Limited PCORI Funding Announcement:
Health Systems PCORnet Demonstration Project

Published February 23, 2016
Updated April 4, 2016

This limited PCORI Funding Announcement (PFA), which applies to the Health Systems PCORnet Demonstration Project, closes on April 19, 2016 at 5 p.m. (ET). Funding announcements, templates, and other resources are available at http://www.pcori.org/2016-health-systems.
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 in order to enhance its work. PCORI helps people make informed healthcare decisions and improves healthcare delivery and outcomes by producing and promoting high-integrity, evidence-based information that comes from research guided by patients, caregivers, and the broader healthcare community.

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

PCORI provided an initial $105 million in 2014 to fund the development of the National Patient-Centered Clinical Research Network (PCORnet) infrastructure. PCORnet is intended to improve our nation’s capacity to conduct clinical research efficiently and to answer important questions faced by patients, clinicians, and other key stakeholders. PCORnet is a “network of networks” that includes, but is not limited to, Clinical Data Research Networks (CDRNs) composed of several health systems working in collaboration to support research to improve health outcomes. Currently, more than 100 health systems are participating through CDRNs in Phase II of advancing PCORnet as members of CDRNs, and the engagement of health systems leaders is a key component to its sustainability. This funding announcement is directed at enabling CDRNs to engage with their health systems leaders to identify and prioritize a set of data-driven research activities of high interest to both health systems and clinicians.

PCORI seeks research study proposals that involve CDRN researchers and leaders from the health system(s) participating in PCORnet. Proposals must address research questions of interest to systems leaders and that examine the features of healthcare delivery that might influence outcomes relevant to patients. This research may directly address comparative clinical effectiveness of various aspects of care delivery or may address more basic information needs commonly faced by health system communities.

This PCORnet demonstration project takes place in two steps.

Step 1: Health systems leaders convene to develop priority topics for research using PCORnet (completed).
Step 2: PCORI releases a limited-competition funding announcement for up to five research studies.

This limited PCORI Funding Announcement (PFA) will provide the CDRNs participating in PCORnet with an opportunity to test their capacity to conduct collaborative research with health systems leaders across the network.

Applicant Resources
http://www.pcori.org/2016-health-systems

Key Dates

<table>
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<tr>
<th>Category</th>
<th>Date/Time</th>
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<tr>
<td>Online System Opens</td>
<td>February 23, 2016</td>
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<tr>
<td>Applicant Town Hall</td>
<td>March 14, 2016, 2:00 – 3:00 p.m. (ET)</td>
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<tr>
<td>Application Deadline</td>
<td>April 19, 2016, by 5 p.m. (ET)</td>
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<td>Budget Deadline</td>
<td>May 3, 2016, by 5 p.m. (ET)</td>
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<tr>
<td>Application Review</td>
<td>May 2016</td>
</tr>
<tr>
<td>Awards Announced</td>
<td>June 2016</td>
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<tr>
<td>Earliest Project Start Date</td>
<td>July 2016</td>
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Maximum Project Budget (Total Costs)

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<tr>
<th>Amount</th>
<th>Description</th>
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<tr>
<td>$4 million</td>
<td>to fund up to five projects</td>
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Funds Available up to

<table>
<thead>
<tr>
<th>Amount</th>
<th>Description</th>
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<tbody>
<tr>
<td>$4 million</td>
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Maximum Project Period

<table>
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<th>Period</th>
<th>Description</th>
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<td>One year</td>
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<td>Elgibility</td>
<td>For this limited PFA, PCORI is soliciting applications only from organizations or institutions that are part of the CDRNs funded by PCORI as part of Phase II of the PCORnet initiative. Organizations or institutions, including their affiliate health systems, can be listed as a Principal Investigator/Primary Applicant only once. These organizations or institutions are encouraged to participate in other proposals. The Internal Revenue Service must recognize all applicant organizations.</td>
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<td>Review Criteria</td>
<td>1. Potential for the study to fill critical gaps in evidence and generate actionable evidence 2. Potential for the study findings to be rapidly 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</td>
</tr>
<tr>
<td>Contact Us</td>
<td>For programmatic questions, please email (<a href="mailto:sciencequestions@pcori.org">sciencequestions@pcori.org</a>), phone (202-627-1884), or contact us online (<a href="http://www.pcori.org/PFA/inquiry">http://www.pcori.org/PFA/inquiry</a>). PCORI will provide a response within three business days. However, we cannot guarantee that all questions will be addressed three business days before an application deadline. Please email (<a href="mailto:pfa@pcori.org">pfa@pcori.org</a>) for any administrative, financial, or technical questions. PCORI will provide a response within two business days. Applicants may also call the helpdesk (202-627-1885) for technical or administrative support. Please note that during the week of the application deadline, response times may exceed two business days. Applicants are asked to plan accordingly. It is the applicant’s responsibility to submit the application on or before the application deadline.</td>
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<tr>
<td>Other</td>
<td>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, respectively. The application will not be considered complete until all budget documents are submitted. The budget summary, template, and justification documents must be submitted no later than May 3, 2016, by 5 p.m. (ET). This limited PFA is a one-time opportunity and will not be reissued at a future date.</td>
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**Updates for the Health Systems PCORnet Demonstration Project:**
- The Full-Time Equivalent (FTE) for the Lead PI has been changed from a minimum of 40 percent to a minimum of 20 percent
- The budget summary, template, justification documents must be submitted no later than May 3, 2016, by 5 p.m. (ET)
- Applications will continue with the review process prior to the budget document submissions
- The application will not be considered complete until all budget documents are submitted
- In lieu of these budget documents, the Key Personnel Justification must be submitted with the full application by April 19, 2016, 5 p.m. (ET)
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I. Introduction

