Cycle 2 2015 Funding Cycle

PCORI Funding Announcement: Addressing Disparities

Published June 29, 2015

This PCORI Funding Announcement applies to the funding cycle that closes on November 3, 2015, at 5:00 p.m. (ET). Application guidelines, templates, and other resources are available at http://www.pcori.org/Cycle-2-2015-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 the Patient Protection and Affordable Care Act of 2010 as a nonprofit, nongovernmental organization. PCORI’s purpose, as defined by the Act, 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.”
### Overview

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<th>Published</th>
<th>June 29, 2015</th>
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<td>Letter of Intent Deadline</td>
<td>July 29, 2015, by 5:00 p.m. (ET)</td>
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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 denial or approval to submit a full application will occur no later than September 8, 2015.

### 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 should identify best practices for sharing results and information about patient-centered outcomes research (PCOR) across patient groups.

### Applicant Resources


### Key Dates

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<td>Earliest Project Start Date</td>
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### Maximum Project Budget (Direct Costs)

$1.5 million

### Maximum Project Period

3 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. Impact of the condition on the health of individuals and populations
2. Potential for the study to improve health care and outcomes
3. Technical merit
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 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 5:00 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.* |
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PCORI Funding Announcement: Addressing Disparities
I. Introduction

About PCORI

PCORI funds patient-centered outcomes research (PCOR), a type of comparative effectiveness research (CER) that focuses on outcomes that matter to patients, their caregivers, and their families. The studies PCORI funds 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. Approaches may address diagnostic methods or options, screening, interventions for prevention or treatment, or strategies to improve the healthcare system. “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. In general, through its various funding announcements, PCORI is interested in studies of interventions that may include:

- Specific drugs, devices, and procedures
- Other types of alternatives, such as medical and assistive devices and technologies
- Behavior change, including the use of behavioral or financial incentives (the latter for patients only)
- Organizational models and policies within and across healthcare systems (e.g., patient-centered medical homes, clinical protocols and pathways)
- Communication and/or dissemination strategies

Summary of the Program

PCORI invites applications for clinical CER designed to evaluate and compare new and/or enhanced interventions intended 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 should identify best practices for reducing disparities.

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 as well as to 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 directed to this issue, disparities in care and outcomes remain pervasive, leading to preventable suffering and compromising the ability of individuals and families to live full, healthy lives.

Disparities in health and health care persist and are 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 affect 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 circumstances in which generic quality improvement can augment outcomes and those in which 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 more poorly performing inpatient and outpatient settings, raising concerns about performance- or incentive-based payments. PCORI is interested in comparative effectiveness studies that examine 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—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 best practices for tailoring evidence-based interventions to patient populations at risk for disparities

Proposed research must focus on one or more of the following 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.

All applications must have a comparative component.

In addition, 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 seeks to fund research that includes diverse populations with respect to age, gender, race, ethnicity, geography, or clinical status so that possible differences in clinical CER 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, in such cases, the burden is on the applicant 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. As a result, comparisons should examine the impact of the strategies in various subpopulations, with attention paid to the possibility 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, and 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
• LGBT persons

*This category refers to individuals with long-term, significant disabilities. The Addressing Disparities Program does not consider individuals with multiple chronic conditions or limitations due to stroke, for example, to be in this particular target population.

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 and community health worker/navigator 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 and that they fill a gap within the program’s portfolio.

The following areas are considered high-priority areas for funding:

The Addressing Disparities Program is interested in funding projects that focus on comparing strategies to enhance social support, interventions incorporating team-based care, and strategies to enhance family/caregiver involvement in patient care to reduce disparities and improve patient-centered and clinical outcomes.

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 to facilitate dissemination of research findings that will help patients and the public make better-informed healthcare decisions. To meet this goal, PCORI has set up Evidence to Action Networks, whereby 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 such Evidence to Action Networks as they become available on a topic relevant to their research.

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

Regardless of the approach being studied, all proposed research projects must compare at least two alternatives. Optimally, the study will compare two or more defined strategies. In general, “usual care” is not an appropriate comparator for CER studies submitted to PCORI for funding consideration. “Usual care” is too often poorly defined, difficult to quantify, and subject to considerable geographic and temporal variations, thus limiting interpretability, applicability, and reproducibility. 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). In addition, 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. To be considered responsive, applications must:

- **Describe research that compares two or more strategies that each have established efficacy.** PCORI expects the efficacy or effectiveness of each intervention to be known. If the efficacy/evidence base is insufficient, then data need to be provided to document that the intervention is used widely. The application must provide information about efficacy of the interventions and/or dissemination strategies 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.** These outcomes must be demonstrated to matter to patients, including 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 valid outcome measures and include preliminary data that support the proposed measures. Investigators are encouraged to consider those measures described in the Patient Reported Outcomes Measurement Information System² (PROMIS).

