Limited PCORI Funding Announcement:
The Natural Experiments Network: A Collaborative Initiative

Published August 19, 2015

Eligibility of this limited PCORI Funding Announcement (PFA) is restricted to PCORI funded CDRNs that have applied to the Natural Experiments Network (Funding Opportunity Announcement RFA-DP-15-001). Application for this limited PFA closes on September 16, 2015, at 5:00 p.m. (ET). Funding announcements, templates, and other resources are available at http://www.pcori.org/2015-Natural-Experiments-Network.
About PCORI

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

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

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

Follow us on Twitter: @PCORI

Limited PCORI Funding Announcement: The Natural Experiments Network
**Overview**

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<th>Published Summary</th>
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<tr>
<td>August 19, 2015</td>
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<td>PCORI’s Collaborative Initiative with the Centers for Disease Control and Prevention (CDC) and the National Institutes of Health (NIH)/National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) will expand the number of research projects within the CDC and NIH/NIDDK Natural Experiments Network. The Natural Experiments Network is a multi-center network intended to 1) Test the comparative health impact of naturally occurring interventions; and 2) Improve the methods and research infrastructure for natural experiments for clinical comparative effectiveness in public health. Through this PFA, PCORI aims to fund up to three additional research projects for participation in the Natural Experiments Network. PCORI funding for this one-time announcement is limited to PCORnet Clinical Data Research Networks (CDRN) that have applied to CDC Funding Opportunity Announcement (FOA) RFA-DP-15-001. The research projects will investigate the “impact of population-targeted health policies and large-scale interventions on risk and complications of diabetes, and reducing disparities in these risks and complications” with particular attention to patient-centeredness and patient and stakeholder engagement.¹</td>
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PCORI’s participation in this collaborative initiative aligns with PCORI’s Principles of Collaboration. This will be PCORI’s first co-funded initiative with the CDC. This collaboration allows PCORI to extend the principles of patient-centeredness and engagement while providing its awardees experience in analysis of natural experiments within delivery systems. This initiative also provides the opportunity for additional collaboration among CDRNs funded by PCORI to enable participation in PCORnet and strengthens the CDRNs by supporting engagement around diabetes care. It also provides a vehicle to demonstrate and expand the PCORnet Common Data Model to other systems and researchers.

<table>
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<tr>
<td>See <a href="http://www.pcori.org/2015-Natural-Experiments-Network">http://www.pcori.org/2015-Natural-Experiments-Network</a></td>
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<th>Key Dates</th>
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<tr>
<td>Online System Opens: August 19, 2015</td>
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<td>Application Deadline: September 16, 2015, by 5:00 p.m. (ET)</td>
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<td>Merit Review: December 2015</td>
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<td>Awards Announced: January 2016</td>
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<td>Earliest Project Start Date: February 2016</td>
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<th>Maximum Project Budget (Total Costs)</th>
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<th>Funds Available up to</th>
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<td>$6.75 million</td>
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<th>Maximum Project Period</th>
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<td>Five years</td>
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Limited PCORI Funding Announcement: The Natural Experiments Network
Eligibility
Applications may be submitted only by CDRNs that are currently funded by PCORI and
that have applied to the CDC funding opportunity “Natural Experiments of the Impact of
Population-targeted Health Policies to Prevent Diabetes and Its Complications” (RFA-15-001). Applicants that receive funding from the CDC under the CDC funding opportunity
are ineligible for award under this PFA and will have their application withdrawn for
consideration. To be eligible for this opportunity applicants must submit the following:
• A copy of the full application submitted to CDC in response to the CDC funding
  opportunity RFA-DP-15-001
• A copy of the summary statement from the CDC’s technical review
• A copy of the score given by the CDC during technical review
The Internal Revenue Service must recognize all applicant organizations.

Review Criteria
1. Patient-centeredness
2. Patient and stakeholder engagement

Note: The review process consists of programmatic screening, Merit Review, and a post-
panel review. The two criteria listed above will be used by external merit reviewers. For a full
description of the review processes please see pages 10 – 12.

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 before an 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 the application deadline, response times may exceed two business days.
Applicants may call the Helpdesk (202-627-1885) before the deadline 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, respectively.
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Limited PCORI Funding Announcement: The Natural Experiments Network
Limited PCORI Funding Announcement: The Natural Experiments Network
I. Introduction

Summary of Collaboration

This Natural Experiments Network is a collaboration between PCORI, the Centers for Disease Control and Prevention (CDC), and the National Institutes of Health (NIH)/National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK). The former NEXT-D study, Natural Experiments and Effectiveness Studies to Identify the Best Policy and System Level Practices to Prevent Diabetes and Its Complications, was a collection of five-year research projects that started in September 2010. These research projects were cooperative agreements jointly funded by the CDC and NIDDK under the Funding Opportunity (FOA) Number RFA-DP10-002. This initiative aimed “to understand how population-targeted policies affect preventive behaviors and diabetes outcomes, quantity and quality of care used, morbidity, costs, and unintended consequences.”