Summary of Program

Beginning in 2014, PCORI provided initial infrastructure development funds (Phase I) for the National Patient-Centered Clinical Research Network (PCORnet). Funds were awarded to develop the capacity of 11 Clinical Data Research Networks (CDRNs), 18 Patient-Powered Research Networks (PPRNs), and one Coordinating Center to participate in a national network for conducting comparative clinical effectiveness research (CER). Phase I infrastructure development funding concluded in Fall 2015, 18 months from its launch. Phase II funding awards for both CDRNs and PPRNs were announced on July 21, 2015. In Phase II, PCORI expanded its funding to 13 CDRNs and 20 PPRNs. More information on current PCORnet-related activities and structure can be found at www.pcornet.org.

PCORnet is intended to be a large, representative national network for conducting CER. It is envisioned that PCORnet will support a range of study designs, including large longitudinal observational studies, large pragmatic clinical trials conducted within delivery systems, rapid-cycle research in concert with health systems and plans, and surveillance studies across geographic areas and over time. To create a nimble and efficient national resource, the networks need to be collaborative, well-integrated, and highly adaptable.

Currently, more than 100 health systems are participating through CDRNs in Phase II of PCORnet. The engagement of health systems leaders is a key component to PCORnet’s sustainability. PCORnet’s value will ultimately depend on the ability to facilitate relationships among key stakeholders—including health systems leaders—to conduct collaborative research supported by tools and resources that have broad utility. Healthcare systems include entities organized to deliver, arrange, purchase, or coordinate health services. Healthcare delivery models (e.g., integrated health systems and patient-centered medical homes) and care settings (e.g., hospitals, physician practices, nursing homes, community health clinics, and patients’ homes) also define healthcare system operations. This initiative seeks to test the ability to engage systems leaders and clinicians across CDRNs to do focused and agile research that leverages the PCORnet Common Data Model and new health system data, and to conduct rapid and iterative analysis in collaboration with systems leaders.

Background

The Health Systems Demonstration Project is a two-step process:

**Step 1:** Health systems leaders convene to develop priority topics for research using PCORnet (completed).

**Step 2:** PCORI releases a limited-competition funding announcement for up to five research studies.

Step 1 occurred between July 2015 and January 2016. During this step, PCORI provided funding to support convening activities within the individuals CDRNs. These funds were provided to enable CDRNs to work with health systems leaders to identify and prioritize a set of data-driven research activities of high interest to health systems and clinicians. This step culminated with a convening, Accelerating Clinical Knowledge Generation and Use, hosted in collaboration with the National Academy of Medicine.
on January 21, 2016. Sessions held during this convening helped to foster compelling care questions; explored the views of health systems leaders on high-priority questions needing to be addressed; and identified common priorities to help improve synergy and progress among healthcare organizations with related interests. Characteristics necessary to generate research-ready data systems and usable knowledge were strategically discussed to provide input on using PCORnet’s Common Data Model Version 3.0. Step 2 of the demonstration project is releasing this limited PCORI Funding Announcement (PFA) for PCORnet CDRNs and will fund up to five, one-year research studies informed by outcomes and recommendations from the meetings that occurred in Step 1.

