Cycle 1 2016 Funding Cycle

PCORI Funding Announcement: Addressing Disparities

Published February 1, 2016
Updated February 16, 2016

This PCORI Funding Announcement applies to the funding cycle that closes on June 6, 2016, at 5 p.m. (ET). Application guidelines, templates, and other resources are available at http://www.pcori.org/Cycle-1-2016-disparities/.
About PCORI

The Patient-Centered Outcomes Research Institute (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 Congress in 2010 as a nonprofit, nongovernmental organization. PCORI’s purpose, as defined by our authorizing legislation, 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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## Overview

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<th>Published</th>
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<tr>
<td>Letter of Intent Deadline</td>
<td>March 2, 2016, by 5 p.m. (ET)</td>
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Letters of Intent (LOIs) will be screened for responsiveness to this PCORI Funding Announcement (PFA) and for fit to program goals. Only those selected will be permitted to submit full applications. Notification of denial or approval to submit a full application will occur no later than April 8, 2016.

### Summary

In this PFA, we seek to fund comparative clinical effectiveness research (CER) studies that evaluate and compare 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 should identify best practices for reducing disparities.

### Applicant Resources


### Key Dates

<table>
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<td>Online System Opens</td>
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<tr>
<td>LOI Deadline</td>
<td>March 2, 2016, by 5 p.m. (ET)</td>
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<td>LOI Status Notification</td>
<td>April 8, 2016</td>
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<td>Application Deadline</td>
<td>June 6, 2016, by 5 p.m. (ET)</td>
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<td>Merit Review</td>
<td>September 2016</td>
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<td>Awards Announced</td>
<td>November 2016</td>
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<td>Earliest Project Start Date</td>
<td>January 2017</td>
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### Maximum Project Budget (Direct Costs)

$1.5 million

### Maximum Research 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 U.S. applicant organizations. Nondomestic components of organizations based in the United States and foreign organizations may apply, as long as there is demonstrable benefit to the U.S. healthcare system and U.S. 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

1. Potential for the study to fill critical gaps in evidence
2. Potential for the study findings to be adopted into clinical practice and to improve delivery of care
3. Scientific merit (research design, analysis, and outcomes)
4. Patient-centeredness
5. Patient and stakeholder engagement
**Contact Us**

**Programmatic Inquires:** Please contact the PCORI Helpdesk via email (sciencequestions@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 in three business days prior to an LOI or application deadline.

**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 a deadline, response times may exceed two business days. 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.

**Other**

Deadlines are at 5 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 Cycle 1 2016 Funding Cycle:**
- Updated section on Addressing Disparities (AD) Priority Areas for funding
- Updated section on Community Health Worker/Navigator projects
- Updated Criterion 5 to reflect the new dual-PI plan policy
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I. Introduction to the Addressing Disparities Program

PCORI invites applications for clinical CER designed to evaluate and compare interventions intended to reduce or eliminate disparities in health and health care. Patients, caregivers, and clinicians often lack the appropriate evidence required to make the best choices regarding prevention, screening, diagnosis, monitoring, or treatment. Applications to the Addressing Disparities Program should focus on overcoming barriers that may disproportionately affect health outcomes or focus on identifying best practices for reducing disparities in target populations (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; and lesbian, gay, bisexual, and transgender [LGBT] persons).

Background

The health disparities literature has largely been devoted to describing disparities, including identifying their potential sources and drivers. Previous research has identified pervasive disparities in access to high-quality health care and worse health outcomes for specific populations across multiple conditions and multiple settings, outcomes that are based on race/ethnicity, gender, geographic location, socioeconomic status, disability, and other factors. These disparities have been well documented. Thus, PCORI’s Addressing Disparities Program is seeking applications that compare evidence-based interventions to improve health outcomes and reduce disparities for target populations (see section below on Addressing Disparities Target Populations).

Research of Interest

PCORI seeks to fund studies that provide evidence to help guide decisions about how to eliminate disparities in health and health care, as well as how to ensure that people receive care according to their needs and have the opportunity to achieve the best possible health outcomes.

