Cycle 2 2015 Funding Cycle

PCORI Funding Announcement: Improving Healthcare Systems

Published June 29, 2015 Updated July 7, 2015

This PCORI Funding Announcement applies to the funding cycle that closes on November 3, 2015, at 5:00 p.m. (ET). Application guidelines, templates, and other resources are available at http://www.pcori.org/Cycle-2-2015-systems/. 
About PCORI

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

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

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<td>Letter of Intent Due</td>
<td>July 29, 2015, by 5:00 p.m. (ET)</td>
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<td>Letters of Intent (LOIs) will be screened for responsiveness and fit to program goals. Only those selected will be permitted to submit full applications. Notification of request to submit full application will occur no later than September 8, 2015.</td>
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<tr>
<td>Summary</td>
<td>PCORI is seeking applications to study the comparative effectiveness of alternative features of healthcare systems (e.g., innovative technologies, incentive structures, service designs) that are intended to optimize the quality, outcomes, and/or efficiency of care for patients and that have the most potential for sustained impact and replication within and across healthcare systems. Healthcare systems encompass multiple levels (e.g., national, state, and local health environments; organization and/or practice settings; family and social supports; and the individual patient) and include entities organized to deliver, arrange, purchase, and/or coordinate healthcare services. PCORI seeks to fund studies that will provide information of value to patients, their caregivers, clinicians, and healthcare leaders on which features of delivery systems lead to better patient-centered outcomes, so that those features proven to make a difference ultimately impact health care delivery.</td>
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<td>Key Dates</td>
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<td>Online System Opens:</td>
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<td>Letter of Intent (LOI) Deadline:</td>
<td>July 29, 2015, by 5:00 p.m. (ET)</td>
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| Applicant Town Hall Sessions: | July 7, 2015, 2:30 p.m. – 4:00 p.m. (ET)  
July 13, 2015, 11:00 a.m. – 12:30 p.m. (ET) |
| LOI Status Notification: | September 8, 2015 |
| Application Deadline: | November 3, 2015, by 5:00 p.m. (ET) |
| Merit Review: | February 2016 |
| Awards Announced: | April 2016 |
| Earliest Project Start Date: | June 2016 |
| Maximum Project Budget (Total Direct Costs) | $5 million for large studies  
$1.5 million for small studies |
| Maximum Project Period | Five years for large studies  
Three years for small studies |
| Funds Available up to | $16 million |
### Eligibility
Applications may be submitted by any private-sector research organization, including any nonprofit or for-profit organization, and any public-sector research organization, including any university or college hospital or healthcare system, laboratory or manufacturer, or unit of local, state, or federal government. The Internal Revenue Service must recognize all U.S. applicant organizations. Nondomestic components of organizations based in the United States and foreign organizations may apply, as long as there is demonstrable benefit to the U.S. healthcare system and U.S. efforts in the area of patient-centered research can be clearly shown. Organizations may submit multiple applications for funding. Individuals are not permitted to apply.

### Review Criteria
1. Impact of the condition on the health of individuals and populations
2. Potential for the study to improve health care and outcomes
3. Technical merit
4. Patient-centeredness
5. Patient and stakeholder engagement

### Contact Us
For programmatic questions, please email sciencequestions@pcori.org, phone (202-627-1884), or contact us online (http://www.pcori.org/PFA/inquiry). PCORI will provide a response within three business days. However, PCORI cannot guarantee that all questions will be addressed three business days prior to an LOI or application deadline.

Please email (pfa@pcori.org) for any administrative, financial, or technical questions. PCORI will provide a response within two business days. Please note that during the week of a deadline, response times may exceed three business days. Applicants may call the PCORI Helpdesk (202-627-1885) for technical or administrative support. Applicants are asked to plan accordingly. It is the applicant’s responsibility to submit the application on or before the application deadline.

### Other
*Deadlines are at 5:00 p.m. (ET). If deadlines fall on a weekend or a federal holiday, the deadline will be the following Monday or the next day after the federal holiday.

