Cycle 1 2016 Funding Cycle

PCORI Funding Announcement: Communication and Dissemination Research

Published February 1, 2016

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

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

PCORI was authorized by Congress in 2010 as a nonprofit, nongovernmental organization. PCORI’s purpose, as defined by our authorizing legislation, is to help patients, clinicians, purchasers, and policy makers make better-informed health decisions by “advancing the quality and relevance of evidence about how to prevent, diagnose, treat, monitor, and manage diseases, disorders, and other health conditions.”

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### Overview

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<th>Published</th>
<th>February 1, 2016</th>
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<tr>
<td>Letter of Intent Due</td>
<td>March 2, 2016, by 5 p.m. (ET)</td>
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Letters of Intent (LOIs) will be screened for responsiveness to this PCORI Funding Announcement (PFA) and for fit to program goals. Only those selected will be permitted to submit full applications. Notification of denial or approval to submit full application will occur no later than April 8, 2016.

### Summary

PCORI seeks to fund projects that address critical knowledge gaps in the communication and dissemination process—both the communication and dissemination of research results to patients, their caregivers, and clinicians, and the communication between patients, caregivers, and clinicians—in the service of enabling patients and caregivers to make the best possible decisions in choosing among available options for care and treatment.

### Applicant Resources

See [http://www.pcori.org/cycle-1-2016-communication](http://www.pcori.org/cycle-1-2016-communication).

### Key Dates

- **Online System Opens:** February 1, 2016
- **Applicant LOI Town Hall:** February 8, 2016, 2:00 – 3:00 p.m. (ET)
- **LOI Deadline:** March 2, 2016, by 5 p.m. (ET)
- **LOI Status Notification:** April 8, 2016
- **Application Deadline:** June 6, 2016, by 5 p.m. (ET)
- **Merit Review:** September 2016
- **Awards Announced:** November 2016
- **Earliest Project Start Date:** January 2017

### Maximum Project Budget (Direct Costs)

$1.5 million

### Maximum Research Project Period

Three years

### Budget/Time Limits

Applicants must submit a Greater Than Time/Budget Request with their LOI if the proposed project’s budget or duration exceeds limits specified in this announcement.

### Funds Available Up to

$8 million

### Eligibility

Applications may be submitted by any private-sector research organization, including any nonprofit or for-profit organization, and any public-sector research organization, including any university or college hospital or healthcare system, laboratory or manufacturer, or unit of local, state, or federal government. The Internal Revenue Service must recognize all U.S. applicant organizations. Nondomestic components of organizations based in the United States and foreign organizations may apply, as long as there is demonstrable benefit to the U.S. healthcare system and U.S. efforts in the area of patient-centered research can be clearly shown. Organizations may submit multiple applications for funding. Individuals are not permitted to apply.
Review Criteria

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

Contact Us

Programmatic Inquiries: 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 a Letter of Intent or application deadline.

Administrative, Financial, or Technical Inquiries: Please contact the PCORI Helpdesk at pfa@pcori.org. PCORI will provide a response within two business days. Please note that during the week of a deadline, response times may exceed two business days. Applicants may also call the PCORI Helpdesk (202-627-1885). Applicants are asked to plan accordingly. It is the applicant’s responsibility to submit the application on or before the application deadline.

Other

*Deadlines are at 5 p.m. (ET). If deadlines fall on a weekend or a federal holiday, the deadline will be the following Monday or the next day after the federal holiday.

New or Revised for the Cycle 1 2016 Funding Cycle:

- Summary of Program and Objectives section at beginning of funding announcement text
- Revised LOI template
- Revised Greater Than Budget/Time request
- Updated Criterion 5 to reflect the new dual-PI plan policy
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PCORI Cycle 1 2016 Funding Announcement: Communication and Dissemination Research
I. Introduction

Summary of Program and Objectives

Knowledge needs to be strengthened about how to communicate optimally and facilitate the effective use of patient-centered outcomes research (PCOR) and comparative clinical effectiveness research (CER) findings by patients, caregivers, and healthcare professionals. Well-documented barriers exist to the rapid transfer of evidence. Informed healthcare decisions require innovative and effective strategies to make existing PCOR/CER evidence available to patients and providers in real-world settings. Moreover, the information needs to be understandable in order to improve decision making.