This limited PFA will provide CDRNs with the opportunity to test their capacity to conduct collaborative research with health systems leaders across PCORnet. The Health Systems Demonstration Project has the following objectives and guidelines:

- The project will be of interest and add value to multiple health systems.
- The project must include at least two health systems that span two or more CDRNs.
- The project will leverage PCORnet data resources. (Priority will be given to (1) CDRNs that have data currently organized in the PCORnet Common Data Model Version 3.0 and (2) to proposals that optimize the use of PCORnet Common Data Model Version 3.0, but may also incorporate additional, relevant health system data (e.g. system-level variables, social determinants of health, and genetic determinants of health) as appropriate.
- Topics will be rated as priority by the Chief Executive Officers (CEOs) and systems leaders, and their input will be included in the PFA responses.
- Proposed projects will be identified, vetted, and involve iterative review and discussion between researchers, clinicians and health systems leaders.
- Projects may be comparative, may be descriptive, or they may evaluate utility of new data sources for addressing specific questions of health systems leaders.
- The project will pay particular attention to the needs of a learning healthcare system\(^1\) to optimize decisions made by health systems, care providers, and patients and their families.
- The project may involve linkage to administrative claims data.
- The project will evaluate the impact of the research on PCORnet’s capacity to support collaborative research and extend the breadth of PCORnet’s shared tools and resources (the PCORnet Commons) using PCORnet infrastructure.

Although the project must include a common set of data elements for all participating systems or CDRNs, applicants may include additional data elements of interest to participating institutions.

PCORI expects all awardees to commit to using a centralized or single Institutional Review Board (IRB) for the research study, if possible. In all instances, PCORI expects awardees to address streamlining IRB

processes which will help with generalizing to other research settings.

**Research of Interest**

Studies that are designed to conduct CER—either as observational studies or randomized clinical trials—are strongly encouraged, but not required. The application must provide information on what is known about the efficacy of the interventions; pilot data might be helpful.

Since July 2015 the CDRNs have conducted pre-convening work within their individual networks as the first part of this demonstration project. Within each CDRN, questions and topics for this demonstration project were prioritized. In December 2015 Principal Investigators (PIs) from all of the CDRNs met to discuss the key questions that had been generated and began identifying topic areas that had emerged. Since December, a workgroup of PIs has finalized these topic areas, solicited comments from the other CDRN PIs, and synthesized the key questions by topic area. The final list of areas of interest and sample questions is a result of this prioritization work within the CDRNs and the cross-CDRN meeting on January 21, 2016, hosted by the National Academy of Medicine.

Applications **should address one of the following areas of interest**. The sample questions were developed during the preliminary convening work among the CDRNs. These questions are intended to provide additional guidance on the areas of interest, but applications are **not required to address one of these sample questions listed below**. These sample questions are presented as examples, but proposals addressing other questions will also be reviewed.

<table>
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<tr>
<th>Area of Interest</th>
<th>Sample Questions</th>
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| **1. Identifying and managing high healthcare utilizers**                       | • What are the most useful methods for classifying patients and subsets of patients with certain diseases who use the most healthcare services? How might these methods be efficiently incorporated into care delivery settings? Is there variation in the characteristics of such patients or subsets of patients with certain diseases across different health systems? What patterns of high utilization are likely to be modifiable? Are there successful examples of programs to change such utilization patterns overall or for specific subsets of patients?  
  • When patients are readmitted at various cutoffs (e.g., 15 days, 30 days, 45 days, 60 days, and so on), what hospitals are they readmitted to, what are their predictors, and how well do available data sources capture those readmissions patterns or predict readmission? Can data available through the electronic health record (EHR) improve the characterization of readmission patterns or the predictive validity of existing models? |
| **2. Identifying and managing the needs of specific populations by diagnoses (e.g., behavioral health) or patient characteristics (e.g., socioeconomic)** | • What are the utilization patterns and outcomes of patients who have co-occurring behavioral and physical health conditions? Are certain combinations of behavioral health and physical health conditions associated with higher utilization or poorer outcomes? What interventions are most successful for patients with co-occurring conditions (e.g., focusing on the behavioral health condition or co-locating behavioral and physical health treatment), particularly in the context of population health programs? |

CLOSED
### 3. Comparative performance of alternative models of healthcare delivery (e.g., accountable care organizations [ACOs])

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<td>How do individuals enrolled in an ACO (or Primary Care Medical Homes [PCMH]) compare with those not enrolled in an ACO/PCMH in rates of admission, 30-day readmission, and emergency department utilization, with a focus on individuals with pneumonia, chronic obstructive pulmonary disease, heart failure, acute myocardial infarction, total hip arthroplasty, total knee arthroplasty, and coronary artery bypass graft?</td>
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### 4. Novel analytical tools and methods (e.g., risk adjustment and predictive modeling)

