



Cycle 3 2016 Funding Cycle

PCORI Funding Announcement: Addressing Disparities

Published August 15, 2016
Updated May 19, 2017

This PCORI Funding Announcement (PFA) applies to the funding cycle that closes on December 19, 2016, at 5 p.m. (ET). Application Guidelines, templates, and other resources are available at <http://www.pcori.org/Cycle-3-2016-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 and other stakeholders.

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, caregivers, clinicians, policy makers, and other healthcare system stakeholders 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."

Patient-Centered Outcomes Research Institute
1828 L St. NW, Suite 900
Washington, DC 20036
Phone: 202-827-7700
Fax: 202-355-9558
Email: info@pcori.org

Follow us on Twitter: [@PCORI](https://twitter.com/PCORI)

Overview

Published	August 15, 2016
Updated	May 19, 2017
Letter of Intent Deadline	September 14, 2016, by 5 p.m. (ET)
	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 October 21, 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	See http://www.pcori.org/Cycle-3-2016-disparities/
Key Dates	<p>Online System Opens: August 15, 2016</p> <p>LOI Deadline: September 14, 2016, by 5 p.m. (ET)</p> <p>LOI Town Hall: August 29, 2016, 2 – 3 p.m. (ET)</p> <p>LOI Status Notification: October 21, 2016</p> <p>Application Deadline: December 19, 2016, by 5 p.m. (ET)</p> <p>Merit Review: March 2017</p> <p>Awards Announced: August 15, 2017</p> <p>Earliest Project Start Date: October 2017</p>
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 shown clearly. Organizations may submit multiple applications for funding. Individuals are not permitted to apply.
Review Criteria	<ol style="list-style-type: none"> 1. Potential for the study to fill critical gaps in evidence 2. Potential for the study findings to be adopted into clinical practice and improve delivery of care 3. Scientific merit (research design, analysis, and outcomes) 4. Investigator(s) and environment 5. Patient-centeredness 6. 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

	<p>an LOI 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 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.</p>
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 3 2016 Funding Cycle:

- New Criterion 4 added and updated Section IV Merit Review
- Removed the Replication and Reproducibility of Research and Data-Sharing Plan requirement during the application phase
- Includes links to new [PCORI Policy on Data and Safety Monitoring Plans for PCORI-Funded Research](#) and [Process for Peer Review of Primary Research and Public Release of Research Findings](#)

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I. Introduction to the Addressing Disparities Program

The Patient-Centered Outcomes Research Institute (PCORI) invites applications for comparative clinical effectiveness research (CER) designed to evaluate and compare interventions intended to reduce or eliminate disparities in health and health care. Patients and other stakeholders 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, 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 or 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 the section below on Addressing Disparities Targeted 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.

PCORI strongly encourages applicants to review the funded research on our website to ensure that their proposed research is not duplicative of projects we have already funded.

Addressing Disparities Targeted Populations

PCORI's Addressing Disparities Program is interested in studies focusing on previously understudied populations for whom effectiveness information is needed. Proposed research must focus on at least one of the following 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, or limited English proficiency
- LGBT persons

Addressing Disparities Priority Areas

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

- Interventions to address disparities in human immunodeficiency virus (HIV) prevention and treatment
- Interventions to reduce sleep disorder disparities among racial and ethnic minorities
- Pharmacologic and non-pharmacologic treatments for Alzheimer's disease and other forms of dementia
- 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 following 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, or limited English proficiency; and LGBT persons.

