Patient-Centered Outcomes Research Institute

PCORI Funding Announcement

Pilot Projects Grants

Revision date: 9/30/2011

PFA No: PI-12-001

I. Program Overview

PCORI Pilot Projects

Following is an overview of the PCORI Pilot Projects Grant Program. Please refer to the remainder of the PCORI Funding Announcement (PFA) for full details.

Purpose

The purpose of the PCORI Pilot Projects Grant Program is threefold. First, the applications themselves will assist PCORI with ongoing development and enhancement of national research priorities for patient-centered outcomes research. Applicants will be expected to establish the significance of the proposed research and build a case for why it should be considered a guiding question for PCORI.

Second, the PCORI Pilot Projects Grant Program will support the collection of preliminary data that can be used to advance the field of patient-centered outcomes research, providing the platform for a future PCORI research agenda.

Third, the PCORI Pilot Projects Grant Program will support the identification of methodologies that can be used to advance patient-centered outcomes research as well as identify gaps where methodological research needs further development.

Eligibility

Eligible applicants include but are not limited to higher education institutes, nonprofit, public and commercial organizations, and tribal governments with no restrictions as to geographic location within the United States. (For a more specific list of eligible applicants see Section IV, Eligibility Information.) Collaborative efforts are expected. In particular, applicants without prior research experience are encouraged to partner with researchers who have the relevant experience. Similarly, experienced researchers are expected to include PCORI stakeholders (as defined below in Section IV, Eligibility Information) as members of the study team. Applications from applicants based outside the United States will be considered provided that the investigators are able to demonstrate a benefit to the US health care system and US efforts in the area of patient-centered research.

Total Awards

PCORI intends to commit up to $13 million under this program during the first year in support of approximately 40 awards. Funding may be requested for up to $250,000 in direct costs per year for up to two years, with justification. (See Section III, Award Information for more details.)

Deadlines

Letters of Intent are required and must be received on or before November 1, 2011. Grant applications must be received on or before December 1, 2011. (See Section V, Application and Submission Information for more details.)

How to Apply

Letters of Intent and full applications must be submitted in hard copy via US. mail or private mail service. (See Section V, Application and Submission Information for more details.)

Title and Number

The title of this PFA is “PCORI Pilot Projects”. The reference number is PI-12-001.

Contents

II. Funding Opportunity Description

PCORI Background

PCORI was created by the Patient Protection and Affordable Care Act of 2010 as a non-profit, non-governmental organization. PCORI's purpose, as defined by the law, 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."

The statutory language defining PCORI is broad and authorizes research that will support a strong patient-centered orientation, inform better choices among alternative treatment and prevention strategies, and direct attention to individual and system differences that may influence strategies and outcomes. PCORI was designed to produce knowledge through the analysis and synthesis of existing research or the support of new research.

Patient-Centered Outcomes Research (Working Definition)

PCORI is continuing to consider stakeholder input and to develop the definition of Patient-Centered Outcomes Research (PCOR). Below is the current working definition and will apply to this PFA. To remain informed about the latest definition, go to www.pcori.org.

PCOR helps people make informed health care decisions and allows their voice to be heard in assessing the value of health care options. This research answers these patient-focused questions:

1. "Given my personal characteristics, conditions and preferences, what should I expect will happen to me?"
2. "What are my options and what are the benefits and harms of those options?"
3. "What can I do to improve the outcomes that are most important to me?"
4. "How can the health care system improve my chances of achieving the outcomes I prefer?"

To answer these questions, PCOR:

- Assesses the benefits and harms of preventive, diagnostic, therapeutic, or health delivery system interventions to inform decision making, highlighting comparisons and outcomes that matter to people;
- Includes an individual's preferences, autonomy, and needs, focusing on outcomes that people notice and care about such as survival, function, 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; and
- Investigates (or may investigate) optimizing outcomes while addressing burden to individuals, resources, and other stakeholder perspectives.

PCORI Mission

PCORI helps people make informed health care decisions and improves health care delivery and outcomes by producing and promoting high integrity, evidence-based information that comes from research guided by patients, caregivers, and the broader health care community.