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<td>Can a risk adjustment model that incorporates claims, as well as clinical and socioeconomic data more accurately predict high utilization than existing claims-based risk adjustment models? If so, how could these prediction models be incorporated into care delivery settings?</td>
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### 5. Assessment of value in health care (including quality, safety, and utilization)

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<td>How can overuse and underuse of testing and treatment be efficiently identified or predicted?</td>
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<td>How can diagnostic errors and delays be defined, detected, and predicted or prevented?</td>
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### Targeted Populations of Interest

PCORI is interested in studies focusing on populations prioritized by the health systems leaders, for whom effectiveness information is particularly needed, such as vulnerable, hard-to-reach populations or high utilizers. As appropriate, analyses or comparisons should examine the impact of the proposed strategies in various subpopulations, with attention paid to the possibility that the strategy’s effect might differ across various populations. Populations of interest include those that are less frequently studied. PCORI encourages applications that focus on one of the following populations of interest:

- Racial and ethnic minority groups
- Low-income groups
- Women
- Children (age 0–17 years)
- Residents of rural areas
- Frail elderly
- Individuals with special healthcare needs
- Individuals with multiple chronic diseases
- Individuals with rare diseases
- Individuals whose genetic makeup affects their medical outcomes
- Patients with low health literacy or numeracy and/or limited English proficiency
Lesbian, gay, bisexual, and transgender persons
Veterans and members of the armed forces and their families

II. Guidance for Proposing Research

The application must include a detailed Research Plan with a clear collaboration component, an engagement plan, an evaluation plan, a dissemination plan, a staffing plan, and a budget. Please see the Research Plan Template and Application Guidelines, which can be found in the PCORI Funding Center, for more detailed instructions on these elements.

Successful progress toward and completion of milestones (which will be determined during the contract negotiation phase) must be assessed in a quarterly interim report. The interim report will identify challenges encountered, solutions identified, and enhancements made to the research study throughout the first year. The milestones and interim report will need to demonstrate the feasibility of the Research Plan and redesign, where appropriate, based on iterative and nimble review processes with health systems leaders.

Guidance on the Research Plan

All Research Plans must accomplish the following:

• Provide a convincing description of the clinical or health system burden imposed by the problem or condition under study.
• Identify variations in practice patterns that suggest clinical uncertainty.
• Describe the decisional dilemmas experienced by clinicians, systems leaders, or other stakeholders that this study would address.
• Provide examples of the study’s potential to fill the identified evidence gaps and inform decision making for key stakeholders.
• Provide information that indicates how closing the evidence gap could be important to patients and other stakeholders, including health systems leaders.
• Include a justification for the research question’s importance and added value for multiple PCORnet health systems participating in the study.
• Provide information that justifies a demand or need for such a study by end-user stakeholders.
• Justify and provide examples of the study’s potential to inform decision making for key stakeholders. Describe the likelihood that findings would be valuable to others, leading to implementation of changes and improvements in practice and patient outcomes. The explanation should identify potential barriers that could hinder adoption of the intervention by others.
• As appropriate, describe a conceptual framework and reference background literature that informs the proposed study.
• Provide a thorough description about which outcomes (both benefits and harms) or other variables will be in the study plan. PCORI is interested in studies that provide practical information that can be useful to health systems, clinicians, or others in making informed healthcare decisions.

• Provide justification that the outcome measures are validated and appropriate for the study population.

• Describe how the application addresses outcomes of interest to all participating health systems and, if applicable, describe local or site-specific outcomes of interest.

• Describe rigorous methods that demonstrate adherence to the PCORI Methodology Standards.

• As appropriate, justify sample sizes and power estimates, or alternatively, provide estimates for confidence intervals on key estimates—overall and for important subgroups.

• Describe the study plan’s feasibility, including presenting a realistic project timeline with specific scientific and engagement milestones.

• If recruitment of participants (patients and clinicians) is proposed, provide a feasible recruitment strategy using realistic assumptions about participant attrition and plans to adequately address patient or site attrition.

• The PCORnet Common Data Model must be used across participating sites to the extent that it covers needed data elements. Proposals will be explicitly evaluated on the extent to which the Common Data Model Version 3.0 is leveraged. For additional data not currently captured in the Common Data Model, provide evidence that the data will be available.

• If applicable, provide details for how administrative claims data will be obtained and linked.

• Describe how this study will, or could, potentially inform a CER question or topic.

In addition, where relevant, the plan should:

• Justify, in comparative studies, that the interventions being compared in the study are available to patients now and are the best options for comparison (including whether patients and their healthcare providers would choose them for managing the condition being studied).