**New or Revised for the Cycle 2 2015 Funding Cycle:**

- Among the interventions that the Improving Healthcare System Program is particularly interested in are: behavioral and financial incentives for patients; behavioral incentives (i.e. non-financial) incentives for providers; and organizational models and policies within and across healthcare systems.
- “Veterans and members of the Armed Forces and their families” has been added to PCORI’s list of populations of interest

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I. Introduction

About PCORI

PCORI funds Patient-Centered Outcomes Research (PCOR), a type of comparative effectiveness research (CER) that focuses on outcomes that matter to patients, their caregivers, and their families. The studies PCORI funds must include the perspectives of patients and other healthcare stakeholders.

To be considered responsive, applications must describe research that compares at least two alternative approaches. Approaches may address diagnostic methods or options, screening, interventions for prevention or treatment, or strategies to improve the healthcare system. “Usual care” (or no specific intervention) may be an appropriate comparator if this is a realistic choice faced by patients and other stakeholders, but the clinical characteristics must be specified. In general, through its various funding announcements, PCORI is interested in studies of interventions that may include:

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

Summary of Program

The Improving Healthcare Systems (IHS) Program within PCORI invites applications for research that study the comparative effectiveness of alternative features of healthcare systems (e.g., innovative technologies, incentive structures, and/or healthcare service delivery service designs) intended to optimize the quality, outcomes, and/or efficiency of patient care and that have the greatest potential for sustained impact and replication within and across healthcare systems. Healthcare systems encompass multiple levels (e.g., individual patients, family and social supports, providers and care teams, organizations and/or practice settings, local community resources, and the state- and national-level policy environments) and include entities organized to deliver, arrange, purchase, and/or coordinate health services. Healthcare delivery models (e.g., integrated health system, patient-centered medical home) and settings of care (e.g., hospital, physician practice, nursing home, community health clinic, patient’s home) also define healthcare system operations. PCORI seeks studies that will affect healthcare delivery by determining which system features lead to improved Patient-Centered Outcomes (PCOs) and which provide valuable knowledge to patients, their caregivers, and clinicians, as well as other key stakeholders, including payers and employers. The following diagram is intended to illustrate this summary. Please note that two levels, National Health Environment and State Health Environment, are
shaded to indicate that although they clearly influence and shape the broader health policy environment, PCORI does not include them as specific targets for research interventions.

**The Healthcare System**

Figure adapted from: Taplin, S. H., Clauser, S., et al. (2012) Introduction: Understanding and Influencing Multilevel Factors Across the Cancer Care Continuum. *Journal of the National Cancer Institute, 44*, 2-10.

**Background**

Healthcare organizations are under constant pressure from competing sources to improve aspects of care, but they often lack the critical information needed to guide decisions related to system-level change. Research could help develop a body of evidence supporting effective interventions that would enable organizations to provide higher-quality care that is more accessible, coordinated, effective, and efficient, and that would ultimately improve PCOs.

PCORI is entrusted by the public to fund research that will matter to patients, their caregivers, and other stakeholders (defined as clinicians and their professional societies, hospitals, health systems administrators, payers [insurance], purchasers [business], industry [pharmaceutical, medical device companies], researchers, policy makers, and training institutions). PCORI seeks to change how research is conducted by emphasizing the role of diverse research teams that include the varying perspectives of such key stakeholders. PCORI distinguishes itself by supporting research in which patients, caregivers, and other stakeholders are actively engaged in all phases of the research process, from its inception to its conclusion, and includes generating research questions, reviewing research proposals, conducting research, disseminating research findings, promoting the implementation of research findings, and using the results to understand and address patient and other stakeholder needs.
Over the past two decades, the Institute of Medicine (IOM) and others have sharpened the focus on ensuring that healthcare systems are also designed and oriented to achieve the health outcomes most desired by individual patients—that is, to become more patient-centered. In particular, the IOM has addressed key aspects of systems improvement, including making care:

- Accessible
- Effective
- Patient-centered
- Timely
- Efficient
- Safer
- Equitable
- Coordinated

IHS seeks to fund comparative effectiveness research (CER) that addresses these areas.