The Communication and Dissemination Research Program at PCORI invites applications that study the comparative effectiveness of communication and dissemination strategies. We are looking for strategies aimed at informing and empowering patients, caregivers, and other healthcare decision makers so that they know what questions to ask and have the information needed to provide support in shared decision making.

This announcement is designed to solicit applications that include:

- The direct comparison of two or more health communication and dissemination interventions or strategies, each of which has established efficacy or is in widespread use
- Research conducted in real-world, clinical care settings and situations
- Proposed research questions and health outcomes that will matter to the patient population, their caregivers, and family members under study, and that will help to guide their healthcare decisions

Research appropriate for this PCORI Funding Announcement (PFA) includes:

- Communication strategies to promote the use of health and healthcare CER evidence by patients and clinicians
- Dissemination strategies to promote the use of health and healthcare CER evidence by patients and clinicians
- Explanation of uncertain health and healthcare CER evidence to patients and clinicians

Note: Proposed research that includes “usual care” as the control condition or one arm of an intervention trial should clearly explain how the term “usual care” is defined, assessed, and justified as an appropriate comparator.

Research not appropriate for this PFA includes:

- Applications that focus on the development, testing (establishing efficacy), and validation of individual decision aids/tools
- Applications that include a formal cost-effectiveness analysis
- Applications that directly compare the costs of care of two or more alternative approaches to providing care
Applications that include creation of clinical practice guidelines or clinical pathways

See Categories of Nonresponsiveness (p. 8) for a more detailed explanation and examples of topics that will be considered nonresponsive.

Background

Making an informed healthcare choice requires critically assessing the potential benefits and harms of the options within the context of the patient’s personal characteristics, conditions, and preferences.\(^1,2\) The environment in which patients, caregivers, and their providers communicate is also evolving rapidly to include a wide array of available health information and communication applications. These tools can help fill critical information gaps, but are often confusing and difficult to use. The type of healthcare decisions being made is an important determinant of the appropriate information needed and of the best vehicle for providing it. (For example, the information needs of a patient weighing options for treating high blood pressure will differ from those of a patient facing a terminal cancer diagnosis with complicated treatment options.) Furthermore, patients and caregivers desire information that does not necessarily deliver decisions or tell them what to do, but instead informs them of the relevant trade-offs and facilitates improved decision making in collaboration with their healthcare team.

Clear communication approaches and active dissemination of PCOR/CER research findings to all audiences (in easy-to-understand formats) are critical to increasing the awareness, consideration, adoption, and use of these data by patients, caregivers, and healthcare providers.\(^3\) This PCORI Funding Announcement (PFA) focuses on three key areas: 1) communication strategies, 2) dissemination strategies, and 3) explaining uncertainty.

Communication strategies to promote the use of health and healthcare CER evidence by patients and clinicians

Translating existing scientific research into accessible and usable formats that clearly outline the risks and benefits of various healthcare options for patients, caregivers, and healthcare providers is an important area of research in both clinical and community-based settings. In clinical care, shared decision making and decision support interventions are two of the primary ways in which medical evidence is translated into a usable format for patients, families, and caregivers. Understanding the best ways to communicate, while addressing numeracy and health literacy, is fundamental to communicating

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PCOR/CER effectively via shared decision making. For example, the integration of patient decision support, electronic health records (EHRs), and associated patient systems holds considerable promise, but little evidence is available to guide best practices.

Research gaps identified in a systematic review included the need for more head-to-head comparisons of communication strategies. For example, more CER is needed to determine how shared decision-making and decision-support interventions perform using different media, what level of information and detail they require, how they perform in different patient subpopulations, and how they can reflect new evidence and remain current. In addition, CER is needed to determine whether the use of efficacious applications of newer conceptual approaches to decision making, such as use of gist representation approaches in evidence communication or the use of behavioral economic strategies to improve healthcare decisions, can improve patients’ and clinicians’ use of evidence in decision making compared to more traditional methods. Furthermore, most of the CER research to date consists of comparisons of communication strategies relative to “usual care.” In most cases, it is difficult to determine what “usual care” is or how it differs from “standard of care.” Therefore, proposed research that includes “usual care” as the control condition or one arm of an intervention trial should clearly explain how the term “usual care” is defined, assessed, and justified as an appropriate comparator.