The Addressing Disparities Program is interested in funding CER of evidence-based interventions aimed at reducing and eliminating disparities in health and health care. Interventions to reduce persistent disparities have been understudied and are multifactorial, complex, and context-specific. Often, evidence-based interventions have been shown to be effective in the general population but lack evidence for effectiveness in populations at risk for disparities. The Addressing Disparities Program is interested in studies that tailor and test these types of interventions in these populations.

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—e.g., by accounting for possible differences at the patient, provider, or systems level, we are interested in research to determine which interventions can be most effective for eliminating disparities in outcomes
- Compares benefits and risks of treatment, diagnostic, prevention, or service options, with a focus on eliminating disparities
• Compares and identifies practices for tailoring evidence-based interventions to patient populations at risk for disparities

Applicants are strongly encouraged to review the funded research on PCORI’s website to ensure that their proposed research is not duplicative of projects that have already been funded.

Addressing Disparities Targeted Populations

PCORI’s Addressing Disparities Program is interested in studies focusing on previously understudied populations for whom effectiveness information is particularly needed. Proposed research must focus on at least one of these groups:

• 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
• Lesbian, gay, bisexual, and transgender (LGBT) persons

Addressing Disparities Priority Areas

The Addressing Disparities Program is interested in applications that include team-based care and/or strategies to enhance family/caregiver involvement in patient care to reduce disparities and improve patient-centered and clinical outcomes. In addition, the Addressing Disparities Program is particularly interested in funding comparative effectiveness studies that focus on:

• Interventions to address disparities in HIV prevention and treatment
• Interventions to reduce sleep disorder disparities among racial/ethnic minorities
• Pharmacologic and non-pharmacologic treatments for Alzheimer’s disease and other forms of dementia
• Use of opioid and non-opioid pain relievers, avoiding unintentional overdoses and substance dependence
• Interventions to improve communication between clinicians and people with disabilities

Applications that cover any of these high-priority areas must also focus on one or more of the Addressing Disparities target populations: 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; and lesbian, gay, bisexual, and transgender (LGBT) persons.

Community Health Worker/ Navigator Projects

The Addressing Disparities Program has funded a large number of projects that focus on community health worker/navigator interventions. Applications that aim to study these types of interventions must
focus on one of the following areas, which are based on existing evidence gaps:

- Comparing different community health worker/patient navigator program models, worker functions, training and certification levels, and implementation approaches across different settings, conditions, and populations

- Examining the integration of community health workers/patient navigators into the care team, determining specifically the organizational strategies and components that are essential to well-functioning teams and the factors that increase acceptance by care teams

- Comparing community health worker/patient navigator interventions to interventions using nurse case managers or social workers

Applications that propose research focusing on community health workers or navigators will undergo substantial scrutiny to ensure that the studies do not overlap significantly with previously funded studies or concurrent applications and that they fill a gap within the program’s portfolio. Applicants are encouraged to review the current portfolio to avoid redundancy with funded projects.

II. Requirements for PCORI Research

This section includes language that is specific to PCORI’s requirements for applications for funding. Applicants should use this section as guidance when preparing their applications.

Research Priorities

To be considered responsive, applications must:

- *Describe comparators.* Regardless of the approach being studied, all proposed research projects must compare at least two alternatives. If the applicant proposes “usual care” as a rational and important comparator in the proposed study, then it must be described in detail, coherent as a clinical alternative, and properly justified as a legitimate comparator (e.g., usual care is guidelines-based). Additionally, it must be accompanied by an explanation of how the care given in the “usual care” group will be measured in each individual patient and how appropriate inferences will be drawn from its inclusion. “Usual care” must be described as mentioned above to ensure that it accounts for geographic and temporal variations, and to ensure that it has wide interpretability, applicability, and reproducibility.

- *Describe research that compares two or more alternatives each of which has established efficacy.* PCORI expects that the efficacy or effectiveness of each intervention be known. If the efficacy/evidence base is insufficient, then data need to be provided to document that the

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intervention is used widely. The application must provide information about efficacy of the interventions that will be compared; pilot data may be appropriate. Projects that aim to develop new or novel interventions that lack evidence of efficacy or effectiveness will be considered out of scope.