Community Health Worker and Navigator Projects

The Addressing Disparities Program has funded many projects focusing on community health worker and navigator interventions. Applications aiming 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 and patient navigator program models, worker

functions, training and certification levels, and implementation approaches across different settings, conditions, and populations¹

- Examining the integration of community health workers and 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 teams²

Applications that propose research focusing on community health workers or navigators as a primary component of interventions being studied 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. PCORI encourages applicants 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). It must also be accompanied by an explanation of how the care given in the “usual care” group will be measured in each 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 it has wide interpretability, applicability, and reproducibility.
- *Describe research that compares two or more alternatives, each of which has established efficacy.* PCORI expects the efficacy or effectiveness of each intervention to be known. If the efficacy or evidence base is insufficient, then data need to be provided to document that the intervention is used widely. The application must provide information about the efficacy of the interventions that will be compared; pilot data might be appropriate. Projects aiming to develop new 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

¹ Institute for Clinical and Economic Review. [2013]. A review of program evolution, evidence on effectiveness and value, and status of workforce development in New England. Retrieved April 8, 2015 from Comparative Effectiveness Public Advisory Council: <http://cepac.icer-review.org/wp-content/uploads/2011/04/CHW-Draft-Report-05-24-13-MASTER1.pdf>.

² McDonald KM, Sundaram V, Bravata DM, et al. Closing the Quality Gap: A Critical Analysis of Quality Improvement Strategies (Vol. 7: Care Coordination). Rockville (MD): Agency for Healthcare Research and Quality (US); 2007 Jun. (Technical Reviews, No. 9.7.) 4, Review of Systematic Reviews of Care Coordination Interventions. Available from: <http://www.ncbi.nlm.nih.gov/books/NBK44016/>.

health outcomes.

- *Describe consultation with patients and other stakeholders about how the study is answering a critical question.* Explain the pertinent evidence gaps and why the project questions represent decisional dilemmas for patients, caregivers, clinicians, policy makers, and other healthcare system stakeholders. Describe why project outcomes are especially relevant and meaningful endpoints to patients and other stakeholders.

Leveraging Existing Resources

PCORI encourages investigators to propose studies that leverage existing resources, such as adding patient-centered outcomes research (PCOR) to an existing large clinical trial or analyzing existing large databases that contain valuable, relevant information that may be used to answer important CER questions.

Patient-Centered Outcome Measures

PCORI encourages investigators to design their research using validated outcome measures. Include preliminary data that support using the proposed measures in the study population. We encourage investigators to consider those measures described in the [Patient-Reported Outcomes Measurement Information System³](#) (PROMIS).

Studies in Rare Diseases

PCORI is interested in the investigation of strategies addressing care for patients with rare diseases. These conditions are defined as “life-threatening” or “chronically debilitating.” They are of such low prevalence (affecting 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—might be needed to address them.

Studies of Cost-Effectiveness

PCORI will consider an application 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 services, but may not employ direct measurements of care costs. For further information, please reference our [cost-effectiveness analysis FAQs](#).

PCORI does have an interest, however, in studies addressing questions about conditions leading to high costs to the individual or to society. This is included in our review criterion on the condition’s impact 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

³ Available at <http://www.nihpromis.org/>.

- 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 and tools, or clinical prognostication tools
- Pilot studies intended to inform larger efforts
- Comparing patient characteristics rather than clinical strategy options
- Applies to Assessment of Prevention, Diagnosis, and Treatment Options (APDTO) and Improving Healthcare Systems (IHS) program applicants ONLY: Comparing interventions for which the primary focus is the role of community health workers or patient navigators

Consistent with PCORI's [authorizing law](#),⁴ 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 the study of biological mechanisms

Avoiding Redundancy

PCORI encourages potential applicants to review funded research at pcori.org. We intend to balance our funded portfolio to achieve synergy and avoid redundancy where possible.

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 these standards when planning and

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

conducting their research projects. These cross-cutting categories are:

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

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

1. Standards for Data Registries
2. Standards for Data Networks as Research-facilitating Infrastructures
3. Standards for Causal Inference Methods
4. Standards for Adaptive and Bayesian Trial Designs
5. Standards for Studies of Diagnostic Tests
6. Standards for Systematic Reviews

Most of these standards are minimal. The PCORI Methodology Standards⁵ 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 conducting clinical trials or observational studies—should be addressed, if applicable, in the PCORI funding application.