Effective communication skills of both patients and healthcare providers are important for the optimal use of CER results. Research on doctor-patient communication has focused primarily on the doctor-patient dyad, but little is known about other health professionals who communicate with patients and play a critical role in the patient care experience. Moreover, additional information is needed on how family involvement and family dynamics affect communication and the decision-making process. Applicants should consider broadening their focus beyond the patient-clinician dyad by recognizing that patient-centered care and communication are characterized by a complex web of communication among patients, caregivers, and a variety of healthcare professionals with whom they interact during different stages of the care continuum (pre-diagnosis to end-of-life).

Dissemination strategies to promote the use of health and healthcare CER evidence by patients and clinicians

The dissemination of CER information to patients, caregivers, and providers (in both clinical and community-based settings) is an area that has not received sufficient research attention. Dissemination

is defined as the active and targeted approach of spreading evidence-based interventions to potential adopters and the target audience through determined channels using planned strategies.\(^9\) The goals of dissemination are to increase the reach of information, motivation, and ability of patients, caregivers, and providers to use and apply evidence; the goals of dissemination research are to make such efforts more effective in accomplishing these aims.\(^3\) Little is known about the comparative effectiveness of dissemination methods and approaches for achieving these goals.

More research is needed to identify the most effective approaches for disseminating CER results to healthcare providers, with the goals of sustained changes in clinical practice and effective dissemination to patients of results that enable behavior changes (e.g., adherence and self-care). Additionally, further investigation is needed to explore how strategies used in public health communication and social marketing can be adapted to disseminate the results of CER and to identify creative ways of combining multiple channels of communication and dissemination to increase exposure to CER. Research is also needed to examine the reliability of any CER data currently available through social media sites and to understand how individuals evaluate and use the information in their prevention, screening, diagnosis, and treatment decision-making processes. In order to ensure that the “e-health revolution” does not widen existing health-related knowledge gaps between low-income and racial and ethnic minority populations, further exploration is needed to understand the disparities that may remain regarding access to social media resources.

Finally, the majority of work to date lacks a theoretical or conceptual justification for the dissemination strategy tested and/or the associated hypothesis for why the strategy tested was expected to be more effective than another strategy. With no underlying framework, published results are difficult to interpret.\(^3\)

**Explaining uncertain health and healthcare CER evidence to patients and clinicians**

Risk and uncertainty are ubiquitous in health care. Like most decisions, many healthcare decisions have consequences and involve uncertainties and trade-offs. A significant gap exists in the limited research on risk communication in general, and with underserved individuals and those with limited health literacy and numeracy in particular. In addition, research is lacking on effective methods for communicating risk to healthcare providers and enabling them to use the information effectively. A seminal publication on patient-centered communication from the National Cancer Institute identified managing uncertainty as a core function of patient-clinician communication.\(^7\) Uncertainty creates many challenges, including difficulties such as: a) determining whether preventive services and treatments should be implemented in clinical practice; b) determining for whom and in what settings services and treatments should be implemented; and c) communicating evidence so that consumers can make informed decisions.\(^3\) A systematic review identified research gaps that revealed a need for analyses that identify and prioritize uncertainties that should be communicated; methods that measure and provide a better understanding of uncertainties as they pertain to risks, practice recommendations, and other types of evidence; and

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standardized language used to communicate uncertainties in clinical evidence. The systematic review also revealed a need for formal systems used to rate uncertainty arising from clinical evidence that incorporates the patient perspective to ensure comprehensibility, meaningfulness, and appropriate use.\textsuperscript{10}

**Research of Interest**

The Communication and Dissemination Research Program seeks to fund investigator-initiated CER that includes, but is not limited to, the following:

**Communication Strategies**

- Compares strategies that increase knowledge of how to communicate complex information to patients and caregivers
- Identifies and compares practices that increase understanding of the tension between strongly held beliefs and contrary evidence and those practices’ impact on the shared decision-making process
- Compares strategies meant to generate conversations between patients and providers about what is appropriate and necessary treatment (e.g., Choosing Wisely\textsuperscript{11}), based on patients’ preferences and conditions, to improve patient satisfaction with their decision process and enable them to use the best available evidence
- Compares strategies and methods that optimize communication among the patient, family/caregiver, and healthcare team (e.g., role of family member/caregiver in patient-provider, patient-caregiver, and healthcare team interactions)
- Compares the influence of family, friends, and other patients on healthcare decisions that occur outside the healthcare setting
- Compares strategies in situations where there is not a single “right” choice (e.g., preference-sensitive decisions) to improve patients’ satisfaction with their decision process and to enable them to use the best available evidence

**Dissemination Strategies**

- Compares and identifies best practices of dissemination and translation techniques to facilitate shared decision making in everyday practice
- Identifies the most effective approaches to disseminating CER results to healthcare providers, with the goals of sustained changes in clinical practice and effective dissemination to patients of results that enable behavior changes (e.g., self-care)
- Understands how strategies used in public health communication and social marketing can be adapted to disseminate the results of CER and to identify creative ways of combining multiple strategies

\textsuperscript{11} Available at http://www.choosingwisely.org/.
channels of communication to increase exposure to CER

Explaining Uncertainty

- Compares strategies for conveying uncertainty associated with health and healthcare evidence that increase the likelihood that patients and caregivers will understand the information, incorporate it into decision making, and evaluate personal trade-offs
- Compares strategies to reduce the cognitive burden required to understand complex numeric and risk-related information to improve understanding of the potential outcomes and improve decision making
- Compares the effectiveness of health literacy- and numeracy-sensitive health communication strategies that relay risks and benefits of health decisions so that individuals can make sound healthcare decisions
- Compares interventions that help patients and families/caregivers facing difficult medical decisions in which the outcomes are ambiguous or uncertain to improve their understanding of the outcomes and facilitate their decision making

PCORI is interested in understanding the role of shared decision making and established, effective decision aids in communicating and implementing PCOR/CER. Applications focused on the development, testing (establishing efficacy), and validation of individual decision aids/tools will be considered nonresponsive to this PFA.

PCORI’s 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 comprised of 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 if they become available on a specific 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

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

Describe research that compares two or more alternatives, each of which has established efficacy. PCORI expects 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 that will be compared; pilot data may be appropriate. Projects that aim to develop new or novel interventions that lack evidence of efficacy or effectiveness will be considered out of scope.

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

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

Leveraging Existing Resources

Investigators are encouraged to propose studies that leverage existing resources, such as adding PCOR to an existing large clinical trial or analyzing existing large databases that contain valuable relevant information that may be used to answer important clinical CER questions.

Patient-Centered Outcome Measures

PCORI encourages investigators to design their research using validated outcome measures. Include preliminary data that support the use of the proposed measures in the study population. Investigators are encouraged to consider those measures described in the Patient Reported Outcomes Measurement Information System12 (PROMIS).

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12 Available at http://www.nihpromis.org/.
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 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 costs of care. For further information, please reference our cost-effectiveness analysis FAQs.

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

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

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

Categories of Nonresponsiveness

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

- Instrument development such as new surveys, scales, etc.
- Developing, testing, and validating new decision aids/tools or clinical prognostication tools
- Pilot studies intended to inform larger efforts
- Comparisons of patient characteristics rather than clinical strategy options
- Applies to APDTO (Assessment of Prevention, Diagnosis, and Treatment Options), IHS (Improving Healthcare Systems) program applicants ONLY: Studies comparing interventions for which the primary focus is the role of community health workers or patient navigators
Consistent with PCORI’s authorizing law, PCORI does not fund research whose findings will include:

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

Avoiding Redundancy

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

Methodological Considerations

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

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

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

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

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Standards for Systematic Reviews

Most of these standards should be considered minimal. The methodology standards\(^\text{14}\) reflect practices that should be followed in all cases, and all deviations need to be explained and well justified. Additional best practices, including accepted guidelines for the conduct of clinical trials or observational studies, should be addressed, if applicable, in the application for PCORI funding.

