, as well as any other relevant stakeholders, will be involved in study activities. Because this type of engagement in research is a relatively new concept, PCORI has developed the Engagement Rubric to guide both applicants and merit reviewers. Additionally, studies are expected to adhere to PCORI's Methodology Standards Associated with Patient-centeredness and to the PCOR Engagement Principles found within the rubric. These and additional resources are available in [PCORI's Funding Center](#).

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 CER may be examined, otherwise known as heterogeneity of treatment effects. PCORI recognizes that some proposed studies may represent important PCOR opportunities even in the absence of a broadly diverse study population. However, the burden is on the applicant in such cases to justify the importance of the study in the absence of diversity and to discuss which subgroups are most important and how they will be analyzed, including whether there will be power to examine the question of effectiveness in subgroups. 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 a full list of priority populations to guide our efforts in research and engagement, which includes:

- Racial and ethnic minority groups
- Low-income groups
- Women
- Children (age 0–17 years)
- Older adults (age 65 years 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 makeup affects their medical outcomes
- Patients with low health literacy/numeracy and/or limited English proficiency



- LGBT persons

Please refer to the section above for Addressing Disparities' specific targeted populations.

Protection of Human Subjects

PCORI adopts, by reference, the Human Subjects requirements of 45 CFR Part 46. If the proposed research will involve human subjects, refer to the Supplemental Instructions for Preparing the Protection of Human Subjects Section of the Research Plan in Part II of the Instructions for the PHS 398 Form provided by the [National Institutes of Health](#). 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.

Replication and Reproducibility of Research and Data Sharing Plan

PCORI is committed to maximizing the utility and usability of data collected in our funded projects. This is essential to building confidence in the accuracy of these findings. PCORI supports policies to promote sharing of study documentation (e.g., study protocol, programming code, and data definitions) so that other researchers may replicate the findings in other populations. Please propose a method for sharing data and appropriate documentation on request.

Budget and Project Duration

The maximum budget for this PFA is \$1.5 million total direct costs. The maximum period of performance is three years. This program does **not** consider exceptions to the budget and period of performance limits. If you submit an application that exceeds the \$1.5 million total direct cost cap and/or the three-year period of performance, your application will be removed for noncompliance.

III. How to Submit a Proposal

Letter of Intent

Applicants should download the [Letter of Intent template for the Addressing Disparities PFA](#) from the PCORI Funding Center. They must complete the document and convert it to a PDF with a three-page limit. All references should be included as in-text citations. Letters of Intent that exceed the page limit will **not** be reviewed. Do not upload additional documents as part of your LOI, including letters of endorsement or support, as they are not requested at this stage. Their inclusion will result in LOI rejection without review. Please visit the PCORI Funding Center for additional applicant resources, including the PFA and required templates.

Please answer all of the questions in the Letter of Intent template. Then upload your document into the PCORI Online System. The deadline for LOI submission is September 5, 2014, by 5:00 p.m. (ET).

Letter of Intent Review

Letters of Intent are qualitatively evaluated on the following criteria (note that PCORI does not score the LOI):



- Importance and relevance of the topics to PCORI priorities, as evidenced by critical gaps identified by clinical guidelines developers and/or recent relevant systematic reviews
- Clarity and credibility of applicants' responses to the LOI questions
- Prior relevant experience of the Principal Investigator (PI) and research team
- Programmatic fit and balance, taking into consideration whether the study proposed significantly overlaps with previously funded studies or concurrent proposals or, conversely, whether the proposal fills a gap in the portfolio of proposals with certain characteristics, including disease category, topics, priority population, and methodologies

Only Letters of Intent deemed most responsive to this PFA will be invited to submit a full application. Notification of request to submit full application will occur no later than September 19, 2014. Please refer to the [Application Guidelines](#) for due dates and information on how to submit your LOI via PCORI Online.

Note: An individual may submit only one LOI per PFA as a PI. While a PI may submit an LOI to other PFAs, the research topic/project must be distinct. Letters of Intent with scientific overlap or that appear to be duplicate submissions will be removed during the LOI screening process.

Submission Dates

Letters of Intent and applications must be submitted in accordance with the published dates and times listed in the Overview in this PFA and in the [PCORI Funding Center](#).

PCORI Online System

To submit a proposal, you must register with the [PCORI Online System](#) and submit both a Letter of Intent and an application for each cycle in which you are applying.

Applicant Resources

PCORI Funding Center	http://www.pcori.org/fall-2014-disparities/
PCORI Online System	pcori.fluxx.io
PCORI Funding Awards	pcori.org/pfaawards

IV. Merit Review

PCORI Merit Review is a multiphase process that includes: evaluation of Letters of Intent; preliminary review of full applications by review panels; in-person panel discussion of a subset of full applications (identified by PCORI's Research Priority Area Program Staff, based on the preliminary review and program priorities); Selection Committee recommendation of applications for funding; and finally, Board of Governors award approval (no later than May 2015).