• Explain how each of the comparators and interventions will be measured. If usual care is one of the aims, it must be justified as a comparator and carefully measured during the study.

Guidance on the Engagement Plan

PCORI requires all applicants to describe clearly the patient and stakeholder engagement planned for their proposed projects. We understand that patient and stakeholder engagement in research can take many forms. Applicants should communicate how patients (those with lived experience), family members, caregivers, and the organizations that represent them, as well as other relevant stakeholders—particularly health systems leaders—will be involved in all aspects of study activities. In addition, studies are expected to adhere to the PCORI Methodology Standards Associated with Patient-Centeredness and to the Patient-Centered Outcomes Research (PCOR) Engagement Principles found...
within the PCORI Engagement Rubric. The PCORI Engagement Rubric also provides guidance on promising practices to consider when developing an engagement plan. These and additional resources are available in the PCORI Funding Center.

The engagement plan for this application must:

- Describe how the participating health systems communities generated the research question. Input must be included from health systems leaders (e.g., CEOs, Chief Medical Information Officers [CMIOs], and Chief Information Officers [CIOs]) and physician champions.

- Provide a well-justified description of how the research team is interdisciplinary, ensuring that the project will be carried out successfully by researchers, patients, clinicians, physician champions, and other stakeholders.

- Show evidence of active engagement and iterative review and discussion among scientists, patients, health systems leaders, physician champions, and others throughout the research process (e.g., formulating questions, identifying outcomes, monitoring the study, conducting iterative reviews, disseminating, and implementing), and also show that the frequency and level of patient and stakeholder involvement will sufficiently support the study goals.

- Clearly describe the roles and decision-making authority of all study partners.

Applicants are encouraged to budget for engagement activities appropriately, including the cost of meetings, travel, and other necessary expenses. In recognition of the value of their contributions, PCORI strongly encourages financial compensation for patient and stakeholder partners serving on research teams.

**Guidance on the Evaluation Plan**

A significant component of this demonstration project is to test, evaluate, and report on the research implementation readiness of PCORnet’s collaborative infrastructure, including scientific, operational, and logistical components. The applicant should propose a plan to formally test and evaluate the research project’s impact on PCORnet’s capacity to support collaborative research and engage health systems leaders in rapid-cycle research.

The application should include a list of activities and a timeline describing the necessary evaluation process to evaluate the research study. The evaluation plan must:

- Describe the study’s collaborative aspects and address how these collaborative aspects provide an opportunity to transform or enhance PCORnet processes or infrastructure.

- Propose a robust approach to sharing project learnings—especially learnings related to the utility and validity of new data elements—with other PCORnet networks and the public through the PCORnet Commons—a repository of shared tools, knowledge, expertise, and infrastructure processes—and the impact of these learnings on PCORnet’s capacity to support an increasing volume and breadth of research.

- Acknowledge future collaborations with health system research leaders within PCORnet on the finalization of an evaluation framework.
The final evaluation framework and plan will be developed in collaboration with health system research leaders within PCORnet after the award announcement. The evaluation plan proposed in the application will serve as a preliminary framework for the final evaluation plan.

**Guidance on the Dissemination Plan**

The application must include a dissemination plan. The dissemination plan must describe a plan for how study findings will be disseminated beyond publication in peer-review journals and national conferences. The priority of the Health Systems leaders from the pre-convening activities conducted during the first step of this demonstration project, was the dissemination of study results.

The dissemination plan must:

- Identify who will make decisions or use the findings produced by this study, such as local and national stakeholders.
- Describe a plan for disseminating study findings outside of PCORnet beyond publication in peer-review journals and at national conferences.
- Present a credible plan through which findings could be feasibly disseminated and implemented quickly within PCORnet (including at the local hospital or clinic level and at the leadership level including health systems leaders and clinical leaders), resulting in improvements in healthcare system, practice and patient outcomes.
- Outline clearly the roles of patient and stakeholder partners (including health systems leaders and clinical leaders) in the planning of disseminating the study’s findings.

**Studies of Cost-Effectiveness**

Applications will be considered nonresponsive if the proposed research:

- Conducts a formal cost-effectiveness analysis
- 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 might not employ direct measurements of care costs. For further information, please reference our cost-effectiveness analysis FAQs.