Applicants should discuss 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, as well as differences in participation, adherence, or follow-up that might affect outcomes independent of the interventions being compared.

Upcoming New and Revised Methodology Standards

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

Patient and Stakeholder Engagement

PCORI encourages all applicants to outline how patients and other stakeholders will participate as partners in various phases of the proposed research. Before completing this section of the Research

⁵ Available at <http://www.pcori.org/research-we-support/the-pcori-methodology-report/>.

Strategy, applicants are encouraged to review the [Engagement Rubric](#)⁶, which can be found in the PCORI Funding Center. Applicants should also review the PCORI Methodology Standards Associated with Patient-Centeredness and [PCORI's Sample Engagement Plans](#).⁷ The rubric and Sample Engagement Plans are not intended to be comprehensive or prescriptive; instead, they provide a variety of examples to incorporate engagement, where relevant, into the research process.

Applicants are expected to consult with patients and other stakeholders on their decisional dilemma and evidence needs, or to reference previously documented decisional dilemmas in preparation for the submission of Letters of Intent (LOIs) and applications. To describe the decisional dilemma, state the specific clinical decision(s) or treatment choice(s) confronted by the decision makers and explain how the findings from the proposed research will inform those decisions. State why this decision—such as choosing a specific medication, surgical approach, or care delivery strategy to treat a condition or manage a specific population—is important to patients. Document the uncertainty patients and other stakeholders face in making this decision. Identify the patients and other stakeholders you consulted in determining that the proposed study addresses their evidentiary needs for decision making, and indicate your commitment to continue engaging them actively in the conduct of the study. Similarly, applicants should document how the project outcomes are especially relevant and meaningful endpoints to patients and other stakeholders.

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 HTE. PCORI recognizes that some proposed studies might represent important PCOR opportunities, even in the absence of a broadly diverse study population. However, the burden is on the applicant to justify the study's importance in the absence of diversity; to discuss which subgroups are most important; and to discuss how the subgroups will be analyzed, including whether or not the study will be powered to examine the question of effectiveness in subgroups. PCORI is particularly interested in including 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 possibility that the strategy's effects might differ across subpopulations. PCORI has developed the following 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
- Children (age 0–17 years)

⁶ Available at <http://www.pcori.org/sites/default/files/Engagement-Rubric.pdf>.

⁷ Available at <http://www.pcori.org/sites/default/files/PCORI-Sample-Engagement-Plans.pdf>

- 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, 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, titled “Human Subjects Research Policy,” in the [Supplemental Grant Application Instructions for All Competing Applications and Progress Reports](#),⁸ which is issued by the U.S. Department of Health and Human Services. PCORI does not require that applicants comply with sections of this policy that refer to requirements for federal-wide assurance or that refer to standards for including women, minorities, and children. Awardees must also comply with appropriate state, local, and institutional regulations and guidelines pertaining to the use of human subjects in research.

PCORI requires awardees to ensure that there is a Data and Safety Monitoring Plan, which may include the need to appoint a Data and Safety Monitoring Board, as provided in the [PCORI Policy on Data and Safety Monitoring Plans for PCORI-Funded Research](#).⁹

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 Protections](#)¹⁰). Reviewers’ comments on human subject research are not reflected in the overall application score, but PCORI staff might use them during potential funding negotiations. Final determinations about the adequacy of human subject protections rest with the Institutional Review Board or international equivalent that have jurisdiction for the study.