- Describe research that studies the benefits and harms of interventions and strategies delivered in real-world settings. PCORI is interested in studies that provide practical information that can help patients and other stakeholders make informed decisions about their health care and health outcomes.

- Describe research that is based on health outcomes that are meaningful to the patient population, their caregivers, and family members under study, and that are likely to guide their decisions. Applications must demonstrate that patients, caregivers, and/or family members influenced the choice of outcomes to be measured. These outcomes may be measures of quality of life, symptoms of disease, relevant physiological measurements, treatment-related symptoms (side effects), healthcare utilization, and/or clinical outcomes.

**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 clinical CER questions.

**Patient-Centered Outcome Measures**

PCORI encourages investigators to design their research using validated outcome measures and to include preliminary data that support the use of the proposed measures in the study population. Investigators are encouraged to consider those measures that are described in the Patient Reported Outcomes Measurement Information System\(^3\) (PROMIS).

**Studies in Rare Diseases**

PCORI is interested in the investigation of strategies that address care for patients with rare diseases. These types of conditions are defined as life-threatening or chronically debilitating. They occur with such low frequency (conditions that affect fewer than 200,000 in the United States [i.e., less than 1 in 1,500 persons]) that special efforts, such as combining data across large populations, may be needed to address them.

**Studies of Cost-Effectiveness**

Applications will be considered nonresponsive if the proposed research:

- Conducts a formal cost-effectiveness analysis of alternative approaches to providing care
- Directly compares the costs of care between two or more alternative approaches to providing care

Proposals that include studies of these issues may measure and report utilization of any or all health care.

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\(^3\) Available at [http://www.nihpromis.org/](http://www.nihpromis.org/).
services, but may not employ direct measurements of costs of care. For further information, please reference our cost-effectiveness analysis FAQs.

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 the impact of the condition on the health of individuals and populations. Thus, PCORI is 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
- Evaluate interventions to reduce health system waste or increase health system efficiency

Addressing specifically the issue of conditions that lead to high costs, our PCORI Funding Announcements (PFAs) say that “proposals that include studies of these issues without utilizing a formal cost-effectiveness analysis or directly measuring and comparing costs of care alternatives will be considered responsive and will be reviewed.”

Categories of Nonresponsiveness

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

- Instrument development such as new surveys, scales, etc.
- Developing, testing, and validating new decision aids/tools or clinical prognostication tools
- Pilot studies intended to inform larger efforts
- Comparisons of patient characteristics rather than clinical strategy options
- **Applies to APDTO (Assessment of Prevention, Diagnosis, and Treatment Options), IHS (Improving Healthcare Systems) program applicants ONLY:** Studies comparing interventions for which the primary focus is the role of community health workers or patient navigators

Consistent with PCORI’s authorizing law, PCORI does not fund research whose findings will include:

- Coverage recommendations
- Payment or policy recommendations
- Creation of clinical practice guidelines or clinical pathways
- Establishment of efficacy for a new clinical strategy
- Pharmacodynamics
- Study of the natural history of disease
- Basic science or study of biological mechanisms

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4 Available at http://www.pcori.org/sites/default/files/PCORI_Authorizing_Legislation.pdf/.
Avoiding Redundancy

PCORI encourages potential applicants to review funded research at pcori.org, because PCORI intends to balance its funded portfolio to achieve synergy where possible and to avoid redundancy.

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 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 certain types of 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 standards should be considered minimal. The methodology standards\(^5\) reflect practices that should be followed in all cases, and all deviations need to be explained and well justified. Additional best practices, including accepted guidelines for the conduct of clinical trials or observational studies, should be addressed, if applicable, in the application for PCORI funding.

Applicants should discuss specifically how the planned study design will measure and adjust for potential confounding factors that may obscure or artificially create differences attributable to the alternatives being compared. Examples include, but are not limited to, baseline differences in disease severity or other risk factors within the study population, or differences in participation, adherence, or follow-up that may affect outcomes independently of the interventions being compared.