PCORI Activities

PCORI is developing National Priorities for PCOR that will incorporate PCORI's evolving mission statement, definition of PCOR, and PCORI strategies. The National Priorities will be published as an initial priority set, open for public comment, and are likely to evolve over time.

PCORI will also develop a Research Agenda, which will derive from the National Priorities, and will be published after publication of the National Priorities, as the core research program for PCORI. The Research Agenda will be open for public comment, and will evolve over time.

Supporting Programs

In parallel with the development of the National Priorities and the Research Agenda, supporting programs and projects will:

- Provide a planning function to optimize infrastructural and organizational needs in the development of the National Priorities and Research Agenda, or
- Inform the National Priorities and Research Agenda through stakeholder engagement.

The supporting programs include:

- A set of landscape reviews that will populate the PCORI Library with key information that will aid in the development and optimization of the National Priorities and the Research Agenda;
- Small, competitive, innovative grants focused on discrete planning and research process problems;
- PCORI Pilot Project grants designed to inform the National Priorities and Research Agenda via initial application, progress reports, and results; and
- Conference Grants, which are aimed at developing white paper solutions to discrete problems.

PCORI Pilot Projects Research Objectives

The focus of this funding initiative is PCORI Pilot Projects. The purpose of this PCORI Program is threefold:

- First, the applications themselves will inform PCORI with ongoing development and enhancement of national research priorities for patient-centered outcomes research. Such input will be limited to an assessment of the general types of research proposed. No specific information from unfunded applications will be used or shared by PCORI.
- Second, PCORI Pilot Projects will support the collection of preliminary data that can be used to advance the field of patient-centered outcomes research, providing the platform for a future PCORI research agenda.

- Third, the Pilot Projects will support the identification of methodologies that can be used to advance patient-centered outcomes research as well as identify gaps where methodological research needs further development.

Areas of Interest

For the purposes of this PFA, PCORI is not interested in CER studies aimed at determining comparative efficacy for specific diseases or conditions. Rather, PCORI is interested in the development of research methods, patient-oriented outcomes instruments, patient-provider communication and other decision-making strategies, building collaborative research teams, translating research findings into clinical practice, stakeholder engagement, and research agenda setting strategies that can be used in future comparative effectiveness research.

Eligible projects under this PFA must address one or more of the following PCORI areas of interest:

- Developing, testing, refining, and/or evaluating new or existing methods (qualitative and quantitative) and approaches that can inform the process of establishing and updating national priorities for the conduct of patient-centered outcomes research (PCOR). This may include research prioritization approaches (such as Value of Information (VOI), burden of illness, peer review/expert opinion/Delphi approaches) or methods for incorporating the perspectives of patients or other stakeholders into the development of national priorities.
- Developing, testing, and/or refining existing methods for bringing together patients, caregivers, and clinicians, including stakeholders in all stages of a multi-stakeholder research process, from the generation and prioritization of research questions to the conduct and analysis of a study to dissemination of study results – including methods for training participants in participatory research and the potential use of new technologies to facilitate engagement.
- Developing, refining, testing, and/or evaluating patient-centered approaches, including decision-support tools, for translating evidence-based care into health care practice in ways that account for individual patient preferences for various outcomes. This may include developing or comparing conceptual models of translation or dissemination of CER research findings from the patient perspective.
- Developing, refining, testing, and/or evaluating methods to identify gaps in CE knowledge such as tools for the ongoing collection and assessment of gaps as perceived by patients and providers. Of special interest are gaps that are particularly relevant to vulnerable populations, including but not limited to, low-income populations; underserved minorities; children; the elderly; women; and people with disabilities, chronic, rare, and/or multiple medical conditions.
- Identifying, testing, and/or evaluating patient-centered outcomes instruments. This may include predictive tools (eg: instruments that measure or predict outcomes of interest to patients) or identifying standards for measurement properties of patient-reported outcomes for use in comparative effectiveness research, across a variety of interventions and patient populations.
- Identifying, testing, and/or evaluating methods that can be used to assess the patient perspective when researching behaviors, lifestyles, and choices within the patient's control that may influence their outcomes.