This PFA reflects a collaboration between the CDC, NIH/NIDDK, and PCORI to expand the number of research projects within the Natural Experiments Network. The Natural Experiments Network is a multi-center network similar to the earlier NEXT-D study and intended to 1) Test the comparative health impact of naturally occurring interventions; and 2) Improve the methods and research infrastructure for natural experiments for clinical comparative effectiveness in public health. Through this PFA, PCORI aims to fund up to three additional research projects for participation in the Natural Experiments Network. In the corresponding CDC Funding Opportunity Announcement (FOA) (RFA-DP-15-001), research projects are referenced as Natural Experiment Sites. The CDC FOA also outlines two components of the funding initiative. Component A is the research project (referred to by the CDC as a site) and Component B is the coordinating center. This funding announcement from PCORI supports only additional research projects. All participating research projects that receive funding from PCORI must comply with PCORI standards and follow PCORI’s nonresponsiveness guidelines. PCORI funding is limited to Clinical Data Research Networks (CDRNs) in the PCORnet initiative that have applied to CDC FOA – RFA-DP-15-001.

PCORI’s participation in this collaborative initiative aligns well with PCORI’s Principles of Collaboration. This will be PCORI’s first co-funded initiative with the CDC and allows PCORI to extend the principles of patient-centeredness and engagement while providing its awardees experience in analysis of natural experiments within delivery systems. This initiative provides the opportunity for additional collaboration among CDRNs funded by PCORI to advance PCORnet and strengthens the CDRNs by supporting engagement around diabetes care. It also provides a vehicle to demonstrate and expand the PCORnet Common Data Model to other systems and researchers.

Summary of PCORnet Program

The goal of The National Patient-Centered Clinical Research Network, PCORnet, is to bring researchers, patients, clinicians, and health systems together to create a large national “network of networks” that is linked by interoperable data using a common data model (CDM) and prepared to conduct clinical comparative effectiveness research (CER).

2 Available at http://www.cdc.gov/diabetes/programs/research/nextd.html
The long-term vision is for PCORnet to improve the nation’s capacity to conduct research more efficiently by providing a sustainable national research infrastructure that embeds research in everyday practice across multiple healthcare systems, drawing from the rich clinical data available in electronic health records and claims data, as well as patient-generated data sources. Phase I began in early 2014 as an 18-month investment for initial infrastructure development. By the end of Phase I, it is envisioned that PCORnet will function as a collaborative community that ensures the engagement of all stakeholders, facilitates sharing of analysis-ready standardized data with strong privacy protections using a CDM, and supports timely research that is trusted by the larger research community and the public.

The Natural Experiments Network Background and Purpose

As noted above, the former NEXT-D study, Natural Experiments and Effectiveness Studies to Identify the Best Policy and System Level Practices to Prevent Diabetes and Its Complications, was a collection of five-year research projects that started in September 2010. These research projects were cooperative agreements jointly funded by the CDC and NIDDK under the FOA Number RFA-DP10-002. This previous initiative aimed “to understand how population-targeted policies affect preventive behaviors and diabetes outcomes, quantity and quality of care used, morbidity, costs, and unintended consequences.” The Natural Experiments Network will be a collaborative initiative with the shared vision for this partnership articulated in the CDC FOA (RFA-DP-15-001):

“Diabetes is one of the nation’s leading public health threats and a key target of public health interventions and health care reform because of the high prevalence, diverse comorbidities and extensive need for health services that follow. Despite improvements in clinical care and the rates of diabetes-related complications, there remains a considerable preventable burden of diabetes complications and continued increases in diabetes prevalence. Randomized controlled trials and observational cohorts have established a diverse evidence base for clinical and behavioral interventions, including lifestyle interventions, glycemic and cardiovascular disease risk factors control, and early screening to reduce diabetes and its complications. However, reducing the incidence of diabetes, and further reducing its complications, will depend upon population-targeted strategies, or health policies, to alter the health systems, communities, and behaviors in the population.