\(^5\) Available at http://www.pcori.org/research-we-support/the-pcori-methodology-report/.
Upcoming New and Revised Methodology Standards

In 2015 the Methodology Committee undertook a process to review the existing Methodology Standards, updating and adding new Standards where indicated. While these proposed revised and new Standards are still under review and not yet benefited from public comment, we encourage you to refer to the potential 2015 revisions. Applicants should continue to adhere to the current Methodology Standards.

Patient and Stakeholder Engagement

PCORI encourages all applicants to describe clearly 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. This rubric is intended to provide examples of engagement and is not intended to be prescriptive. As noted above, studies are expected to adhere to PCORI’s Methodology Standards Associated with Patient-Centeredness as well as to the PCOR Engagement Principles found within the rubric. These and additional resources are available on PCORI’s Engagement in Research page.

Populations Studied

PCORI seeks to fund research that includes populations that are diverse with respect to age, gender, race, ethnicity, geography, or clinical status, so that possible differences in outcomes may be examined in defined subpopulations, otherwise known as heterogeneity of treatment effect (HTE). 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 the study will be powered to examine the question of effectiveness in subgroups. PCORI is particularly interested in the inclusion of previously understudied populations for whom effectiveness information is especially 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 subpopulations. PCORI has developed a list of populations of interest to guide our efforts in research and engagement (note that the Addressing Disparities Program requires that proposed research focus on at least one of the groups indicated by an asterisk below):

- Racial and ethnic minority groups*
- Low-income groups*
- Women

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• 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*
• Veterans and members of the Armed Forces and their families

Protection of Human Subjects
This component (up to five pages) is included in the Research Plan Template. Describe the protection of human subjects involved in your proposed research. PCORI follows the Federal Policy for the Protection of Human Subjects (45 CFR part 46), including the Common Rule. For more detailed information, please see Section 5, “Human Subjects Research Policy,” in the Supplemental Grant Application Instructions for All Competing Applications and Progress Reports,7 issued by the U.S. Department of Health and Human Services (HHS). PCORI does not require that applicants comply with sections of this policy that refer to requirements for federal-wide assurance (FWA) or that refer to standards for including women, minorities, and children. PCORI requires that applicants proposing clinical trials include a data- and safety-monitoring plan. Awardees must also comply with appropriate state, local, and institutional regulations and guidelines pertaining to the use of human subjects in research.

PCORI merit reviewers will examine plans for protection of human subjects in all applications and may provide comments regarding the plans (see How To Evaluate Human Subjects Protections8). Reviewers’ comments on human subjects research are not reflected in the overall application score, but PCORI staff may use them during any potential funding negotiations. Final determinations about adequacy of human subject protections rest with the Institutional Review Board (IRB) or IRBs that have jurisdiction for the study.

The Awardee Institution or organization, whether domestic or foreign, bears ultimate responsibility for safeguarding the rights and welfare of human subjects in PCORI-supported activities.

Required Education of Key Personnel on the Protection of Human Subject Participants
PCORI requires that all applicants adhere to the National Institutes of Health (NIH) policy on education in the protection of human subject participants in the conduct of research. This applies to all personnel


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listed as Key Personnel in the application. The policy and FAQs are available from the NIH website.9

Replication and Reproducibility of Research and Data-Sharing Plan

PCORI is committed to maximizing the utility and usability of data generated and 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 upon request.

Recruitment

Proposals should include information about the size and representativeness of the potential pool of patients from which recruitment will occur and the means by which this size estimate was determined. Likewise, proposals should provide evidence-based estimates of how many participants are ultimately expected in the study, based on expected recruitment, application of the study’s inclusion and exclusion criteria, anticipated acceptance (or refusal) rates, and other factors, such as participant loss to follow-up. Such estimates must be discussed in the applications, must be specified in the milestones, will be reviewed by merit reviewers and PCORI staff, and will be monitored by PCORI in the funded research.