² Available at http://www.nihpromis.org/.

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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 are of such low prevalence (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 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

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 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

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

• Instrument development
• 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
• 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:

• Practice guidelines

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

**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)

The remaining six 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 Standards⁴ reflect practices that should be followed in all cases, and all deviations need to be explained and well justified. Additional

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⁴ Available at http://www.pcori.org/content/pcori-methodology-report.
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.

**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 diverse populations 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 (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 there will be sufficient statistical power 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 the following list of priority populations to guide our efforts in research and engagement:

- 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

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” from the Supplemental Grant Application Instructions for All Competing Applications and Progress Reports,5 issued by the U.S. Department of Health and Human Services (DHHS). 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 inclusion of women, minorities, and children. PCORI also requires applicants proposing clinical trials to 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 Protections6). Reviewers’ comments on human subjects research are not reflected in the overall application score but may be used by PCORI staff during any potential funding negotiations. Final determinations about adequacy of human subject protections rest with the Institutional Review Board (IRB) or IRBs that has or 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 all applicants to 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 listed as “key personnel” in the application. The policy and FAQs are available from the NIH website.7

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

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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.

**Recruitment**

Proposals should include information about the size 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 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 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: a 500-word abstract for medical professionals, a standardized summary of the study’s results for patients and the general public, and 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 a Proposal

**Letter of Intent (LOI)**

Applicants should download the Letter of Intent Template for the Addressing Disparities PFA from the PCORI Funding Center. The LOI has a three-page limit. References should be numbered in the text and full citations provided on a separate page following the LOI. Complete the document and convert it to a PDF file no longer than three pages. LOIs that exceed the page limit (excluding references) 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. 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 into the PCORI Online System. The deadline for LOI submission is July 29, 2015, by 5:00 p.m. (ET).

**Letter of Intent Review**

LOIs 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 PI and the research team
- Programmatic fit and balance, taking into consideration whether the study proposed significantly overlaps 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 applicants whose LOIs are deemed most responsive to this PFA will be invited to submit a full application. Notification of denial or approval to submit an application will occur no later than September 8, 2015. Please refer to the Application Guidelines for information on how to submit your LOI via PCORI Online.

You 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
- PI
- Institution

If you need to change any of this information or have any questions, email pfa@pcori.org.

**Note:** A PI may submit multiple LOIs in a cycle but the research topics/projects should not be similar. If a PI submits an LOI to multiple PFAs, LOIs that show scientific overlap or that appear to be duplicate submissions will be disqualified. PCORI will contact the PI and give them an opportunity to choose which PFA they would like to apply to. An individual listed as a PI on one LOI may be listed and serve in another role (e.g., co-investigator, co-PI) on other LOIs within the same PFA during the same cycle.

**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.

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

Applicant Resources

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<th>PCORI Funding Center</th>
<th><a href="http://www.pcori.org/Cycle-2-2015-disparities/">http://www.pcori.org/Cycle-2-2015-disparities/</a></th>
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<td>PCORI Online System</td>
<td>pcori.fluxx.io</td>
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<tr>
<td>PCORI Funding Awards</td>
<td>pcori.org/pfaawards</td>
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IV. Merit Review

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 of Governors (Board) award approval (no later than April 2016).

Preliminary Review

PCORI conducts rigorous merit reviews 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, 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 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.

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. 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 U.S. 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 the research 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 the 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?
- Does the research plan describe rigorous methods that demonstrate adherence to PCORI’s Methodology Standards?
- Are the comparison interventions realistic options that exist in current practice?
- Are the sample sizes and power estimates presented 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?
- Are the organizational structure and 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 PCOR?

**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 the preliminary review is completed, PCORI program staff members evaluate panel scores and critiques 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 to clarify further the merits of the proposed research, as well as to identify areas for improvement. Additionally, 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 informed by the standards outlined in the PFA.

**Post-Panel Review**

After the in-person panel review, PCORI program staff review meritorious applications’ merit review 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 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 and funding decision notifications are provided to applicants contemporaneously. If an application progresses to in-person discussion, the applicant will receive a summary statement inclusive of the panel discussion notes, the final average overall score, and preliminary reviewer critiques. 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 satisfactorily address the merit review criteria while adhering to PCORI’s Methodology Standards. Programs also consider the funds allotted for the current funding announcement when deciding which applications to recommend to PCORI’s Board for approval. Applicants will receive summary statements and notification of the funding status of their application no later than April 2016.