Policy-level innovations may come from private or public sectors and may work through health systems, business and community organizations, and through laws, ordinances, regulations, and enforcement. Policies are frequently aimed at expanding, changing, re-organizing services or increasing or redirecting resources to change health by affecting the health care people receive, the behaviors they engage in, or the social factors underlying their condition. For example, legislation at state and local levels frequently affect the coverage of services for diabetes care and prevention, incentives and availability of healthy foods and programs for physical activity and positive lifestyle changes. Similarly, large employers and health plans implement policies that affect the provision of preventive care, wellness programs, and the connection to community services. Policies outside the

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3 Available at http://www.cdc.gov/diabetes/programs/research/nextd.html
health sector, including changes to education, employment, and housing, may also have important effects on health status. Despite the diversity of innovative policies, there has been little rigorous empirical examination of such approaches.

Thus, the aim of [Natural Experiments Network] is to fund rigorous natural experiments of impact of population-targeted health policies and large scale interventions on risk and complications of diabetes, and reducing disparities in these risks and complications. Specific goals of the research program are to:

1) Test the health impact of naturally occurring health policies and interventions, including public health policies, clinical community partnerships, and health system-wide strategies; and
2) Improve the methods and research infrastructure for natural experiments in public health. Findings could be used to inform the prioritization of policies and interventions for policy-makers, health plan directors, and community leaders. "4

PCORI’s participation in the Natural Experiments Network will enhance the role of patient-centeredness and patient engagement in the assessment of these programs and contribute to meaningful practice change through comparative effectiveness research (CER).

II. Guidance for Proposing Research

The application must include a Research Justification that adheres to PCORI guidelines, an engagement plan, a staffing plan, and a budget. To provide evidence of a fully developed research plan, applicants will also submit to PCORI a copy of the full application that was submitted to the CDC, the summary statement from CDC in response to the application, and the score given by CDC. Please see the Research Justification Template and Application Guidelines for more detailed instructions on how to include these elements in the proposal.

Guidance on the Research Justification

The Research Justification must describe how the Research Plan submitted to the CDC:

- Meets the requirements of CER
- Adheres to the applicable PCORI Methodology Standards (See Adherence to Methodology Standards section)

The Research Justification must include additional information or modification as appropriate to the CDC research application in order to meet PCORI requirements (see below about comparative effectiveness studies and nonresponsive characteristics). The additional information should be provided for the purpose of complying with PCORI guidelines in instances in which the CDC application would otherwise be deemed noncompliant by PCORI. Applicants should not modify the CDC application. Instead, applicants should use the PCORI Research Justification Template to indicate appropriate but minimal modifications that would be made to the CDC application if the applicant were receiving funds from

PCORI. This justification should only call attention to areas of the application that address the PCORI methodology standards, inclusion of patient-centeredness, exclusion of cost effectiveness analysis (CEA), and/or respond to CDC reviewer requests for optimization of the proposal where applicable to PCORI.

Generally, comparative effectiveness studies should:

- Compare at least two alternative clinical/health system delivery interventions or approaches of proven efficacy
- Evaluate the benefit and harm of each intervention as delivered in typical clinical and community settings
- Ensure that the health outcomes studied have been established as meaningful to the patient population under study; in selected instances, surrogate physiological measurements may be sufficiently linked to final health outcomes of interest, but they may not be the sole study outcome

The CDC FOA RFA-DP-15-001 accepted applications for proposals for natural experiments from one of two tracks:

1. "Public policy approaches: involves legislative or other public approaches that could affect, whether beneficially or adversely, diabetes risk and health status in large segments of the community. This may involve changes to food availability, the built environment, or nutritional or physical activity practices of large communities that in turn, affect the diabetes risk of populations. This may also include reimbursement policies by CMS and Medicaid aimed at screening, behavioral change, or other aspects of diabetes risk. In some cases, the principal goal of the policy may be non-health related (e.g., education, urban planning, economic development)."

2. Health system-community partnerships: are formal partnerships between clinical settings and community organizations, including employers. For example, this may include health system policies to reimburse for services provided in communities, referral programs to community programs, and partnerships to change the health context of communities."

PCORI will accept applications to either track. However, all applications must be administratively and programmatically responsive to PCORI requirements as described in this PFA.

**Patient and Stakeholder Engagement**

PCORI encourages all applicants to describe clearly the 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 limited PCORI Funding Announcement: The Natural Experiments Network

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the Engagement Rubric\(^6\) to guide both applicants and merit reviewers. PCORI has also developed a Financial Compensation Framework\(^7\) for patients, caregivers, and patient/caregiver organizations engaged in PCORI-funded research as engaged research partners. The Financial Compensation Framework should guide applicants while developing engagement plans. Additionally, studies are expected to adhere to PCORI’s Methodology Standards Associated with Patient-Centeredness\(^8\) and to the PCOR Engagement Principles found within the rubric. These and additional resources are available in PCORI’s Funding Center.