Peer Review and Release of Research Findings

PCORI has a legislative mandate to ensure the scientific integrity of the primary research it supports and to make study findings widely available and useful to patients, clinicians, and the general public within a specific timeframe. The PCORI Board of Governors (Board) adopted the following process for peer review and public release of the results of all funded studies.

Awardee Institutions are required to submit to PCORI for peer review a draft final research report that provides the methodological details, describes the main study results, and properly interprets the findings in clinical or other decisional contexts. Subject matter experts, individuals with expertise on research methodology or biostatistics, and patients, caregivers, and other healthcare stakeholders, will review the draft final research report. After awardees have responded to reviewers’ comments to PCORI’s satisfaction, the report will be accepted and considered final. PCORI will then prepare a 500-word abstract summarizing the study results for patients and the general public, which the Awardee Institution will review and approve.

PCORI will post the following materials on its website no later than 90 days after the draft final research report is accepted: (1) a 500-word abstract for medical professionals, (2) a standardized summary of the study results for patients and the general public, and (3) a link to the study record on ClinicalTrials.gov (as applicable). The final research report, along with anonymized reviewer comments, will be made publicly available on the PCORI website no later than 12 months after its acceptance, except by prior mutual agreement with the Awardee Institution.

III. How To Submit an Application

Letter of Intent (LOI)

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 file; the LOI is limited to three pages and applicants should use in-text citations. The final references page will not be included in the three-page limit. LOIs 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, because they are not requested at this stage. Inclusion of additional documents will result in LOI rejection without review. Please visit the PCORI Funding Center for additional applicant resources, including the PFA and required templates.

Please address all categories in the LOI Template, and then upload your document onto the PCORI Online System. The deadline for LOI submission is March 2, 2016, by 5 p.m. (ET).

Letter of Intent Review

Please refer to the Application Guidelines for information on how to submit an LOI via PCORI Online. LOIs are qualitatively evaluated by a minimum of two program staff on the following criteria:

- Importance and relevance of the topics to PCORI priorities, as evidenced by critical gaps identified by clinical guidelines and/or recent relevant systematic reviews
- Clarity of applicants’ responses to the LOI questions
- Programmatic fit and balance, taking into consideration whether the study proposed overlaps previously funded studies or concurrent applications to a significant degree or, conversely, whether the application fills a gap in the portfolio of applications with certain characteristics, including disease category, topics, priority population, and methodologies

Applicants of LOIs that are deemed responsive to this PFA will be invited to submit a full application. Notification of denial or an invitation to submit an application will occur no later than April 8, 2016.

Applicants are invited to submit an application based on the information provided in the LOI. Any changes to the following require PCORI’s approval:

- Research question(s)
- Specific aims
- Study design
- Comparators
- Principal Investigator (PI)
- Institution

To obtain prior approval for changes or to ask questions, please email pfa@pcori.org.

Note: A PI can only submit one LOI per PFA. However, an individual listed as a PI on one LOI may be listed as and serve in another role (e.g., co-investigator or consultant) on other LOIs within the same PFA during the same cycle. A PI may submit multiple LOIs to different program PFAs in a cycle, but the PI
must ensure that the research topics and projects are not similar. If a PI submits an LOI to multiple program PFAs, LOIs that exhibit scientific overlap or that appear to be duplicate submissions will be disqualified. PCORI will contact the PI and provide him or her with an opportunity to choose which PFA he or she would like to apply to. This applies to single and dual-PI submissions.

**Budget and Project Duration**

The maximum budget for this PFA is $1.5 million total direct costs. The maximum research period of performance is three years (not including peer review). The maximum budget includes all research and peer review-related costs. (Please refer to the Application Guidelines for further details.) Refer to Appendix 2 in the Application Guidelines for a list of allowable and unallowable costs. 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 or the three-year period of research performance, your application will be removed for noncompliance.

**Submission Dates**

LOIs 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 an application, you must register with PCORI Online and submit both an LOI and an application for each cycle to which you are applying.