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

Upcoming New and Revised Methodology Standards

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

Patient and Stakeholder Engagement

PCORI encourages all applicants to describe clearly patient and stakeholder engagement in their research proposals. PCORI understands that patient and stakeholder engagement in research can take many forms; it is not seeking one particular type or method of engagement. Rather, applicants should communicate how patients (those with lived experience), family members, caregivers, and the organizations that represent them, as well as any other relevant stakeholders, will be involved in study activities. Because this type of engagement in research is a relatively new concept, PCORI has developed the Engagement Rubric\(^\text{15}\) to guide both applicants and merit reviewers. This rubric is intended to provide examples of engagement and is not intended to be prescriptive. As noted above, studies are expected to adhere to PCORI’s Methodology Standards Associated with Patient-Centeredness as well as to the PCOR Engagement Principles found within the rubric. These and additional resources are available on PCORI’s Engagement in Research page.

Populations Studied

PCORI seeks to fund research that includes populations that are diverse with respect to age, gender, race, ethnicity, geography, or clinical status, so that possible differences in outcomes may be examined in defined subpopulations, otherwise known as heterogeneity of treatment effect (HTE). PCORI recognizes that some proposed studies may represent important PCOR opportunities even in the absence of a broadly diverse study population. However, the burden is on the applicant in such cases to justify the importance of the study in the absence of diversity and to discuss which subgroups are most

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\(^{14}\) Available at http://www.pcori.org/research-we-support/the-pcori-methodology-report/.

\(^{15}\) Available at http://www.pcori.org/sites/default/files/Engagement-Rubric.pdf.
important and how they will be analyzed—including whether the study will be powered to examine the question of effectiveness in subgroups. PCORI is particularly interested in the inclusion of previously understudied populations for whom effectiveness information is especially needed, such as hard-to-reach populations or patients with multiple conditions. Thus, comparisons should examine the impact of the strategies in various subpopulations, with attention to the possibilities that the effects of the strategy might differ across subpopulations. PCORI has developed a list of populations of interest to guide our efforts in research and engagement (note that the Addressing Disparities Program requires that proposed research focus on at least one of the groups indicated by an asterisk below):

- Racial and ethnic minority groups*
- Low-income groups*
- Women
- 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*
- Lesbian, gay, bisexual, and transgender (LGBT) persons*
- Veterans and members of the Armed Forces and their families

**Protection of Human Subjects**

This component (up to five pages) is included in the Research Plan Template. Describe the protection of human subjects involved in your proposed research. PCORI follows the Federal Policy for the Protection of Human Subjects (45 CFR part 46), including the Common Rule. For more detailed information, please see Section 5, “Human Subjects Research Policy,” in the Supplemental Grant Application Instructions for All Competing Applications and Progress Reports,16 issued by the U.S. Department of Health and Human Services (HHS). PCORI does not require that applicants comply with sections of this policy that refer to requirements for federal-wide assurance (FWA) or that refer to standards for including women, minorities, and children. PCORI requires that applicants proposing clinical trials include a data- and safety-monitoring plan. Awardees must also comply with appropriate state, local, and institutional regulations and guidelines pertaining to the use of human subjects in research.

PCORI merit reviewers will examine plans for protection of human subjects in all applications and may provide comments regarding the plans (see How To Evaluate Human Subjects Protections\(^{17}\)). Reviewers’ comments on human subjects research are not reflected in the overall application score, but PCORI staff may use them during any potential funding negotiations. Final determinations about adequacy of human subject protections rest with the Institutional Review Board (IRB) or IRBs that have jurisdiction for the study.