Due to PCORI’s requirements related to patient-centeredness and patient engagement, which are key requirements for PCORI awards, applicants should:

1. Assess the CDC application and budget to identify areas where they may have already budgeted for such activities

2. Assess the CDC application to determine whether there is a need to supplement the activity in this area to meet PCORI standards, and adapt the application accordingly using the appropriate process:
   a. Assess the budget for activities that would render an application nonresponsive for PCORI (please see the Studies of Cost-Effectiveness and Categories of Non-Responsiveness sections)
   b. Determine the possibility of re-allocating existing funds
   c. Prepare an itemized budget to accompany the specified activities related to patient-centeredness and patient engagement

**Studies of Cost-Effectiveness**

Applications will be considered nonresponsive if the proposed research:

- Conducts a formal cost-effectiveness analysis in the form of dollar-cost per quality-adjusted life year to compare two or more alternatives
- Measures the relative costs of care of two or more alternative approaches

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

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

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• 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

PCORI is interested in studies that examine differentials in healthcare resources or costs as a determinant of—or barrier to—good outcomes. Examples include ways in which out-of-pocket costs may constitute barriers to care. Proposals that include studies of the aforementioned issues without using a formal cost-effectiveness analysis or comparing the costs of alternatives are considered responsive.

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,\(^9\) 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 of efficacy for a new clinical strategy
• Pharmacodynamics
• Study of the natural history of disease
• Fundamental science or study of biological mechanisms

Selection of the Principal Investigators

The Principal Investigator(s) (PI(s)) must be affiliated with the applicant CDRN. To be considered affiliated with the applicant CDRN, the PI must be employed by an organization funded by PCORI as part

\(^{9}\) Available at http://www.pcori.org/sites/default/files/PCORI_Authorizing_Legislation.pdf
of the CDRN under the PCORnet initiative either as a prime or subcontractor awardee. The sponsoring institution may be different from the sponsoring institution of the Phase II CDRN award, however, the sponsoring institution must be an official affiliate (such as a subcontractor), entity or partner of the Phase II CDRN to be eligible. Additional guidance for the PI(s) can be found in the Application Guidelines.

Features of Patient-Centered Outcomes Research

Patient-Centered Outcomes Research (PCOR) helps patients and their caregivers make informed healthcare decisions, allowing their voices to be heard in assessing the value of healthcare options. This research:

- Assesses the benefits and harms of preventive, diagnostic, therapeutic, palliative, or health-delivery-system features to inform decision-making, highlighting the choices that matter to individuals and patients, providers, and healthcare organizations
- Is inclusive of an individual's preferences, autonomy, and needs, focusing on outcomes that people notice and care about, such as survival, functioning, symptoms, and health-related quality of life
- Incorporates a wide variety of settings and diversity of participants to address individual differences and barriers to implementation and dissemination
- Directly compares clinical interventions that are generally available in settings where people access health care

Preliminary Data and Use of Accepted Measures

PCORI encourages investigators to design their research using validated patient-centered outcome (PCO) measures and to include preliminary data that support the proposed measures. Investigators are encouraged to consider those measures described in the Patient-Reported Outcomes Measurement Information System.10

Justification of Assumptions

PCORI specifically seeks studies that are sufficiently powered to detect clinically meaningful effects. To that end, applicants must justify the proposed sample sizes by explaining the assumptions used in all study power calculations. The application should clearly state all the necessary assumptions (i.e., the primary outcome measure, estimated difference in the mean value of this measure between study arms, standard deviation of the measure, type I error rate, and any other assumptions). All such estimates must be justified by referring to prior published research or preliminary data.

Adherence to Methodology Standards

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:

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10 Available at http://www.nihpromis.org/
• 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

Five other categories of standards will be applicable to particular study designs and methods and should be used for guidance when relevant. 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

These standards should be considered minimal standards. Additional best practices—including guidelines for the conduct of clinical trials developed by other organizations—should be addressed in the application.