Interventions designed to achieve these ends may target:

- Technology (e.g., inter-operative electronic health records [EHRs], telemedicine, patient-accessible health records)
- Patient incentives (e.g., free or subsidized preventive care, automatic enrollment in certain followup programs)
- Provider incentives (e.g., free continuing medical education units for certain courses, reduced paperwork, provision of key comparative quality performance information); only non-financial incentives are acceptable for providers
- Organizational models and policies within and across healthcare systems (e.g., patient centered medical homes, standing orders)
- Personnel (e.g., multidisciplinary teams, peer navigators, community health workers)

Although personnel is a key intervention, the IHS portfolio is already saturated with a broad representation of personnel-focused interventions designed to transform existing delivery systems. This includes patient navigator and community health worker interventions. Thus, unless the personnel intervention is part of a multicomponent intervention, or addresses issues of multidisciplinary teams, IHS is not interested in funding additional applications whose primary intervention focuses solely on the inclusion of personnel.

Innovation and changes in healthcare systems and in the behavior of healthcare system participants are often driven by economic, political, and social needs to improve access to care or quality of care, to attract patients or enrollees, and to contain costs. The effects of all such innovations may vary considerably among subgroups of the general population, but this heterogeneity of treatment effects (HTE) is often inadequately measured. Studies that include adequately powered subgroup analysis and
address understudied and/or underrepresented patient populations in research are of particular interest to PCORI and the IHS program. See the “Populations Studied” section below.

Research of Interest

PCORI seeks to fund investigator-initiated research on the effects of system changes on the broad outcomes listed below. We are especially interested in studies that conduct head-to-head comparisons with or without “usual care” as a comparator (see the “Guidance for Proposing Research” section for more on usual care), such as:

• Patients’ access to care, high quality of care, support for self-care, and coordination of care across healthcare settings
• Professional decision making on the basis of patients’ personal values
• Experiences that are important to patients and their caregivers, such as overall health, functional ability, health-related quality of life, stress, severity of symptoms, survival, and unanticipated healthcare utilization, such as unexpected hospital stays or visits to the emergency department
• The efficiency of healthcare delivery, as measured by the amount of ineffective, duplicative, or wasteful care provided to patients

The IHS Program is particularly interested in testing practices that combine evidence-based guidelines (such as Choosing Wisely, http://www.choosingwisely.org/) with patient and/or provider incentives and/or redesign to simultaneously elicit patient preferences and reduce harms faced by patients.

The IHS Program is also interested in funding studies that:

• Leverage existing research resources, such as adding PCOR to an existing large clinical trial, using established practice-based research networks, or analyzing large databases that contain valuable, relevant information that may be used to answer important CER questions
• Leverage healthcare system resources in support of some or all of the requirements for the intervention. Especially attractive is the possibility of broader and sustained impact through potential adoption by participating or supporting healthcare organizations and stakeholders (e.g., payers), should the intervention prove effective

Sample Research Questions

The following are examples of the types of questions that patients, clinicians, or healthcare administrators might ask, and that your research might help answer. This list is by no means exhaustive.

• An 84-year-old woman in a rural community with multiple chronic diseases is having increasing difficulty managing at home alone but does not want to leave her home or neighborhood to live in a nursing home. What are the benefits and drawbacks of a new care management program designed to help her stay at home and remain safe and independent compared with a program that links her to comprehensive community services?
• A 27-year-old Hispanic man with diabetes, chronic back pain, and depression has been invited by his public hospital-based clinic to participate in a group visit program for patients with chronic conditions that is led by a behavioral care specialist and a health educator. How likely is it that he will benefit from this program compared with the “usual care” he has been receiving (defined by quarterly visits with his primary-care practitioner punctuated by referrals to specialists as needed)? What is the nature of the benefit? Are there any risks? What should his physician recommend?