PCORI does have an interest, however, in studies 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 care access
- Address cost-related issues, such as the resources needed to replicate or disseminate a successful intervention
- Evaluate interventions to reduce health systems waste or increase health system efficiency
Addressing the issue of conditions that lead to high costs, PCORI’s previous funding announcements state 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:**

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

Consistent with PCORI’s authorizing law,² PCORI does not fund research whose findings will include:

- Coverage recommendations
- Payment or policy recommendations
- Creating clinical practice guidelines or clinical pathways
- Establishing efficacy for a new clinical strategy
- Pharmacodynamics
- Studying the natural history of disease
- Basic science or studying biological mechanisms

**Avoiding Redundancy**

Applicants are strongly encouraged to review the lists of funded research on PCORI’s website and ClinicalTrials.gov, because PCORI intends to balance its funded portfolio to achieve synergy where possible and to avoid redundancy.

**Staffing and Organizational Capacity Requirements**

PCORI requires that each applicant propose one Lead PI who will be named in the award contract and at least two co-PIs. The PIs must have the following qualifications:

- **Lead PI:** Primary experience or expertise in health research or CER and be either a health systems participant or a PCORnet participant. The Lead PI must contribute a minimum of 20 percent Full-Time Equivalent (FTE). The Lead PI must be a full-time employee of the prime applicant.

- **One co-PI:** Primary experience or expertise as a health systems leader. The co-PI must contribute up to 5 percent FTE.

- **One co-PI:** Primary experience or expertise as a physician champion. The co-PI must contribute up to 5 percent FTE.

Health systems leaders, physician champions, and other key stakeholders must also be involved throughout the research process.

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² Available at http://www.pcori.org/sites/default/files/PCORI_Authorizing_Legislation.pdf/.
Methodological Considerations

Regardless of study design, proposals must adhere to all relevant PCORI Methodology Standards. These 47 individual standards fall into 10 categories. The first five categories are cross-cutting and relevant to most PCOR studies. Researchers should refer to the standards in these categories when planning and conducting their research projects. The 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 Effects

Six additional standards categories will be applicable to particular 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 PCORI Methodology Standards\(^3\) reflect practices that should be followed in all cases, and all deviations need to be explained and well justified. Additional best practices, including accepted guidelines for conducting clinical trials or observational studies, should be addressed (if applicable) in the PCORI funding application.

Applicants should specifically discuss how the planned study design will measure and adjust for potential confounding factors that might 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 could 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 PCORI Methodology Standards, updating and adding new standards where indicated. Although these proposed revised and new standards are still under review and have yet to benefit from public comment, we encourage you to refer to the potential 2015 revisions. Applicants should continue to adhere to the current PCORI

\(^3\) http://www.pcori.org/research-results/research-methodology/pcori-methodology-report
Protection of Human Subjects

This component (up to five pages) is included in the Research Plan Template. Describe the protection of human subjects involved in your proposed research. PCORI follows the Federal Policy for the Protection of Human Subjects (45 CFR part 46), including the Common Rule. For more detailed information, please see Section 5, titled “Human Subjects Research Policy,” in the Supplemental Grant Application Instructions for All Competing Applications and Progress Reports, which was issued by the U.S. Department of Health and Human Services. PCORI does not require that applicants comply with sections of this policy referring to requirements for Federal-wide assurance or 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). Reviewers’ comments on human subject 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 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 individuals listed in the application as key personnel. The policy and FAQs are available on the NIH website.

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 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.

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. Consistent with this obligation, the PCORI Board of Governors adopted the PCORI Process for Peer Review of Primary Research and Public Release of Research Findings (Peer-Review and Public Release Process), which provides more details about the Peer-Review and Public Release Process.

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In summary, under the Peer-Review and Public Release Process, Awardee Institutions are required to submit a draft final research report to PCORI for review, which provides the methodological details, describes the main study results, and properly interprets the findings in clinical or other decisional contexts. Subject matter experts (SMEs) and individuals with expertise in research methodology or biostatistics, as well as 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.

Under the Peer-Review and Public Release Process, PCORI will also post the following materials on its website no later than 90 days after the draft final research report is accepted following peer review: (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.

Budget and Project Duration

The maximum budget in this limited PFA is $4 million in total costs for up to five funded studies. The maximum period of performance is one year (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: Allowable and Unallowable Costs in the Application Guidelines for a list of allowable and unallowable costs. PCORI will not consider exceptions to the budget and period of performance limits. If you submit an application that exceeds the $4 million total cost cap or one year in period of performance, your application will be removed for noncompliance. In the Budget Justification, the budget for the research activities should be clearly delineated from the budget for the evaluation activities.

The budget summary, template, and justification documents must be submitted no later than May 3, 2016, by 5 p.m. (ET). Applications will continue with the review process prior to the budget document submission.

Key Personnel Justification

In lieu of submitting these budget documents by the initial deadline, complete the Key Personnel Justification Template and upload under “Budget” to PCORI Online by April 19, 2016, 5 p.m. (ET).