**Applicant Resources**

- PCORI Funding Center: [http://www.pcori.org/Cycle-1-2016-disparities/](http://www.pcori.org/Cycle-1-2016-disparities/)
- PCORI Online System: [pcori.fluxx.io](pcori.fluxx.io)
- PCORI Funding Awards: [pcori.org/pfaawards](pcori.org/pfaawards)

**IV. Merit Review**

PCORI’s merit review process is designed to support the following goals:

- To identify applications that have the strongest potential to help patients, caregivers, clinicians, and other stakeholders make informed decisions to improve patient outcomes
- To implement a transparent, fair, objective, and consistent process to identify these applications
- To elicit high-quality feedback that reflects a diversity of perspectives to ensure that the research funded by PCORI reflects the interests and views of patients and those who care for them and that it meets the criteria for scientific rigor
- To fund projects that fill important evidence gaps and have strong implementation potential
- To regularly evaluate and continually improve the merit review process and policies in support
of PCORI’s mission

PCORI merit review is a multiphase process that includes PFA development; staff evaluation of LOIs; 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 award approval.

Preliminary Review

PCORI conducts rigorous merit reviews of all of the full applications it receives. Note that applications may be eliminated from the review process for administrative or scientific reasons (e.g., nonresponsiveness). An application may be administratively withdrawn if it is incomplete; is submitted past the stated due date and time; or does not meet the formatting criteria outlined in the Application Guidelines, in the PCORI templates, and in PCORI Online. An application may be withdrawn for scientific reasons 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.

PCORI Merit Review Officers (MROs) recruit each panel based on the number and topic areas represented by invited LOIs. MROs recruit the panel chair, scientist reviewers who are subject matter experts, patient representatives, and representatives of other stakeholder groups. All panel members receive training during the review cycle to ensure that they understand the programmatic and organizational goals of review.

Below are PCORI’s merit review criteria. PCORI’s merit review panels use these criteria during the preliminary and in-person review phases to evaluate and score all submitted applications:

**Criterion 1. Potential for the study to fill critical gaps in evidence**

The proposal should address the following questions:

- Does the application convincingly describe the clinical burden?
- Does the application identify a critical gap in current knowledge as noted in systematic reviews, clinical practice guidelines, or previous research prioritizations?
- Does the application identify a critical gap in current knowledge evidenced by inconsistency in clinical practice and decision making?
- Would research findings from the study have the potential to fill these evidence gaps?

**Criterion 2. Potential for the study findings to be adopted into clinical practice and improve delivery of care**

The application should describe how evidence that is generated from this study could be adopted into clinical practice and delivery of care by others. The application should address the following:

- Does the application identify who will make the decision (i.e., the decision maker) or use (i.e., the end-user) the study findings (not the intervention) produced by this study, such as local and national stakeholders?
• Does the application identify potential end-users of study findings, such as local and national stakeholders, and describe strategies to engage these end-users?
• Does the application provide information that supports a demand for this kind of a study from end-users?
• Would research findings from this study have the potential to inform decision making for key stakeholders? Provide example(s). How likely is it that positive findings could be reproduced by others, resulting in improvements in practice and patient outcomes? Identify the potential barriers that could hinder adoption of the intervention by others.
• Does the application describe a plan for how study findings will be disseminated beyond publication in peer review journals and national conferences?

Criterion 3. Scientific merit (research design, analysis, and outcomes)
The application should show sufficient technical merit in the research design to ensure that the study goals will be met.
• Does the proposal describe a clear conceptual framework anchored in background literature which informs the design, key variables, and relationship between interventions and outcomes being tested?
• Does the application provide justification that the outcome measures are validated and appropriate for the population?
• Does the research plan describe rigorous methods that demonstrate adherence to PCORI’s Methodology Standards?
• Is each of the comparators (e.g., active intervention arm and comparator arm) clearly described and well justified? If “usual care” is one of the arms, is it sufficiently justified and will it be sufficiently measured?
• Are the sample sizes and power estimates based on careful evaluations of the anticipated effect size? Is the effect size adequately justified in relation to the size or dose of the intervention and the research design (e.g., cluster randomized design)?
• Is the study plan feasible?
  o Is the project timeline realistic, including specific scientific and engagement milestones?
  o Is the strategy for recruiting participants feasible?
  o Are assumptions about participant attrition realistic, and are plans to address patient or site attrition adequate?