• A 50-year-old African American man has frequent exacerbations of his chronic obstructive pulmonary disease that trigger recurrent emergency department (ED) visits and acute hospitalizations. Does regularly scheduled home-based respiratory care reduce his ED utilization and hospital readmissions, compared to physician office visits that he or his caregiver must schedule? Does it improve functional status, health-related quality of life, or other patient-centered outcomes?

Evidence to Action Networks

PCORI is interested in connecting PCORI-funded investigators who are studying similar research topics and populations to help strengthen the body of research and to facilitate collaborative learning and dissemination of research findings. To meet this goal, PCORI has set up Evidence to Action Networks, whereby PCORI facilitates engagement among awardees and cross-learning between projects and teams comprising researchers, patients, caregivers, and other stakeholders. In addition, PCORI facilitates exchanges between awardees and end-users (e.g., patients, caregivers, and other stakeholders, such as payers, employers and purchasers, clinicians, professional societies, policy makers, and training institutions) for dissemination and implementation of important research findings.

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

II. Requirements for PCORI Research

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

Research Priorities

Regardless of the approach being studied, all proposed research projects must compare at least two alternatives. Optimally, the study will compare two or more defined strategies. In general, “usual care” is not an appropriate comparator for CER studies submitted to PCORI for funding consideration. “Usual care” is too often ill-defined, difficult to quantify, and subject to considerable geographic and temporal variations, thus limiting interpretability, applicability, and reproducibility. If the applicant proposes “usual care” as a rational and important comparator in the proposed study, then it must be described in detail, coherent as a clinical alternative, and properly justified as a legitimate comparator (e.g., usual care is guidelines-based). 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. To be considered responsive, applications must:
• **Describe research that compares two or more strategies 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 and/or dissemination strategies that will be compared; pilot data may be appropriate. Projects that aim to develop new or novel interventions, which lack evidence of efficacy or effectiveness, will be considered out of scope.

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

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

**Leveraging Existing Resources**

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

**Patient-Centered Outcome Measures**

PCORI encourages investigators to design their research using valid outcome measures. Include preliminary data that support the proposed measures. Investigators are encouraged to consider those measures described in the Patient Reported Outcomes Measurement Information System\(^1\) (PROMIS).

**Studies in Rare Diseases**

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

**Studies of Cost-Effectiveness**

Applications will be considered nonresponsive if the proposed research:

• Conducts a formal cost-effectiveness analysis in the form of dollar-cost per quality-adjusted lifeyear to compare two or more alternatives

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\(^1\) Available at http://www.nihpromis.org/.
• Measures the relative costs of care of two or more alternative approaches

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

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

• Examine the effect of costs on patients, such as patients’ out-of-pocket costs, hardship or lost opportunity, or costs as a determinant of or barrier to access to care

• Address cost-related issues, such as the resources needed to replicate or disseminate a successful intervention

• Evaluate interventions to reduce health system waste or increase health system efficiency

Categories of Nonresponsiveness

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

• Instrument development

• Developing, testing, and validating new decision aids/tools or clinical prognostication tools

• Pilot studies intended to inform larger efforts

• Comparisons of patient characteristics rather than clinical strategy options

• Studies comparing interventions for which the primary focus is the role of community health workers or patient navigators

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

• Practice guidelines

• Coverage recommendations

• Payment or policy recommendations

• Creation of clinical practice guidelines or care pathways

• Establishing efficacy for a new clinical strategy

• Pharmacodynamics

• Study of the natural history of disease

• Fundamental science or study of biological mechanisms

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Avoiding Redundancy

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

Methodological Considerations

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

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

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

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

Most of these standards should be considered “minimal.” The methodology standards3 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 specifically 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, or differences in participation, adherence, or follow-up that may affect outcomes independently of the interventions being compared.