III. How To Submit a Proposal

Submission Dates

Applications must be submitted in accordance with the published dates and times listed in the Overview section of this limited PFA and in the PCORI Funding Center. Please note that the application will not be considered complete until the budget template and justification documents are submitted.
PCORI Online System
To submit an application, you must register with PCORI Online.

Applicant Resources

PCORI Funding Center http://www.pcori.org/2016-health-systems
PCORI Online System https://pcori.fluxx.io
PCORI Funding Awards pcori.org/pfaawards

IV. Application Review

The application review process for this limited PFA is designed to support the following goals:

- To identify applications that have the strongest potential to help patients, caregivers, clinicians, health systems, 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 PCORI-funded research 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

This application review is a multiphase process that includes PFA development; preliminary review of full applications by an expert review panel; a panel discussion of full applications (identified by PCORI’s Research Infrastructure Program staff, based on the preliminary review and program priorities); Selection Committee recommendations of applications for funding; and finally, PCORI Board of Governors award approval (expected to be no later than June 2016).

Preliminary Review

PCORI conducts a rigorous 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 scientifically withdrawn if it is not responsive to the guidelines as described in this limited PFA, includes cost-effectiveness analysis, or otherwise does not meet PCORI’s programmatic requirements.

PCORI’s Research Infrastructure Program, in collaboration with Merit Review and Improving Healthcare Systems, will recruit an expert review panel based on the number of research proposals and the topic areas represented. The expert review panel will be comprised of PCORI staff and external experts and include an external panel Chair, scientist reviewers who are SMEs, patient representatives, and representatives of key stakeholder groups. Panel members receive training during the review cycle to ensure that all members understand the programmatic and organizational goals of review.
Below are PCORI’s application review criteria for this limited PFA. PCORI’s expert review panels use these criteria during the preliminary and in-person review phases to evaluate and score submitted applications:

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

The application should address the following questions:

- Does the application convincingly describe the clinical or health system burden imposed by the problem or condition under study?
- Does the research question address a critical gap in current knowledge as noted in systematic reviews, guideline development efforts, or previous research prioritizations?
- Does the study identify variations in practice patterns that suggest clinical uncertainty?
- Does the application describe the decisional dilemmas experienced by clinicians, systems leaders, or other stakeholders that this study would address?
- Does the study have the potential to fill these evidence gaps and inform decision making for key stakeholders (provide examples)?
- Does the application add value for multiple health systems participating in PCORnet?
- Does the application include at least two health systems that span two or more CDRNs?

**Criterion 2. Potential for the study findings to be rapidly 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 questions:

- Does the application identify who will make the decision (i.e., the decision maker) or use (i.e., the end-user) the study findings (not the intervention) produced by this study, such as local and national stakeholders?
- 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 examples)? How likely is it that positive findings could be of value to others, leading to implementation of changes and improvements in practice and patient outcomes? Identify potential barriers that could hinder adoption of the intervention by others.
- Does the application describe a plan for how study findings will be disseminated outside of PCORnet beyond publication in peer-review journals and at national conferences?
- Can the study be readily adopted in other settings with minimal adaptations or complexities?
- Does the applicant present a credible plan by which findings could be feasibly disseminated and implemented quickly within PCORnet (at the local hospital or clinic level and at the leadership level, including health systems leaders and clinical leaders), resulting in improvements in healthcare system, practice and patient outcomes?
Criterion 3. Scientific merit (research design, analysis, and outcomes)
The application should show sufficient technical merit in the research design to ensure that the study goals will be met. The application should address the following questions:

- If applicable, does the application describe a clear conceptual framework and reference background literature that informed the proposed study?
- Does the application provide justification that the outcome measures are validated and appropriate for the population?
- Does the application address outcomes of interest to all participating CDRNs and health systems and, if applicable, include local or site-specific outcomes of interest?
- Does the Research Plan describe rigorous methods that demonstrate adherence to the PCORI Methodology Standards?
- Where applicable, are the selected appropriate interventions or comparators clearly described and well justified? If usual care is one of the arms, is it sufficiently justified as a comparator and will it be measured carefully?
- If applicable, are the sample sizes and power estimates justified and based on realistic and careful evaluations of the anticipated effect size? Are estimates provided for confidence intervals on key estimates, those overall and those for important subgroups?
- Where applicable, does the application address the potential for this research to inform a CER question?
- Is the study plan feasible?
  - Is the project timeline realistic, including specific scientific and engagement milestones?
  - Is the strategy for recruiting participants feasible?
  - Are assumptions about participant attrition realistic, and are plans to address patient or site attrition adequate?
  - Does the study leverage data resources? (Priority will be given to (1) CDRNs that have data currently organized in the PCORnet Common Data Model Version 3.0 and (2) proposals that optimize the use of the PCORnet Common Data Model Version 3.0.)
  - Does the application provide evidence that data required outside the PCORnet Common Data Model will be available?
  - Where applicable, does the application involve linkage to administrative claims data?
- Do the collaborative aspects of the proposed research project provide an opportunity to transform PCORnet processes or enhance aspects of the PCORnet infrastructure?
- Does the applicant propose a robust approach to sharing project learnings—especially learnings related to the utility and validity of new data elements—with other PCORnet networks and the public through the PCORnet Commons?
• Does the applicant acknowledge work with health system research leaders within PCORnet on finalizing an evaluation framework?