The Awardee Institution, 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

⁸ See <http://grants.nih.gov/sites/default/files/supplementalinstructions.docx>

⁹ See <http://www.pcori.org/sites/default/files/PCORI-Policy-Data-Safety-Monitoring-Plans.pdf>

¹⁰ See <http://www.pcori.org/sites/default/files/PCORI-Checklist-for-Evaluating-Human-Subjects-Protections.pdf/>.

the protection of human subject participants in the conduct of research. This applies to all individuals listed as key personnel in the application. The policy and FAQs are available on the [NIH website](#).¹¹

Data Management and Data-Sharing Plan

PCORI encourages openness in research and making research data available for purposes of replication and reproducibility. Although not required to be submitted as a component of the research application, if an award is made, the awardee is required to develop and maintain a plan that addresses data management and data sharing of research project data in a manner that is appropriate for the nature of the research project and the types of research project data, and that is consistent with applicable privacy, confidentiality, and other legal requirements.

Recruitment

Proposals should include information about the size and representativeness of the potential pool of patients from which recruitment will occur, and describe the means by which this size estimate was determined. Likewise, proposals should provide evidence-based estimates of how many participants are expected in the study, based on expected recruitment; applying the study's inclusion and exclusion criteria; anticipated acceptance (or refusal) rates; and other factors, such as failure to follow up. Such estimates must be discussed in the application, specified in the milestones, reviewed by merit reviewers and PCORI staff, and 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. Accordingly, the PCORI Board of Governors (Board) adopted the [Process for Peer Review of Primary Research and Public Release of Research Findings](#).¹²

In summary, 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 interprets the findings in clinical or other decisional contexts. Subject matter experts; individuals with expertise in research methodology or biostatistics; and patients, caregivers, and other healthcare stakeholders will review the draft final research report. After Awardee Institutions 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; (3) a link to the study record on [ClinicalTrials.gov](#) (as applicable); and (4) ancillary information, including conflict of interest disclosures. 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

¹¹ See <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-08-054.html>.

¹² See <http://www.pcori.org/sites/default/files/PCORI-Peer-Review-and-Release-of-Findings-Process.pdf>

Awardee Institution.

III. How To Submit an Application

Applying for funding from PCORI is a two-stage process. An LOI must be submitted and an applicant must be invited to submit an application.

Letter of Intent (LOI)

Applicants should download the [LOI Template](#) from the [PCORI Funding Center](#). They must complete the document and convert it to a PDF file. The LOI is limited to three pages, excluding references. PCORI suggests including all references as in-text citations using American Medical Association citation style, but other citation styles are accepted. Do not upload additional documents as part of your LOI, including Letters of Endorsement or Letters of Support, because 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.

The LOI for the proposed study should contain the following information:

- Title of the proposed study that preferably captures the comparative nature of the study
- Specific aims (clearly stated)
- How the study will improve the quality and relevance of evidence available to help patients and stakeholders make informed health decisions
- Knowledge gap being addressed by research question(s)
- Concise description of study design
- Study population (description of participants and participating study sites)
- Outcomes (identification and description of why they are important to patients)
- Sample size
- Comparators (described and listed clearly, with demonstrated efficacy specified for each and details on how the strategies will be delivered in real-world settings)
- Patient and other stakeholder engagement (involvement through planning, conducting, and disseminating)

The LOI Template provides guidance on responding to each item. Please refer to the [Application Guidelines](#) for due dates and information on how to submit an LOI via PCORI Online. **The deadline for LOI submission is September 14, 2016, by 5 p.m. (ET).**

LOI Review

LOIs are evaluated based on the following:

- Importance and relevance of the topics to PCORI priorities, as evidenced by critical gaps identified by clinical guidelines developers and recent systematic reviews
- Clarity and credibility of responses to the LOI questions

- Programmatic fit and balance, considering whether the application overlaps with previously funded studies or concurrent applications to a significant degree or, conversely, whether the application fills a gap in the portfolio with certain characteristics, including disease category, topics, priority population, methodologies, and other variables

Only applicants whose LOIs are deemed most responsive to this PFA will be invited to submit a full application. A minimum of two PCORI staff review the LOIs, which are not scored during review. Notification of the request to submit a full application will occur no later than October 21, 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

If you need to change any of this information or have 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 non-PI role (e.g., co-investigator or consultant) on other LOIs within the same PFA, during the same cycle. A PI can 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.

