



Winter 2015 Funding Cycle

Limited PCORI Funding Announcement: Optimal Maintenance Aspirin Dose for Patients with Coronary Artery Disease

Published October 27, 2014
Last Revised January 22, 2015

This limited PCORI Funding Announcement (PFA) applies to the Winter 2015 funding cycle that closes February 13, 2015, at 5:00 pm (ET). Application guidelines, templates, and other resources are available at <http://www.pcori.org/winter-2015-aspirin/>.



About PCORI

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

PCORI was authorized by the Patient Protection and Affordable Care Act of 2010 as a nonprofit, nongovernmental organization. PCORI's purpose, as defined by the 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."

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](https://twitter.com/PCORI)



Overview

Published	October 27, 2014										
Summary	<p>The goal of PCORI's National Patient-Centered Clinical Research Network (PCORnet) is to create a large, highly representative, national network for conducting comparative effectiveness research (CER). Concomitant with PCORnet Phase I, PCORI is launching a demonstration to support the first randomized CER trial within PCORnet. PCORI intends to fund a clinical trial that will test PCORnet's data infrastructure using efficient recruitment strategies embedded within the clinical care setting to ensure broad representation from the patient community. The trial is expected to use the network's ability to capture relevant patient-centered outcomes from real-world clinical settings; optimize cross-network data collection; build management and analysis strategies; identify a suitable dissemination plan; and engage patients, clinicians, and health system leaders throughout the research process. The trial will investigate the optimal maintenance dose of aspirin for patients with coronary artery disease (CAD).</p>										
Applicant Resources	See http://www.pcori.org/winter-2015-aspirin										
Key Dates	<table><tr><td>Online System Opens:</td><td>October 27, 2014</td></tr><tr><td>Application Deadline:</td><td>February 13, 2015, by 5:00 pm (ET)</td></tr><tr><td>Merit Review:</td><td>March 20, 2015</td></tr><tr><td>Awards Announced:</td><td>TBD</td></tr><tr><td>Earliest Project Start Date:</td><td>TBD</td></tr></table>	Online System Opens:	October 27, 2014	Application Deadline:	February 13, 2015, by 5:00 pm (ET)	Merit Review:	March 20, 2015	Awards Announced:	TBD	Earliest Project Start Date:	TBD
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Application Deadline:	February 13, 2015, by 5:00 pm (ET)										
Merit Review:	March 20, 2015										
Awards Announced:	TBD										
Earliest Project Start Date:	TBD										
Total Direct Costs	\$10 million										
Maximum Project Period	Three years										
Eligibility	<p>Applications may be submitted by clinical data research networks (CDRNs) and patient-powered research networks (PPRNs) that are currently funded by PCORI, and the PCORnet Coordinating Center only. The Internal Revenue Service must recognize all US applicant organizations. Investigators from CDRNs and PPRNs are expected to collaborate on the development of the research plan and submit one cohesive proposal to PCORI. Included in the development of this plan should be other members of the PCORnet community, patients with coronary artery disease, and outside experts, including platelet/aspirin experts, trialists, and biostatisticians, as needed. Collaboration with other CDRNs and PPRNs participating in the network is strongly encouraged. PCORI will make one award under this PFA. The awardee institution will assume responsibility for the trial, including oversight and dispersion of funds to any and all necessary subcontracts.</p>										



Review Criteria	<ol style="list-style-type: none">1. Technical merit2. Patient-centeredness3. Patient and stakeholder engagement
Contact Us	<p>For programmatic questions, please email (pfa@pcori.org), phone (202-627-1884), or contact us online (http://www.pcori.org/PFA/inquiry). PCORI will provide a response within three business days. However, PCORI cannot guarantee that all questions will be addressed three business days prior to an application deadline.</p> <p>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) prior to 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.</p>
Other	<p>Deadlines are at 5:00 pm (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.</p>

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Contents

I. Introduction	1
Summary of Program	1
Topic Selection	1
Research Characteristics and Objectives	1
PCORnet Capacity Building	2
Evidence to Action Networks	3
II. Guidance for Proposing Research	3
Research Priorities	3
Non-responsiveness	4
Features of Patient-Centered Outcomes Research (PCOR)	4
Preliminary Data and Use of Accepted Measures	5
Justification of Assumptions	5
Adherence to Methodology Standards	5
Patient and Stakeholder Engagement	6
Populations Studied	6
Protection of Human Subjects	7
Replication and Reproducibility of Research and Data Sharing Plan	7
Budget and Project Duration	7
III. How to Submit a Proposal	7
Submission Dates	7
PCORI Online System	7
Applicant Resources	7
IV. Merit Review	8
Preliminary Review	8
Panel Discussion	10
Post-Panel Review	10
Funding Recommendations	10
Protocol Refinement	10
Contract Execution and Activation	11

I. Introduction

Summary of Program

The goal of PCORnet is to create a large, highly representative, national network for conducting clinical CER. This network will improve the nation's capacity to conduct CER efficiently and will learn from the healthcare experiences of millions of Americans by embedding research within the clinical care setting.