3 Available at http://www.pcori.org/content/pcori-methodology-report.
Patient and Stakeholder Engagement

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

Populations Studied

PCORI seeks to fund research that includes diverse populations with respect to age, gender, race, ethnicity, geography, or clinical status, so that possible differences in outcomes may be examined in defined subpopulations, otherwise known as heterogeneity of treatment (HTE). PCORI recognizes that some proposed studies may represent important PCOR opportunities even in the absence of a broadly diverse study population. However, the burden is on the applicant in such cases to justify the importance of the study in the absence of diversity and to discuss which subgroups are most important and how they will be analyzed—including whether there will be power to examine the question of effectiveness in subgroups. PCORI is particularly interested in the inclusion of previously understudied populations for whom effectiveness information is especially needed, such as hard-to-reach populations or patients with multiple conditions. Thus, comparisons should examine the impact of the strategies in various subpopulations, with attention to the possibilities that the effects of the strategy might differ across subpopulations. PCORI has developed a list of populations of interest to guide our efforts in research and engagement, which includes:

• Racial and ethnic minority groups
• Low-income groups
• Women
• Children (age 0–17 years)
• Older adults (age 65 years and older)
• Residents of rural areas
• Individuals with special healthcare needs, including individuals with disabilities
• Individuals with multiple chronic diseases
• Individuals with rare diseases
• Individuals whose genetic makeup affects their medical outcomes
• Patients with low health literacy/numeracy and/or limited English proficiency
• LGBT persons
• 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” from the Supplemental Grant Application Instructions for All Competing Applications and Progress Reports, issued by the U.S. Department of Health and Human Services (DHHS). PCORI does not require that applicants comply with sections of this policy that refer to requirements for federal-wide assurance (FWA) or that refer to standards for inclusion of women, minorities, and children. PCORI equires applicants proposing clinical trials to include a data- and safety monitoring plan. Awardees must also comply with appropriate state, local, and institutional regulations and guidelines pertaining to the use of human subjects in research.

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

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

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

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

Replication and Reproducibility of Research and Data-Sharing Plan

PCORI is committed to maximizing the utility and usability of data collected in our funded projects. This is essential to building confidence in the accuracy of these findings. PCORI supports policies to promote sharing of study documentation (e.g., study protocol, programming code, and data definitions) so that

other researchers may replicate the findings in other populations. Please propose a method for sharing data and appropriate documentation on request.

Recruitment

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

Peer Review and Release of Research Findings

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

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

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

III. How To Submit a Proposal

Letters of Intent

In order to submit a full application to the IHS program, applicants are required to submit a Letter of Intent (LOI). Applicants should download the Letter of Intent Template for the Improving Healthcare Systems PCORI Funding Announcement (PFA) from the PCORI Funding Center. They must complete the document and convert it to a PDF with a limit of three pages. LOIs that exceed the page limit (excluding references) will not be reviewed. All references must be listed at the end of the LOI. Do not upload...
additional documents as part of your LOI, including letters of endorsement or support, as they are not requested at this stage. Their inclusion will result in LOI rejection without review. Please visit the PCORI Funding Center for additional applicant resources, including the PFA and required templates.

**LOIs are screened on five basic criteria:**

1. The inclusion of a suitable comparison group
2. The exclusion of any cost-effectiveness analysis
3. Overall fit with the PCORI IHS program’s Research of Interest section of this document
4. Responsiveness to PCORI and PFA goals, including evaluation of PCOs, patient and stakeholder engagement, and anticipated impact
5. Alignment with at least one of the IHS Program intervention targets (e.g., incentives, technology) listed in the “Background” section of this PFA; at this time, IHS is especially interested in proposals to test the effectiveness of novel uses of technology, incentives in improving healthcare systems and patient outcomes, or organizational policies

**Letter of Intent Review**

In addition to the above criteria, LOIs are evaluated and competitively screened 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
- Prior relevant experience of the investigators
- Programmatic fit and balance, taking into consideration whether the proposals significantly overlap with previously funded studies or concurrent proposals, or, conversely, whether the proposal fills a gap in the portfolio of proposals with certain characteristics, including disease category, topics, priority population, 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 not scored;** you will receive a notification that your LOI has either been invited for a full proposal or has not been invited. Notification of request to submit full application will occur no later than September 8, 2015. Please refer to the Application Guidelines for due dates and information on how to submit your LOI via PCORI Online. The IHS Program will only accept full applications from those who have been invited to submit them.