Project Budget and Duration

The maximum budget and research period of performance for this PFA can be found in the Overview section. At the time of contract execution, PCORI sets aside all of the funds associated with an awarded project to be made available throughout the contract's period of performance. The maximum budget includes all research- and peer-review-related costs. Refer to the [Application Guidelines](#) for additional details. Appendix 2 within the guidelines provides a complete list of allowable and unallowable costs. This program does not consider exceptions to the budget or to period-of-performance limits. PCORI will not review requests exceeding the stated maximum budget or period of performance. Note that although subcontractor indirect costs are included in the prime applicant's direct-cost budget, subcontractor indirect costs are not factored when determining adherence to the PFA's direct-cost limit.

Submission Dates

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

PCORI Online System

To submit an application, you must register with [PCORI Online](#) and submit an LOI and an application for each cycle to which you are applying.

Applicant Resources

PCORI Funding Center	http://www.pcori.org/Cycle-3-2016-disparities/
PCORI Online System	pcori.fluxx.io
PCORI Funding Awards	http://www.pcori.org/research-results

IV. Merit Review

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

- Identify applications that have the strongest potential to help patients, caregivers, clinicians, policy makers, and other healthcare system stakeholders make informed decisions to improve patient outcomes.
- Implement a transparent, fair, objective, and consistent process to identify these applications.
- Elicit high-quality feedback that reflects a diversity of perspectives to ensure that the PCORI-funded research reflects the interests and views of patients and other stakeholders and those who care for them, and that it meets the criteria for scientific rigor.
- Fund projects that fill important evidence gaps and have strong implementation potential.
- 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; the review panel's preliminary review of full applications; an in-person panel discussion of a subset of full applications (identified by PCORI's Research Priority Area Program staff and based on the preliminary review and program priorities); the Selection Committee's recommendation of applications for funding; and, finally, Board award approval.

Preliminary Review

PCORI conducts rigorous merit review of the full applications it receives. Note that PCORI may eliminate applications 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 can be scientifically withdrawn if it is not responsive to the guidelines described in this PFA, describes research that is not comparative, includes a cost-effectiveness analysis, or otherwise does not meet PCORI programmatic requirements.

PCORI Merit Review Officers (MROs) recruit each panel based on the number of 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.

The table below is designed to help applicants understand how the PCORI merit review criteria align with criteria from other funding organizations with which applicants might be familiar (e.g., NIH). Though PCORI’s criteria do map to most NIH criteria, there are areas where we ask for different information (i.e., PCORI does not include a criterion that tracks to NIH’s innovation criterion, but does include criteria evaluating patient-centeredness and engagement) reflecting PCORI’s unique approach.

Crosswalk of PCORI Merit Review Criteria with NIH Criteria	
SIGNIFICANCE	<ol style="list-style-type: none"> 1. Potential for the study to fill critical gaps in evidence 2. Potential for the study findings to be adopted into clinical practice and improve delivery of care
APPROACH	<ol style="list-style-type: none"> 3. Scientific merit (research design, analysis, and outcomes) NEW 4. Investigator(s) and environment
PCORI-only Merit Review Criteria	
PATIENT-CENTEREDNESS/ENGAGEMENT	<ol style="list-style-type: none"> 5. Patient-centeredness 6. Patient and stakeholder engagement

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, and to ensure consistency and fairness in how applications are evaluated.