The long-term vision is for PCORnet to provide 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 (EHRs) and claims data, as well as other patient-generated data sources. Phase 1 began in early 2014 as an 18-month investment for initial infrastructure development. By the end of Phase 1 it is envisioned that PCORnet will be a collaborative community that ensures the engagement of all stakeholders, facilitates sharing of analysis-ready standardized data with strong privacy protections, and supports timely research that is trusted by the larger research community and the public. To this end, PCORI intends to pursue this limited opportunity to fund the first randomized comparative effectiveness trial using PCORnet. This trial not only will address an important patient-centered question but also will inform future research studies about key operational and collaborative strategies that can maximize efficiencies when conducting research within PCORnet.

Topic Selection

Trial topics were solicited through a March 2014 Request for Topics from the PCORnet networks. The criteria were operational simplicity, use of electronic health systems, inclusion of multiple research networks, and general feasibility within PCORnet. Topic briefs were submitted by investigators from CDRNs and PPRNs, and used as background information during the prioritization exercise. The briefs can be found on PCORI's website. Topics were prioritized and ranked by CDRN and PPRN Principal Investigators (PIs) and a standing PCORI Advisory Panel—the Assessment of Prevention, Diagnosis, and Treatment Options Advisory Panel. For both groups, the top-ranking topic was “Optimal Maintenance Aspirin Dose for Patients with Coronary Artery Disease.” On July 29, 2014, PCORI's Board of Governors approved this topic for the first clinical trial to be funded by PCORI using PCORnet.

Research Characteristics and Objectives

This trial should have the following characteristics:

- Studies benefits and harms of the intervention as delivered in typical clinical and community settings
- Compares at least two alternative clinical approaches
- Compares health outcomes that are meaningful to the patient population under study (e.g., morbidity, mortality, symptoms, functional status, quality of life); 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
- Uses network datasets for recruitment and collection of outcomes to test the ability of PCORnet to advance clinical comparative effectiveness research

PCORI has several primary objectives in this solicitation:

1. To demonstrate PCORnet's capability to advance rapid and efficient research, an early Phase I opportunity
2. To identify key operational, logistical, and collaborative approaches that will inform future research studies on how to maximize efficiencies using PCORnet resources
3. To support research on an important unanswered clinical question faced by patients and their clinicians

PCORnet Capacity Building

For this PFA, PCORI is soliciting CDRNs and PPRNs currently funded by PCORI for Phase I of PCORnet, and the PCORnet Coordinating Center to design and conduct a clinical effectiveness trial on the optimal maintenance dose of aspirin for secondary prevention of coronary artery disease (CAD) events in patients with known CAD.

The protocol may specify two or more daily doses of aspirin within the range from 81 to 325 mg and should assess both the comparative effectiveness of each dosage as well as the comparative harms (safety) of each dose. In addition to specifying the CAD events that will be measured to assess the effectiveness of each dosage, the protocol must also specify outcomes intended to assess the comparative safety of selected aspirin dosages. Bleeding must be included among the adverse events. The size and duration of the study are left to the discretion of the protocol committee, but should optimize the statistical efficiency of the study based on existing event-rate information.

Applications may be submitted by Phase I CDRNs and PPRNs, and the PCORnet Coordinating Center only. The Internal Revenue Service must recognize all US applicant organizations. Investigators of CDRNs and PPRNs are expected to collaborate on the development of the research plan, inclusive of a study protocol, resulting in the submission of one cohesive proposal to PCORI. Included in the development of this plan should be members of the PCORnet community, including the CDRN or PPRN investigator who originated the proposal, patients with CAD, and outside experts, including platelet/aspirin experts, trialists, and biostatisticians, as needed. Collaboration within CDRNs and PPRNs is strongly encouraged. PCORI will make one award under this PFA. The awardee institution is responsible for the trial, including oversight and dispersion of funds to any and all necessary subcontracts. Additional details for developing the research plan can be found in the Application Guidelines.

The applicant is encouraged to be creative and consider innovative strategies that maximize efficient use of PCORnet resources, such as the following, as appropriate and feasible:

- Engage with major patient and stakeholder organizations (including professional organizations) in designing the study, implementing data collection tools, monitoring patient-reported outcomes, and optimizing the dissemination strategy.
- Minimize disruption to participants' daily routines (e.g., minimize participant visits intended solely for study-assessment purposes; capture patient-reported outcomes [PROs] during office visits, electronically or via phone).