Protection of Human Subjects

This component (up to five pages) is included in the Research Justification Template. Applicants are instructed to describe the protection of human subjects involved in their 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 the 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. PCORI does not require that applicants comply with sections of this policy that refer to requirements for federal-wide assurance or that refer to standards for inclusion of women, minorities, and children. PCORI does require applicants proposing clinical trials to consider including 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 program staff will examine plans for the protection of human subjects in all applications and may provide comments regarding the plans (see How to Evaluate Human Subjects Protections). PCORI staff may use these comments during any potential funding negotiations. Final determinations about adequacy of human subject protections rest with the Institutional Review Board (IRB) or IRBs that have jurisdiction for the study.

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

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11 Available at http://grants.nih.gov/grants/funding/424/supplementalinstructions.docx
12 Available at http://www.pcori.org/sites/default/files/PCORI-Checklist-for-Evaluating-Human-Subjects-Protections.pdf
Required Education of Key Personnel on the Protection of Human Subject Participants

PCORI requires all applicants to adhere to NIH policy on education in the protection of human subject participants in the conduct of research. This applies to all personnel listed in the application as key personnel. The policy and FAQs are available from the NIH website.13

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 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. The PCORI Board of Governors has 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.

Budget and Project Duration

The maximum budget for each study in this PFA is $2.25 million total costs. Up to $6.75 million in total costs will be awarded under this PFA for up to three awards. The maximum period of performance is five years. There will not be a consideration of exceptions to the budget and period of performance limits. If an applicant submits an application that exceeds the $2.25 million total cost cap or the five-year period of performance, your application will be removed for noncompliance.

13 Available at http://grants.nih.gov/grants/guide/notice-files/NOT-OD-08-054.html

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III. How To Submit a Proposal

Submission Dates
Applications must be submitted in accordance with the published dates and times listed in the overview of this PFA and in the PCORI Funding Center.

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

Applicant Resources
- PCORI Funding Center: http://www.pcori.org/2015-Natural-Experiments-Network
- PCORI Online System: https://pcori.fluxx.io
- PCORI Funding Awards: pcori.org/pfaawards

IV. Programmatic Screening

Preliminary screening of applications by PCORI program staff ensures that the application is responsive to PCORI’s programmatic requirements. It addresses the following questions:

- Is there a clear research plan with rigorous methods that adhere to PCORI’s Methodology Standards and prevailing accepted best practices?
- Is the study comparative in nature?
- Are the comparison interventions realistic options that exist in current practice?
- Does the study approach capitalize on the existing PCORnet data infrastructure to implement the study protocol?
- Does the study utilize multiple sites within the applicant CDRN?
- Based on the nonresponsiveness guidelines, is the application responsive to the PFA, including confirming the exclusion of cost-effectiveness analysis?
- Does the proposal describe a robust approach to testing and evaluating the data infrastructure and to implementing solutions as the project develops?

Applications that meet the programmatic screening requirements will go through the PCORI Merit Review process.

V. Merit Review

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

A single merit review panel recruited by PCORI Merit Review Officers (MROs) will review administratively and programmatically responsive applications. The review panel is composed of a chairperson, patient representatives trained in the review of scientific proposals, and representatives of other stakeholder groups.

The following are PCORI’s merit review criteria for this announcement. These two criteria are used by the review panel during the preliminary and in-person phases to score and evaluate all submitted applications.

**Criterion 1. Patient-centeredness**

The proposal demonstrates patient-centeredness at every stage of the research. It addresses the following 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 2. 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 following questions:

- Are patients and other stakeholders (including professional and patient organizations) 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?
Does the study include a description of how the CDRN is working with its health systems leaders or health plan collaborators around diabetes care?

Panel Discussion

After the preliminary review is complete, reviewers meet in-person for a panel discussion and further review. During the panel discussion, panelists further clarify the merits of the proposed research and identify areas for improvement. Additionally, applications are rescored based on the discussion. The chair and a 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.

VI. Post-Panel Review

After the panel discussion, PCORI program staff review meritorious applications’ merit review scores and comments and consider the fit of applications within the programmatic vision. PCORI program staff will take into account the technical review scores of the Research Plan from CDC reviewers in response to the CDC funding announcement. Up to three applications will then be recommended to a selection committee that includes members of PCORI’s Board of Governors. The selection committee will discuss this recommendation and work with staff to make a recommendation about funding to PCORI’s Board of Governors based on merit review scores, programmatic balance and fit, and PCORI’s strategic priorities. In this case, a slate of no more than three studies will be proposed to PCORI’s Board of Governors for its consideration and final 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 what slate of 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 January/February 2016.

Contract Execution and Activation

PCORI will issue a contract to each selected awardee institution for the award once it conducts a thorough programmatic and administrative review and the awardee accepts 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. The study will commence only after PCORI and the awardee institution execute the applicable contract.