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

**Required Education of Key Personnel on the Protection of Human Subject Participants**

PCORI requires that all applicants adhere to the National Institutes of Health (NIH) policy on education in the protection of human subject participants in the conduct of research. This applies to all personnel listed as Key Personnel in the application. The policy and FAQs are available from the NIH website.\(^{18}\)

**Replication and Reproducibility of Research and Data-Sharing Plan**

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

**Recruitment**

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

**Peer Review and Release of Research Findings**

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

Awardee Institutions are required to submit to PCORI for peer review a draft final research report that provides the methodological details, describes the main study results, and properly interprets the findings in clinical or other decisional contexts. Subject matter experts, individuals with expertise on


research methodology or biostatistics, and patients, caregivers, and other healthcare stakeholders, will review the draft final research report. After awardees have responded to reviewers’ comments to PCORI’s satisfaction, the report will be accepted and considered final. PCORI will then prepare a 500-word abstract summarizing the study results for patients and the general public, which the Awardee Institution will review and approve.

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

III. How To Submit an Application

Letter of Intent (LOI)

Important to note: The Communication and Dissemination Research Program will be using an LOI screening process. LOIs with the primary focus of tool development, testing, and validation will be screened out and not considered. You may submit a full application only if invited to do so based on your LOI. Research questions proposed in the LOI cannot change if you are invited to submit a full application.

Applicants should download the Letter of Intent Template for the Communication and Dissemination Research PFA from the Funding Center. They must complete the document and convert it to a PDF file; the LOI is limited to three pages and applicants should use in-text citations. The final references page will not be included in the three-page limit. LOIs that exceed the page limit will not be reviewed. Do not upload additional documents as part of your LOI, including letters of endorsement or support, because they are not requested at this stage. Inclusion of additional documents will result in LOI rejection without review. Please visit the 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 proposed study
- Specific aims: clearly stated
- Communication and dissemination issue being addressed by the application and how it 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)
- Study design: a concise description
- Study population: clear description; representative of community practice; inclusion of PCORI priority populations
• Outcomes: primary outcomes identified; description of why they are important to patients
• Sample size stated
• Comparators clearly described, with demonstrated efficacy specified for each and details on how the interventions/strategies will be delivered in real-world settings
• Patient and stakeholder engagement: involvement throughout planning, implementation of the project, and dissemination of findings discussed

Additional consideration will be given to programmatic fit and balance, taking into consideration whether the application overlaps previously funded studies or concurrent applications to a significant degree or, conversely, whether the application fills a gap in the portfolio of applications with certain characteristics, including disease category, topics, priority population, methodologies, and other variables.

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

Letter of Intent Review

LOIs are evaluated on the following criteria:

• 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
• Programmatic fit and balance, taking into consideration whether the applications overlap with previously funded studies or concurrent applications to a significant degree or, conversely, whether the application fills a gap in the portfolio of applications with certain characteristics, including disease category, topics, priority population, methodologies, and other variables

Only applicants whose LOIs are deemed most responsive to this PFA will be invited to submit a full application. LOIs are reviewed by a minimum of two PCORI staff and are not scored during review. Notification of denial or approval to submit a full application will occur no later than April 8, 2016.

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
• Principal Investigator (PI)
• Institution
If you need to change any of this information or have any questions, please email pfa@pcori.org.

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

**Budget and Project Duration**

The maximum budget for this PFA is $1.5 million total direct costs. The maximum research period of performance is three years (not including peer review). The maximum budget includes all research and peer review-related costs. (Please refer to the Application Guidelines for further details.) Refer to Appendix 2 in the Application Guidelines for a list of allowable and unallowable costs. This program does consider exceptions to the budget or to period-of-performance limits. If your proposed project has a budget that exceeds the $1.5 million total direct cost cap and/or has a project period that exceeds the three-year period of research performance, you must also complete and submit with your LOI a Greater Than Time/Budget Request form.

**Submission Dates**

LOIs and applications must be submitted in accordance with the published dates and times listed in the Overview in this PFA and in the PCORI Funding Center.