- Design the study so that the conduct can, as seamlessly as possible, be integrated with routine clinic or office operations.
- Use efficient methods to obtain participant consent while still meeting ethical and legal requirements.
- Capitalize on the existing data infrastructure of CDRNs and PPRNs to identify and recruit eligible patients, monitor study conduct and patient safety, and collect study outcomes information.
- In light of recent activities in this area, PCORI is now requiring the use of a single IRB of record for this study. PCORI will consider exceptions if an institution has a compelling reason that prevents them from using a single IRB.
- If data standardization and interoperability across study sites have not already been accomplished for such key outcomes as mortality, then develop methods that will enhance the standardization of data that are accessed from different EHR systems or other sources of data.

PCORI does not necessarily expect that all CDRNs or all PPRNs will participate in this trial. The awardee institution's final selection of participating sites should be guided by a careful analysis of preliminary data provided by all CDRNs using the common data model (CDM) to the extent possible, by the level of interest in the network, by the current readiness of the network to participate effectively, and by general considerations of sample size, availability of funds, and study efficiency. The awardee institution in collaboration with the study PI and study coordinating center is expected to select participating sites based on the factors above.

Evidence to Action Networks

PCORI is interested in ensuring communication and engagement between awardees with similar needs and interests, and end users, to help refine and improve the research and to facilitate dissemination of research findings that will help patients and the public make better and informed healthcare decisions. To meet this goal, PCORI has set up Evidence to Action Networks, where PCORI facilitates engagement among awardees and cross-learning between projects and teams comprising researchers, patients, caregivers, and other stakeholders. In addition, PCORI facilitates exchanges between awardees and end users (e.g., patients; caregivers; and other stakeholders, such as payers, employers and purchasers, clinicians, professional societies, policy makers, and training institutions) for dissemination and implementation of important research findings.

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

II. Guidance for Proposing Research

Research Priorities

PCORI funds patient-centered outcomes research (PCOR), a type of CER. The studies PCORI supports must include the perspectives of patients and other healthcare stakeholders. To be considered responsive, this trial should have the following characteristics:

- *The trial must compare at least two alternative approaches, both of which are viable alternatives.* This trial should compare two or more commonly used aspirin dosages in patients with CAD.
- *The trial must study the benefits and harms of interventions and strategies delivered in real-world clinical settings.* PCORI is interested in innovative studies that provide practical information that patients and other stakeholders can use to make informed decisions about their health care and health outcomes.
- *The trial must be based on health outcomes that are meaningful to the patient population under study and are likely to guide the decisions regarding care made by patients, caregivers, and providers.* (e.g., morbidity, mortality, symptoms, functional status, quality of life). In select instances, surrogate physiological measurements may be sufficiently linked to final health outcomes of interest, but they may not be the sole study outcome.
- *The trial must use network datasets for recruitment and collection of outcomes* to test the ability of PCORnet to conduct clinical CER.

Non-responsiveness

Applications will be considered non-responsive to this PFA if the proposed research:

- Tests efficacy (or comparative efficacy) within a tightly protocol-controlled research setting (as opposed to more real-world, pragmatic CER)
- Conducts a formal cost-effectiveness analysis in the form of dollar-cost per quality-adjusted life year to compare two or more alternatives
- Directly compares the costs of care between two or more alternative approaches

PCORI does have an interest, however, in studies of conditions that lead to high costs to the individual or to society. PCORI is also 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.

Further, PCORI considers it important for applicants to discuss cost-related issues, such as the resources needed to implement, replicate, or disseminate a successful intervention. PCORI is interested in the evaluation of interventions intended to reduce health system waste or increase health system efficiency. Proposals that include studies of these issues without utilizing a formal cost-effectiveness analysis or comparing the costs of alternatives are considered responsive.

PCORI discourages proposals that include studies of the natural history of disease, instrument development, pharmacodynamics, and fundamental science or study of biological mechanisms. It is not the intended purpose of this funding announcement to seek studies aimed to develop and evaluate new decision aids or clinical prognostication tools.

Features of Patient-Centered Outcomes Research (PCOR)

PCOR helps people and their caregivers communicate and 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 people
- 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 valid PCO measures and to include preliminary data that supports the proposed measures. Investigators are encouraged to consider those measures described in the [Patient-Reported Outcomes Measurement Information System \(PROMIS\)](#).

Justification of Assumptions

PCORI specifically seeks studies that are sufficiently powered to detect clinically meaningful effects. To that end, you 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, the 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:

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

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.