- Identifying, testing, refining and/or evaluating methods for studying the patient care team interaction in situations where multiple options for wellness, prevention, diagnosis or treatment exist. Of special interest are strategies that respect patient autonomy and promote informed decision-making, incorporating the best health care knowledge into the application of care.
- Advancing analytical methods for CER. Examples include but are not limited to the incorporation of mixed methods research designs (qualitative/quantitative), identifying existing methodology to statistically accommodate irregularly spaced multivariate longitudinal data, the use of instrumental variables; and potential solutions for assessing treatment heterogeneity in observational and randomized CER studies.

Research Methodologies

- Research should focus on various methods and approaches appropriate to PCOR, including observational methodologies, systematic reviews, mixed methods, and qualitative methodologies, simulations, small pragmatic pilot trials, and survey methods.
- As outlined above, applications responsive to this PCORI Funding Announcement (PFA) must have a primary focus on developing, testing, refining or evaluating approaches, not on specific interventions or specific medical/health conditions.

III. Award Information

Type of Award: Grants

Funds Available: PCORI will commit up to $13 million in 2012.

Expected Number of Awards: Approximately 40

Maximum Period of Support: The maximum period of support is two years. Second year funding is not guaranteed. Funds beyond the first year must be well justified in the application and are contingent upon PCORI programmatic review to determine successful completion of the first-year research goals.

Initial Budget Period: The initial budget period is one year. If an applicant requests two years of funding, the application must include two budgets, the first for the initial budget period and a second for year two.

Funding Cap: The maximum amount of direct costs is $250,000 per year plus indirect costs. (For more information see Budget Requirements in Section V. Application and Submission Information below.)

Cost Sharing: None required

IV. Eligibility Information

Eligible Applicants

The following types of organizations are eligible to apply:

Higher Education Institutions:

- Public/State-Funded Institutions of Higher Education
- Private Institutions of Higher Education

Nonprofits Other Than Institutions of Higher Education

- Nonprofits with 501(c)(3) IRS Status (Other than Institutions of Higher Education)
- Nonprofits without 501(c)(3) IRS Status (Other than Institutions of Higher Education)

For-Profit Organizations

- Small Businesses
- For-Profit Organizations (Other than Small Businesses)

Governments

- State Governments
- County Governments
- City or Township Governments
- Special District Governments
- Indian/Native American Tribal Governments (Federally Recognized)
- Indian/Native American Tribal Governments (Other than Federally Recognized)
- Eligible Agencies of the Federal Government
- U.S. Territory or Possession
- Independent School Districts

Other

- Public Housing Authorities/Indian Housing Authorities
- Native American Tribal organizations (Other than Tribal Governments)
- Faith-based or Community-based Organizations
- Regional Organizations
- Non-Domestic (non-U.S.) Entities (Foreign Organizations) (Provided that the benefit to the US health care system and US efforts in the area of patient-centered research is justified)
- Foreign (non-U.S.) components of U.S. Organizations (Provided that the benefit to the US health care system and US efforts in the area of patient-centered research is justified)

Number of Applications

Investigators may be named as Principal Investigator (PI) in only one application submitted in response to this PFA. An organization may submit multiple applications provided they are scientifically distinct. However, an individual may be a PI on only one application. An individual who is a PI may participate in

other applications (from the same or different organization) in a different role (co-investigator, consultant, etc.).

Stakeholder Involvement

Stakeholder involvement is required unless the applicant sufficiently explains why such an arrangement is not feasible (for example, when advancing some types of analytical methods). Stakeholders may include but are not limited to one or more of the following: caregivers, health care providers, patients or patient-advocacy groups, community groups, and relevant professional associations. Unless the applicant can demonstrate why stakeholder involvement is not feasible, stakeholders must be included as co-investigators, with significant involvement at all appropriate stages of the project. The extent to which applicants demonstrate that stakeholder involvement was included in the preparation of the application will also be evaluated.

Technical Requirements

To be eligible for initial consideration under this PFA, applicants must:

- Be eligible as defined above including being an eligible applicant, receipt of only one application for each PI, and meeting stakeholder involvement requirements,
- Be responsive to at least one of the PCORI areas of interest as outlined in Section II, Funding Opportunity Announcement,
- Abide by the page limit, font, and formatting requirements in the PCORI Grant Application,
- Submit a timely and complete letter of intent,
- Submit the required number of copies of the completed application to PCORI by the receipt deadline, and
- Use PCORI forms and formats, as described within this PFA and the PCORI Grant Application Instructions.