Preliminary Review

PCORI conducts rigorous merit review of the full applications it receives. Note that applications may be



eliminated from the review process for administrative or scientific reasons (e.g, non-responsiveness). An application may be administratively withdrawn if it is incomplete or submitted past the stated due date and time, or it does not meet the administrative or formatting criteria outlined in the [Application Guidelines](#), in the PCORI templates, and in the PCORI Online System. An application may be scientifically withdrawn if it is not responsive to the guidelines as described in this PFA, describes research that is not comparative, includes cost-effectiveness analysis, or otherwise does not meet PCORI programmatic requirements.

Administratively and scientifically responsive applications will be reviewed by one or more specially convened Merit Review panels. Each panel is recruited by PCORI Merit Review Officers, who identify the Chair; scientist reviewers who are clinical experts familiar with the clinical content of submitted applications; methodological and statistical experts familiar with pragmatic clinical trials and large database analyses; patient representatives trained in review of scientific proposals; and representatives of other stakeholder groups.

The following are PCORI's Merit Review criteria. These five criteria are used by PCORI's review panels during the preliminary and in-person phases to score and evaluate all submitted applications:

Criterion 1. Impact of the condition on the health of individuals and populations

The proposal addresses the following questions:

- 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?
- Alternatively, does the condition or disease impose a significant burden on a smaller number of people who have a rare disease?
- Does the proposal include a particular emphasis on patients with one or more chronic condition(s)?

Criterion 2. Potential for the study to improve health care and outcomes

The proposal has the potential to lead to meaningful improvement in the quality and efficiency of care and to improvements in outcomes important to patients. It addresses the following questions:

- Does the research question address a critical gap in current knowledge as noted in systematic reviews, guideline 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?
- 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 improve care?
- Do preliminary studies indicate potential for a sizable benefit of the intervention relative to current practice? How likely is it that positive findings could be disseminated and implemented quickly, resulting in improvements in practice and patient outcomes?

Criterion 3. Technical merit



The proposal has sufficient technical merit in the research design to ensure that the study goals will be met. It addresses the following questions:

- Does the proposal delineate a clear conceptual framework/theory/model that anchors the background literature and informs the design, key variables, and relationships being tested?
- Are the comparison interventions realistic options that exist in current practice?
- Are sample size and power estimates presented that are based on realistic and careful evaluations of the anticipated effect size?
- Is the project timeline realistic, including specific scientific and engagement milestones?
- Does the research team have the necessary expertise to conduct the project?
- Is the organizational structure and are the described resources appropriate to carry out the project?
- Is there a diverse study population with respect to age, gender, race, ethnicity, and clinical status, appropriate for the proposed research?

Criterion 4. Patient-centeredness

The proposal demonstrates patient-centeredness at every stage of the research. It addresses the questions:

- Is the research focused on questions that affect outcomes of 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?

Criterion 5. Patient and stakeholder engagement

The proposal demonstrates that people representing the population of interest and other relevant stakeholders are engaged in ways that are appropriate and necessary in a given research context. It addresses the questions:

- Are patients and other stakeholders engaged in:
 - Formulating research questions
 - Defining essential characteristics of study participants, comparators, and outcomes
 - Identifying and selecting outcomes that the population of interest notices and cares about (e.g., survival, function, symptoms, health-related quality of life) and that inform decision making relevant to the research topic
 - Monitoring study conduct and progress
 - Designing/suggesting plans for dissemination and implementation activities
- Are the roles and the decision making authority of all research partners clearly stated?
- Does the proposal demonstrate the principles of reciprocal relationships, co-learning, partnership, trust, transparency, and honesty?



In-Person Review

After preliminary review is completed, panel scores and critiques are evaluated by PCORI program staff to identify a subset of applications to be discussed at the in-person review meeting. Not all submitted applications move forward to in-person review, but all applications are evaluated and scored based on PCORI's Merit Review criteria, which include evaluation of adherence to PCORI's Methodology Standards.

During the in-person review, panels meet to discuss applications and further clarify the merits of the proposed research along with identifying areas for improvement. Additionally, each application is re-scored based on the content of discussion. The in-person panel meeting is led by a Chair and a PCORI Merit Review Officer, who ensure that all applications receive a fair and thorough review informed by the standards outlined in the PFA.

Post-Panel Review

Following the in-person panel review, meritorious applications are reviewed by PCORI program staff, who review Merit Review scores and comments, identify duplication or synergy among funded projects, and consider the fit of applications within the programmatic vision. Program staff then recommend projects to a Selection Committee that includes members of PCORI's Board of Governors. The Selection Committee considers recommendations and works with staff to identify a slate of applications for possible funding based on merit review scores, programmatic balance and fit, and PCORI's strategic priorities. This slate is proposed to PCORI's Board of Governors for its consideration and approval.

Funding Recommendations

Factoring in the total available funds allotted for this announcement, high-scoring applications that fit the programmatic needs and satisfactorily address reviewers' critiques and adhere to PCORI's Methodology Standards will be considered for funding by the PCORI Board of Governors. Applicants will receive notification of the funding status of their application no later than May 2015.