**PCORI Online System**

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

**Applicant Resources**

- **PCORI Funding Center**
  
  [http://www.pcori.org/Cycle-1-2016-communication/](http://www.pcori.org/Cycle-1-2016-communication/)

- **PCORI Online System**
  
  [https://pcori.fluxx.io](https://pcori.fluxx.io)

- **PCORI Funding Awards**
  
  [pcori.org/pfaawards](pcori.org/pfaawards)

**IV. Merit Review**

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

- To identify applications that have the strongest potential to help patients, caregivers, clinicians, and other stakeholders make informed decisions to improve patient outcomes

- To implement a transparent, fair, objective, and consistent process to identify these applications
To elicit high-quality feedback that reflects a diversity of perspectives to ensure that the research funded by PCORI reflects the interests and views of patients and those who care for them and that it meets the criteria for scientific rigor

To fund projects that fill important evidence gaps and have strong implementation potential

To regularly evaluate and continually improve the merit review process and policies in support of PCORI’s mission

PCORI merit review is a multiphase process that includes PFA development; staff evaluation of LOIs; preliminary review of full applications by review panels; in-person panel discussion of a subset of full applications (identified by PCORI’s Research Priority Area Program staff, based on the preliminary review and program priorities); Selection Committee recommendation of applications for funding; and finally, Board award approval.

**Preliminary Review**

PCORI conducts rigorous merit review of all of the full applications it receives. Note that applications may be eliminated from the review process for administrative or scientific reasons (e.g., nonresponsiveness). An application may be administratively withdrawn if it is incomplete; is submitted past the stated due date and time; or does not meet the formatting criteria outlined in the Application Guidelines, in the PCORI templates, and in PCORI Online. An application may be withdrawn for scientific reasons if it is not responsive to the guidelines as described in this PFA, describes research that is not comparative, includes cost-effectiveness analysis, or otherwise does not meet PCORI programmatic requirements.

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

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

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

The proposal should address the following questions:

- Does the application convincingly describe the clinical burden?
- Does the application identify a critical gap in current knowledge as noted in systematic reviews, clinical practice guidelines, or previous research prioritizations?
- Does the application identify a critical gap in current knowledge evidenced by inconsistency in clinical practice and decision making?
- Would research findings from the study have the potential to fill these evidence gaps?
Criterion 2. Potential for the study findings to be adopted into clinical practice and improve delivery of care

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

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

 Criterion 3. Scientific merit (research design, analysis, and outcomes)

The application should show sufficient technical merit in the research design to ensure that the study goals will be met.

- Does the proposal describe a clear conceptual framework anchored in background literature that informs the design, key variables, and relationship between interventions and outcomes being tested?
- Does the application provide justification that the outcome measures are validated and appropriate for the population?
- Does the research plan describe rigorous methods that demonstrate adherence to PCORI’s Methodology Standards?
- Is each of the comparators (e.g., active intervention arm and comparator arm) clearly described and well justified? If “usual care” is one of the arms, is it sufficiently justified and will it be sufficiently measured?
- Are the sample sizes and power estimates based on careful evaluations of the anticipated effect size? Is the effect size adequately justified in relation to the size or dose of the intervention and the research design (e.g., cluster randomized design)?
- Is the study plan feasible?
  - Is the project timeline realistic, including specific scientific and engagement milestones?
Criterion 4. Patient-centeredness

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

- Does the application include a thorough description of which outcomes (both benefits and harms) are important to patients, and are those outcomes included in the study plan?
- Does the application provide information that indicates that closing the evidence gap is important to patients and other stakeholders?
- Are the interventions being compared in the study available to patients now, and are they the best options for comparison (including whether they would be chosen by patients and their healthcare providers for managing the condition being studied)?

Criterion 5. Patient and stakeholder engagement

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

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

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

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

Post-Panel Review

After the in-person meeting, PCORI program staff evaluate final merit review panel scores and comments, identify duplication or synergy among funded projects, and consider the fit of applications within the programmatic vision. Program staff members then recommend projects to a Selection Committee, which includes members of PCORI’s Board of Governors. The Selection Committee considers recommendations and works with staff to identify a slate of applications for possible funding based on merit review scores, programmatic balance and fit, and PCORI’s strategic priorities. This slate is then proposed to PCORI’s Board for its consideration and approval.

Summary Statements and Funding Recommendations

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

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

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

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