Because of the volume of applications expected under this PFA, PCORI will be unable to send any application forward for review and further consideration that does not meet these technical requirements.

V. Application and Submission Information

Receiving Application Packages

Full applications packages, including required forms can be accessed at pcori.org.

Content and Format

Letters of Intent

A Letter of Intent is required to be eligible to submit an application under this PFA. The letter must be no longer than two pages, use 11 point Arial font with one-inch margins, and include:

a. Descriptive title of proposed research

b. Legal name of the applicant organization

c. Name, institutional affiliation address, E-mail address and telephone number of the PI

d. Names and institutional affiliation of other key personnel and significant contributors

e. Participating institutions and organizations

f. A brief summary of the proposed research questions and methods

g. A paragraph describing the significance of the research project relative to the stated goals of this PFA

h. Identify the area of interest(s) the proposed project will address

i. Contact information for the appropriate person for PCORI to contact about the application

Application

Application Forms and Structure. Applicants must follow the instructions within the PCORI Grant Application to complete all required forms and narrative requirements. The Grant Application includes:

- Signed Face Page
- Table of Contents
- Project Summary, Relevance to PCORI Objectives
- Project/Performance Site(s),
- Key Personnel and Other Significant Contributors
- Budget and Justification
- Resources
- Biographical Sketches–Principal Investigator, Other Biographical Sketches
- Checklist
- PCORI Pilot Projects-Specific Addendum: Areas of Interest
- Research Plan*, which includes:
  - Specific Aims (one-page maximum)
  - Research Strategy (ten-page maximum)
  - References Cited
  - Protection of Human Subjects
  - Consortium/Contractual Arrangements
  - Letters of Support
  - Resource Sharing Plan(s)

Note: No additional attachments are allowed.

*See the PCORI Grant Application for all page limits and formatting instructions, which must be followed to be considered for funding under this PFA.

Content Guidance. In completing the PCORI Grant Application, applicants must:

- Demonstrate the significance of the proposed research and build a case for why it should be considered as a project that will contribute to PCORI's mission.
- Show how the proposed work is novel and has the potential to be of high impact, either immediately or by increasing the impact of future research.
- Explain how the proposed research project may contribute to enhanced patient outcomes.
- Demonstrate how the project represents a genuine collaboration between stakeholder groups that may include patients, caregivers, clinicians, and conventionally trained scientists.
- Show the scientific rigor of the proposed study design and analytical methods.
- Provide clarity on their project goals and goal benchmarks.
- Document that the experience and training of the investigative team is sufficient to complete the study.
- Justify the appropriateness of the timeline and budget, including clear justification where the proposed project period is more than one year.
- Meet all Human Subjects requirements as outlined within this PFA and in the PCORI Grant Application Instructions.

Budget Requirements

- Acceptable uses of PCORI grant funds include salaries and fringe benefits (up to 35% of salary costs) for study investigators and other project staff, consultant fees, costs associated with collection and analysis of data (including costs associated with obtaining relevant datasets), investigator meetings both in person and via teleconference, supplies, travel that is clearly project related, and other direct research expenses. Small equipment purchases (under $1000) such as computers may be allowed provided there is adequate justification.
- PCORI will not issue a Notice of Grant Award (NGA) prior to IRB approval for those applicants proposing research involving human subjects. Costs associated with IRB review of human research protocols can be included as a direct cost. Such costs are approved as pre-award costs, but payment of those costs is subject to final approval and issuance of an NGA. If an NGA is not issued, for any reason, the costs for IRB review must be borne by the applicant.
- Indirect costs are limited to 40% of the direct costs for salary and fringe for the recipient and all partners receiving PCORI funds.
- PCORI will cap salary reimbursement for any individual at $200,000 per year (included compensated absences such as vacation or sick leave) or the percentage of that amount based on the percentage of time allocated to the project) plus fringe benefits.
- Applicants must budget for travel to the DC area for two nights including transportation, lodging, and reasonable expenses to attend a PCORI Investigators Meeting in May, 2013.