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

The application 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, guideline development efforts, 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 generated from this study could be adopted into clinical practice and delivery of care by others. The application should also address the following questions:

- 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) this study produces, 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 this study’s research findings have the potential to inform decision making for key stakeholders? If so, provide an example. 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 at 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. The application should also address the following questions:

- Does the application 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 Research Plan describe rigorous methods that demonstrate adherence to the PCORI Methodology Standards?
- Is the overall study design justified?
- Are the patient population and study setting appropriate for the proposed research question?
- Does the application provide justification that the outcome measures are validated and appropriate for the population?
- Are each of the comparators (e.g., active intervention arm and comparator arm) described clearly and well-justified? If “usual care” is one of the arms, is it adequately justified and will it be sufficiently measured?
- Are the sample sizes and power estimates appropriate? Is the study design (e.g., cluster randomized design, randomized controlled trial, or observational study) accounted for and is the anticipated effect size adequately justified?
- Is the study plan feasible? Is the project timeline realistic, including specific scientific and engagement milestones? Is the strategy for recruiting participants feasible? Are assumptions about participant attrition realistic, and are plans to address patient or site attrition adequate?

NEW Criterion 4. Investigator(s) and environment

This criterion should assess the appropriateness (e.g., qualifications and experience) of the investigator(s)/team and the environment’s capacity (e.g., resources, facilities, and equipment) to support the proposed project. It should not be an assessment of the institution’s quality.

The application should also address the following questions:

- How well-qualified are the PIs, collaborators, and other researchers to conduct the proposed activities? Is there evidence of sufficient clinical or statistical expertise (if applicable)?
- Does the investigator or co-investigator have demonstrated experience conducting projects of a similar size, scope, and complexity?
- If the project is collaborative or dual-PI, do the investigators have complementary and integrated expertise? Are the leadership, governance, and organizational structures appropriate for the project?
 - (Dual-PI Option Only) Does the Leadership Plan adequately describe and justify PI roles and areas of responsibility?
- Is the level of effort for each team member appropriate for successfully conducting the proposed work?
- Does the application describe adequate availability of and access to facilities and resources (including patient populations, samples, and collaborative arrangements) to carry out the proposed research?
- Is the institutional support appropriate for the proposed research?

Criterion 5. Patient-centeredness

The application should demonstrate that the study focuses on improving patient-centered outcomes and employs a patient-centered research design (i.e., a design informed or endorsed by patients). *(Note: The study can be patient-centered even if the end-user is not the patient, as long as patients will benefit from the information.)*

The application should also address the following questions:

- Does the application include a thorough description about 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 6. Patient and stakeholder engagement

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

The application should also address the following questions:

- Does the application provide a well-justified description of how the research team incorporates

stakeholder involvement? Does the study include the right individuals (e.g., researchers, patients, caregivers, clinicians, policy makers, and other healthcare system stakeholders) to ensure that the projects will be carried out successfully?

- Does the application show evidence of active engagement among scientists, patients, and other stakeholders throughout the research process (e.g., formulating questions, identifying outcomes, monitoring the study, disseminating, and implementing)? Is 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 described clearly?
- Are the organizational structure and resources appropriate to engage patients and stakeholders throughout 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 the PCORI Methodology Standards. After PCORI completes the preliminary review, 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 and to clarify further the merits of the proposed research. They also identify areas for improvement. Each application is re-scored based on the content of discussion. The Panel 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 the 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 the Board for consideration and approval.

In addition, PCORI evaluates applicant risk before issuing a PCORI award. Factors considered include financial stability, quality of management systems, audit findings, and past performance on PCORI awards (e.g., compliance with PCORI reporting requirements, conformance to PCORI terms and conditions on previous awards, and timely achievement of milestones). Based on the risk assessment, PCORI may impose special terms and conditions on awardees or withhold contract issuance until such business risks are mitigated. **PCORI will not award new contracts to current awardees with overdue reports (progress, interim, final, etc.) until the overdue reports have been submitted to PCORI.**

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 inclusive of:

- 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 while adhering to the PCORI Methodology Standards. Programs also consider the funds allotted for the current funding announcement when deciding which applications to recommend to the Board for approval. Applicants to this current cycle's PFA will receive summary statements and notification of the funding status of their application no later than August 2017.