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
• Institution

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

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

Budget and Project Duration

For this PFA, PCORI intends to fund two different-sized projects: large projects (i.e., up to $5 million in total direct costs and/or up to five years in duration) and small projects (i.e., up to $1.5 million in total direct costs for up to three years in duration). Note that extending the time of the project beyond three years will put you into the “large” category.

Any request exceeding $5 million in total direct costs or exceeding a total of five years of duration will be rejected and will not be reviewed.

All applications will be reviewed during the same merit review session.

Submission Dates

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

PCORI Online System

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

Applicant Resources

PCORI Funding Center  http://www.pcori.org/Cycle 2-2015-systems/

PCORI Online System  https://pcori.fluxx.io

PCORI Funding Awards  pcori.org/pfaawards

IV. Merit Review

PCORI Merit Review is a multiphase process that includes: PFA development; staff evaluation of LOIs; preliminary review of full applications by review panels; in-person panel discussion of a subset of full applications (identified by PCORI’s Research Priority Area Program staff, based on the preliminary review and program priorities); Selection Committee recommendation of applications for funding; and, finally, Board of Governors (Board) award approval (no later than April 2016).
Preliminary Review

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

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

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

The proposal addresses the following questions:

- Is the condition or disease associated with a significant burden in the U.S. population, in terms of prevalence, mortality, morbidity, individual suffering, or loss of productivity?
- Alternatively, does the condition or disease impose a significant burden on a smaller number of people who have a rare disease?
- Does the proposal include a particular emphasis on patients with one or more chronic condition(s)?

**Criterion 2. Potential for the study to improve healthcare and outcomes**

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

- Does the research question address a critical gap in current knowledge as noted in systematic reviews, guideline development efforts, or previous research prioritizations?
- Has it been identified as important by patient, caregiver, or clinician groups?
- Do wide variations in practice patterns suggest current clinical uncertainty?
- Is the research novel or innovative in its methods or approach, in the population being studied, or in the intervention being evaluated, in ways that make it likely to improve care?
- Do preliminary studies indicate potential for a sizable benefit of the intervention relative to current practice? How likely is it that positive findings could be disseminated and implemented quickly, resulting in improvements in practice and patient outcomes?
Criterion 3. Technical merit

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

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

Criterion 4. Patient-centeredness

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

- Is the research focused on questions that affect outcomes of interest to patients and their caregivers?
- Does the research address one or more of the key questions mentioned in PCORI’s definition of PCOR?

Criterion 5. Patient and stakeholder engagement

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

- Are patients and other stakeholders engaged in:
  - Formulating research questions?
  - Defining essential characteristics of study participants, comparators, and outcomes?
  - Identifying and selecting outcomes that the population of interest notices and cares about (e.g., survival, function, symptoms, health-related quality of life) and that inform decision making relevant to the research topic?
monitoring study conduct and progress?

- Designing/suggesting plans for dissemination and implementation activities?
  - Are the roles and the decision-making authority of all research partners clearly stated?
  - Does the proposal demonstrate the principles of reciprocal relationships, co-learning, partnership, trust, transparency, and honesty?

**In-Person Review**

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

During the in-person review, panels meet to discuss applications and to clarify further the merits of the proposed research as well as to identify areas for improvement. Additionally, each application is rescored based on the content of discussion. The Chair and PCORI MRO lead the in-person panel meeting and ensure that all applications receive a fair and thorough review informed by the standards outlined in the PFA.

**Post-Panel Review**

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

**Summary Statements and Funding Recommendations**

Summary statements and funding decision notifications are provided to applicants contemporaneously. If an application progresses to in-person discussion, the applicant will receive a summary statement inclusive of the panel discussion notes, the final average overall score, and preliminary reviewer critiques. Summary statements for applications that do not progress to in-person discussion include only the preliminary reviewer critiques.

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