**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: A study can be patient-centered even if the end-user is not the patient, as long as patients will benefit from information.*) The application should address the following questions:

- Does the application include a thorough description about which outcomes (benefits and harms) are important to patients, and are those outcomes included in the study plan?
- Does the application provide information that indicates how closing the evidence gap is important to patients and other stakeholders, including health systems leaders?
- Are the interventions being compared in the study currently available to patients, and are they the best options for comparison (including whether patients and their healthcare providers would choose them for managing the condition being studied)?

**Criterion 5. Patient and stakeholder engagement**
The application 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 research process. The application should address the following questions:

- Does the application address a research question that was generated and prioritized by the participating health systems communities? Does the Research Plan include input from health systems leaders (e.g. CEOs, CMIOs, and CIOs)?
- Does the application provide a well-justified description of how the research team is interdisciplinary? Does the study include the correct individuals (researchers, patients, clinicians, physician champions, and other stakeholders) to ensure that the projects will be carried out successfully?
- Does the application show evidence of active engagement and meaningful discussion among scientists, patients, health systems leaders, and others throughout the research process (e.g., formulating questions, identifying outcomes, monitoring the study, performing iterative reviews, disseminating, and implementing)? Are the frequency and level of patient and stakeholder involvement sufficient to support the study goals?
- Are the roles and the decision-making authority of all study partners clearly described?
- Are the roles of patient and stakeholder partners (including health systems leaders and clinical leaders) clearly outlined in the dissemination of the study’s findings?

**Application Review Discussion**

During preliminary review, all administratively and scientifically compliant applications are evaluated...
and scored based on PCORI’s application review criteria, including evaluation of adherence to the PCORI Methodology Standards. After the preliminary review is completed, PCORI program staff members evaluate panel scores and critiques to identify a subset of applications for discussion at the application review.

During the review discussion, the expert review panel will meet to discuss applications, clarify the merits of the proposed research, and identify areas for improvement. The Chair leads the discussion and ensures that all applications receive a fair and thorough review informed by the standards outlined in the PFA.

**Post-Panel Review**

After the review discussion, PCORI program staff evaluate application 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 the PCORI Board of Governors. The Selection Committee considers recommendations and works with staff to identify a slate of applications for possible funding based on application review scores, programmatic balance and fit, and PCORI’s strategic priorities. This slate is then proposed to the PCORI Board of Governors for consideration and approval. Up to five awards will be proposed to the PCORI Board of Governors for consideration and approval.

**Summary Statements and Funding Recommendations**

Summary statements are provided to applicants approximately two weeks before funding decisions are announced. Summary statements will include only the application review discussion notes that the expert review panel provided.

Funding recommendations are made by identifying meritorious applications that fit the programmatic needs and that satisfactorily address the application review criteria while adhering to the PCORI Methodology Standards. Programs also consider the funds allotted for the current funding announcement when deciding which applications to recommend to the PCORI Board of Governors for approval. It is expected that applicants to this current cycle’s PFA will receive summary statements in early June 2016 and notification of their application’s funding status no later than June 2016. The awards will be for one year, and must demonstrate the project’s feasibility, impact, and ease of health systems leaders’ engagement.

**Contract Execution and Activation**

PCORI will issue a contract to the selected Awardee Institutions for the study once it conducts a thorough programmatic and administrative review. The awardees must accept PCORI’s contract terms and conditions, which will be based on PCORI’s research funding contract terms and conditions, with additional provisions appropriate for the use of the PCORnet infrastructure and the specific research project. Among the expected contractual terms is a fully agreed-upon study plan as evaluated by PCORI. The study will commence only after PCORI and the Awardee Institution execute the applicable contract and agree on the final research project plan.