Submission Requirements

Letters of Intent

Prospective applicants must submit a Letter of Intent to be eligible for further consideration. Letters will be submitted via US mail or private mail service and must be received by 5 pm EST on November 1, 2011. Electronic Submission via either fax or email is not acceptable. Letters of Intent must be sent to:

Patient-Centered Outcomes Research Institute (PCORI)
ATTN: PCORI Pilot Projects Grant Letter of Intent
1701 Pennsylvania Ave. NW – Suite 300
Washington, DC 20006

Applications

Applicants must submit applications in hard copy via US mail or private mail service and received by 5 pm EST on December 1, 2011. Late applications will not be considered. Electronic Submission via either fax or email is not acceptable. Applications must be sent to the location below by the deadline.

A signed, single-sided hard copy original of the application and three signed, single-sided photocopies should be sent in one package to:

Patient-Centered Outcomes Research Institute (PCORI)
ATTN: PCORI Pilot Projects Grant Applications
1701 Pennsylvania Ave. NW – Suite 300
Washington, DC 20006

Assistance with Applications and Applicant Webinar

Questions and Assistance

It is the policy of PCORI to assist applicants with their inquiries during the application process. Upon answering the question, the answer will be shared on the PCORI website for the benefit of all prospective applicants. PCORI will post generalized answers while maintaining the confidentiality of the potential applicant and any specifics about their proposed research.

Applicant Webinar

PCORI will hold at least one webinar for applicants, the first of which is planned for October 18, 2011. Please go to pcori.org prior to the Webinar to ensure that you have the latest details.

- Registration. The webinar(s) will require registration in advance and will each be limited to 200 participants. Please check pcori.org for information.
- Questions. During the webinar, there will be an opportunity for live Q&A. If you wish to submit questions in advance, PCORI will allow each applicant to submit up to two questions to be answered during the webinar or in an accompanying FAQ document. To submit questions, send them to PFA12001@pcori.org no later than 3PM EST on October 15.
- Playback. Following the call, an audio file of the webinar audio content and accompanying slides will be available for download at pcori.org.

VI. Application Review Information

Review Process and Criteria

The PCORI review process includes four stages:

Stage One: Completeness, Compliance and Eligibility Check

Process. This occurs immediately following submission of the grant application and involves a detailed examination by PCORI staff members to ensure that the applications meet PCORI requirements. This process includes a check against the administrative requirements found in Section IV such as page limitations, format requirements, deadlines, etc. It also includes an analysis of the application against the programmatic requirements outlined in Section II of this PFA. Applicationsthatdonotmeetthese criteriawillnotbeforwardedforreview. Organizations excluded during this stage will be notified that their applications were declined.

Criteria. This review will ensure that applications meet the responsiveness requirements. Applications that fail to meet the administrative requirements found in Section IV will not be forwarded for further review. This review will further ensure that the proposed research falls within the programmatic priorities of PCORI as explained established in Section II.

Stage Two: Merit Review

Process. The second stage of review involves rigorous merit review by a team of scientists and other stakeholders and is managed by the National Institutes of Health (NIH) Center for Scientific Review (CSR). An NIH Scientific Review Officer (SRO) will work with the Agency for Healthcare Research and Quality (AHRQ), the PCORI Board of Governors (BOG), and the PCORI Methodology Committee to develop a list of potential reviewers. Final signoff on the pool of potential reviewers will be the responsibility of the PCORI Board of Governors.

The SRO will then assign each application to approximately three reviewers with appropriate expertise for critique preparation. Reviewers will read their assigned applications, prepare a written critique based upon PCORI's selection criteria below, and recommend a preliminary priority score from 1 to 9 that aligns with the critique.

The review group will then meet in person to discuss the applications. At this meeting, applications are presented by the assigned reviewers. Applications scored in the top 50th percentile based on the averaging of the preliminary overall scores assigned by the three reviewers will be discussed by the entire group. Reviewers have the right to request that a specific application of interest scored within the lower half is also discussed at the meeting. Assigned reviewers will summarize their prepared critiques for the group and a general discussion will follow. Final scoring of overall impact/priority scores will be conducted by private ballot by the entire panel.