Criterion 4. Patient-centeredness
The application should demonstrate that the study focuses on improving patient-centered outcomes and employs a patient-centered research design (i.e., design is informed or endorsed by patients). (Note: study can be patient-centered even if the end-user is not the patient, as long as patients will benefit from information.) The proposal should address the following:
Does the application include a thorough description of which outcomes (both benefits and harms) are important to patients, and are those outcomes included in the study plan?

Does the application provide information that indicates that closing the evidence gap is important to patients and other stakeholders?

Are the interventions being compared in the study available to patients now, and are they the best options for comparison (including whether they would be chosen by patients and their healthcare providers for managing the condition being studied)?

Criterion 5. Patient and stakeholder engagement
The proposal should demonstrate the engagement of relevant stakeholders (e.g., patients, caregivers, clinicians, hospitals and health systems, payers [insurance], purchasers [business], industry, researchers, policy makers, and training institutions) in the conduct of the study. Quality of engagement should be evaluated based on the scope, form, and frequency of patient and stakeholder involvement throughout the entire research process. The proposal should address the following:

- Does the application provide a well-justified description of how the research team is interdisciplinary? Does the study include the right individuals (researchers, patients, clinicians, other stakeholders) to ensure that the projects will be carried out successfully?
- Does the application show evidence of active engagement among scientists, patients, and others throughout the entire research process (e.g., formulating questions, identifying outcomes, monitoring study, dissemination, and implementation)? Are the frequency and level of patient and stakeholder involvement sufficient to support the study goals?
- Is the proposed engagement plan appropriate and tailored to the study?
- Are the roles and the decision-making authority of all study partners and investigators clearly described?
  - (Dual-PI Option Only) Does the leadership plan adequately describe and justify roles/areas of responsibility of the PIs?
- Are the organizational structure and resources appropriate to carry out the project?

In-Person Review
During preliminary review, all administratively and scientifically compliant applications are evaluated and scored based on PCORI’s merit review criteria, including evaluation of adherence to PCORI’s Methodology Standards. After the preliminary review is completed, PCORI program staff members evaluate panel scores and critiques to identify a subset of applications for merit reviewers to discuss at the in-person review meeting. Not all submitted applications move forward to in-person review.

During the in-person review, merit reviewers meet to discuss applications, to clarify further the merits of the proposed research, and to identify areas for improvement. In addition, each application is re-scored based on the content of discussion. The chair and PCORI MRO lead the in-person panel meeting and ensure that all applications receive a fair and thorough review according to the standards outlined in the PFA.
Post-Panel Review

After the in-person meeting, PCORI program staff evaluate final merit review panel scores and comments, identify duplication or synergy among funded projects, and consider the fit of applications within the programmatic vision. Program staff members then recommend projects to a Selection Committee, which includes members of PCORI’s Board. 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 then proposed to PCORI’s Board for its consideration and approval.

Summary Statements and Funding Recommendations

Summary statements are provided to applicants approximately two weeks before funding decisions are announced. If an application progresses to in-person discussion, the applicant will receive a summary statement that includes:

- In-person panel discussion notes
- Final average overall score
- Preliminary reviewer critiques
- Application quartile, which provides information for applicants to understand how they did relative to other discussed applications

Summary statements for applications that do not progress to in-person discussion include only the preliminary reviewer critiques.

Funding recommendations are made by identifying meritorious applications that fit the programmatic needs and that satisfactorily address the merit review criteria, including adherence to PCORI’s Methodology Standards. Programs also consider the funds allotted for the current PFA when deciding which applications to recommend to PCORI’s Board for approval. Applicants to this current cycle’s PFA will receive summary statements in October 2016 and notification of the funding status of their applications no later than November 2016.