The SRO will then summarize the discussion in writing and prepare a summary statement that includes a summary of discussion, the written critiques prepared by the assigned reviewers, and the final overall priority score assigned by the entire review committee. The results from all reviewed applications will then be forwarded to PCORI staff to continue the review process, as outline below.

Criteria. Reviewers will consider the following criteria in determining priority scores:

- Significance. Does the project address an important problem or a critical barrier to patient-centered outcomes research? Does the project address one of the key questions outlined in the PCOR definition described in Section II, Funding Opportunity Description? Is the project focused on one of the areas of interest identified in Section II? Will the results produce new knowledge that can advance PCOR methods or infrastructure? Does the investigator demonstrate thorough knowledge of previous and ongoing work related to their proposed topic?
- Patient/Stakeholder Engagement. Will the research make a unique contribution to learning about engagement of patients and stakeholders (as defined in Section II under Stakeholder Involvement) in PCOR efforts? Does the research team demonstrate authentic, feasible, sustainable, novel partnerships with patients, families and caregivers, providers, and other appropriate stakeholders? Is there evidence that stakeholders were involved in the preparation of the research proposal?
- Investigator(s). Is the research team well suited to the project? Are multiple stakeholders and perspectives involved? Is there appropriate scientific expertise? Does at least one member of the study team have experience in patient and other stakeholder engagement? Is there a high level of confidence that the Principle Investigator and rest of the study team will be able to achieve the study aims as described? Does the study team have complementary and integrated expertise; are their leadership approach, governance, and organizational structure appropriate for the project?
- Innovation. Does the project either address a new method or approach or apply a proven method or approach in a novel way to the field of PCOR? Is a refinement, improvement, or new application of theoretical concepts, approaches or methodologies, instrumentation, or interventions proposed?
- Approach. Are the overall strategy, methodology, and analyses well-reasoned and appropriate to accomplish the specific aims of the project? Are potential problems, alternative strategies, and benchmarks for success presented? Will the strategy establish feasibility and will particularly risky aspects be managed? Is the proposed budget and timeframe appropriate for the research plan? Are there appropriate plans for dissemination among key PCOR stakeholders in education, practice, and policy?
- Environment. Will the environment in which the work will be done contribute to the probability of success? Are the institutional support, equipment, and other physical resources available to the investigators adequate for the project proposed? Will the project benefit from unique features of the research environment, community involvement, patient populations, or stakeholder collaborative arrangements?

Stage Three: PCORI Deliberations

Process. Stage three of the process includes a review by the PCORI Board of Governors to select projects for funding.

Criteria. In making funding recommendations and decisions, the PCORI Board of Governors will consider the merit review scores and will seek to achieve an appropriate balance of projects based on considerations including but not limited to the areas of interest and target population. Final funding decisions will be made by a vote of the Board of Governors.

Stage Four: Business Review

Process. Stage four of the process involves PCORI staff review of recommended applications for fiscal compliance with PCORI grants policies and procedures. These include adherence to IRB and other Human Subjects policies, budget, and budget justification requirements, etc. At this stage, PCORI reserves the right to negotiate on specific areas of the application and to request additional information needed to clarify questions or to establish financial management capability. Final funding decisions are based on the successful outcome of the Business Review and negotiations. Final funding decisions will be made following this step.

Criteria. During this review, PCORI staff will consider:

- Budget reasonableness, allowability, and necessity;
- The applicant organization's financial management capabilities; and
- Compliance with Human Subjects policies. Grantees must provide a certification to PCORI that the research application has been approved by an appropriate IRB, consistent with 45 CFR part 46 (which has been adopted by PCORI) prior to award. IRB approval must have been granted within 12 months before the budget period start date to be valid. Certification of IRB approval may be filed at any time before award.

Award Notifications

It is anticipated that award announcements will be made in May, 2012. Notices of Grant Award will be issued following any negotiations and completion of other requirements. For those awards based on a two-year request, only the first year of expenses will be obligated. Grantees will need to complete the reporting requirements and provide any information needed to approve second-year funding eight weeks prior to the end of the initial grant year, or as instructed by PCORI.

VII. Grant Administration Requirements

Following is an overview of the requirements that grantees will be expected to meet following award. Full post-award administration requirements will be included in the terms and conditions of the award and the PCORI Grants Policy Statement will be available at www.pcori.org prior to December 1, 2011. PCORI's goal is to manage funded projects through a streamlined process that limits administrative burdens on the grantees while ensuring proper oversight.

Reporting Requirements

Financial Reports

It is expected that grantees will be required to submit quarterly financial reports similar to those required by the Department of Health and Human Services.

Research Interim Reports

Grantees will be required to submit an interim progress report every six months until a final research report is due. For example, a one-year project would submit a single progress report six months after the award date and then a Research Final Report as described below. The format and due dates for progress reports will be included within the terms and conditions of award.

Noncompeting Second-Year Information

For those applicants who request a two-year project under this RFA, grantees are required to submit deliverables established in the recipient's project plan and other information needed to make a second-year funding decision. PCORI will provide additional information regarding this requirement within the terms and conditions of award.

Research Final Reports

Final reports are due 90 days following the end of the project period. They must include:

- A scientific report that includes:
  - A summary of the study methods, key findings, and interpretations of the relevance of findings to patients and clinicians.
  - Specific discussion of any possible differences in study findings or conclusions among patient subgroups defined by age, gender, race/ethnicity, socio-economic, clinical, or genetic makeup (if studied).
  - A discussion of the limitations of study findings in terms of statistical precision, failure to include or study patient subgroups, and possible mismeasurement of key variables.
- A narrative summary of the report that is written to be understandable by a lay reader, covering the same elements, written in language understandable to patients and providers

Monitoring

Grantees will be assigned both a grant manager and a program officer who will be responsible for receipt of reports, answering inquiries, and remaining informed about the progress of the project. Additionally, because the research funded will inform PCORI National Priorities, grantees will be requested to share actively their insights, issues, or other information relevant to shaping these priorities during an investigator conference.

Investigator Conference

Grantees will be required to attend a meeting of all awardees, to be held in the Washington DC area during the last quarter of the initial year of funding. Travel, lodging, and reasonable expenses are to be budgeted within the grant application. The purpose of the conference is to bring PCORI-funded investigators together to present preliminary findings and to make recommendations regarding PCORI's National Priorities and Research Agenda.

Research Requirements

Human Subjects

For the purposes of this PFA and all grants funded under it, PCORI has adopted, by reference, the Human Subjects requirements of 45 CFR Part 46. For additional information see the PCORI Grant Application.

Publishing

It is PCORI policy that the results and accomplishments of the activities that it funds should be made available to the public. PIs and grantee organizations are expected to make the results and accomplishments of their activities available to the research community and to the public at large through presentation at meetings and publication in scientific and lay journals. Grantees own the rights in data and all research resulting from a grant-supported project. Grantees may be asked to prepare a summary of the research and allow its use on the PCORI website and in PCORI materials. Additionally, grantees will be required to inform PCORI when research has been accepted for publication by a journal, provide a draft advance copy, and submit the final published paper for PCORI's files and internal use to guide the continuing development of National Priorities.

For each publication that results from PCORI grant-supported research, grantees must include an acknowledgment of PCORI grant support and a disclaimer stating the following:

"This publication (or research) was made possible by Grant Number_____from PCORI" or "The project described was supported by Grant Number_____from PCORI" and "Its contents are solely the responsibility of the authors and do not necessarily represent the official views of the Patient-Centered Outcomes Research Institute.]"

If the grantee plans to issue a press release concerning the outcome of PCORI grant-supported research, it must notify PCORI in advance to allow for coordination.

Access to Funds

Generally, payments will be made to grantees on a reimbursement basis. In rare circumstances where appropriate justification is provided and accepted by PCORI, a partial advance payment may be made. Following notification of award, PCORI will work with grantees to complete the information needed to facilitate payments.

VIII. PCORI Contacts

You may reach PCORI for questions or additional information at PFA12001@pcori.org or through the PCORI questions line at (202) 683-6690 x110.