Patient and Stakeholder Engagement

PCORI encourages all applicants to clearly describe 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 the Engagement Rubric to guide both applicants and merit reviewers. Additionally, studies are expected to adhere to PCORI’s Methodology Standards Associated with Patient-centeredness and to the PCOR Engagement Principles found within the rubric. These and additional resources are available in [PCORI’s Funding Center](#).

Populations Studied

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

- Racial and ethnic minority groups
- Low-income groups
- Women
- Children (aged 0–17 years)
- Older adults (aged 65 years and older)
- Residents of rural areas
- Individuals with special healthcare needs, including individuals with disabilities

- Individuals with multiple chronic diseases
- Individuals with rare diseases
- Individuals whose genetic makeup affects their medical outcomes
- Patients with low health literacy/numeracy or limited English proficiency
- Lesbian, gay, bisexual, and transgender (LGBT) persons

Protection of Human Subjects

PCORI adopts, by reference, the Human Subjects requirements of 45 CFR Part 46. If the proposed research will involve human subjects, refer to the Supplemental Instructions for Preparing the Protection of Human Subjects Section of the Research Plan in Part II of the Instructions for the PHS 398 Form provided by the [National Institutes of Health](#). Note: PCORI requires engagement in the research by patients or other stakeholders as research partners. Research subjects protection requirements generally do not apply to co-investigators, members of the research team, or research partners.

Replication and Reproducibility of Research and Data Sharing Plan

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

Budget and Project Duration

The maximum budget for this PFA is \$10 million total direct costs. The maximum period of performance is three years. There will *not* be a consideration of exceptions to the budget and period of performance limits. If you submit an application that exceeds the \$10 million total direct cost cap or the three-year period of performance, your application will be removed for noncompliance.

III. How to Submit a Proposal

Submission Dates

Applications must be submitted in accordance with the published dates and times listed in the Overview and in the [PCORI Funding Center](#).

PCORI Online System

To submit a proposal, you must register with the [PCORI Online System](#) and submit an application for each cycle in which you are applying.

Applicant Resources

PCORI Funding Center	http://www.pcori.org/winter-2015-aspirin
PCORI Online System	https://pcori.fluxx.io

IV. Merit Review

PCORI Merit Review is a multiphase process that includes preliminary review of full applications by review panels; in-person panel discussion of a subset of full applications (identified by PCORI's Research Priority Area Program Staff, based on the preliminary review and program priorities); Selection Committee recommendation of applications for funding; and finally, Board of Governors award approval.

Preliminary Review

PCORI conducts rigorous merit review of the full applications it receives. Applications may be eliminated from the review process for administrative or scientific reasons (e.g., non-responsiveness). 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 scientifically withdrawn if it is not responsive to the guidelines as described in this PFA, describes research that is not comparative, includes cost-effectiveness analysis, or otherwise does not meet PCORI programmatic requirements.

Administratively and scientifically responsive applications will be reviewed by a single merit review panel recruited by PCORI Merit Review Officers (with recommendations from the PCORI Clinical Trial Advisory Panel). The review panel is composed of a chairperson, scientist reviewers who are clinical experts familiar with CAD and platelet therapy, methodological and statistical experts familiar with pragmatic clinical trials and large database analyses, patient representatives trained in review of scientific proposals, and representatives of other stakeholder groups.

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

Criterion 1. Technical merit

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

- Is there a clear research plan with rigorous methods that adhere to PCORI's Methodology Standards and prevailing accepted best practices?
- Is there evidence that the outcome measures are sufficiently sensitive to identify differences between groups?
- Are the pre-specified subgroups reasonable given the proposed interventions and condition? Are the subgroups sufficiently large to allow a rigorous and valid comparative analysis?
- Is the study protocol appropriate to answer the research question asked? Is it feasible to be conducted within time and resource constraints allotted?
- Is the budget appropriate for the proposed research?

- Is there a clear and adequate justification for the study design choices in the proposed trial?
 - Incident or prevalent population
- Do the applicants provide evidence of study feasibility based on availability of participants and experienced staff for efficient start-up?
- Does the project include a realistic timeline that includes clear and specific scientific and engagement milestones?
- Does the research team have the necessary expertise and prior experience conducting large scale multicenter trials and an appropriate organizational structure to successfully complete the study?
- Is the research environment, including the delivery systems that will host the study, well-resourced and highly supportive of the proposed study?
- Does the study approach capitalize on the existing PCORnet data infrastructure to identify and recruit eligible patients, monitor study conduct and patient safety, and collect study outcomes information?

Criterion 2. Patient-centeredness

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

- Does the research question and comparators reflect a choice or choices faced by patients, their caregivers, or clinicians?
- Does the study protocol include health outcomes, including validated patient-reported outcomes (PROs) if appropriate, that are relevant to patients?
- Does the study design minimize disruption to participants' daily routines (e.g., minimize participant visits intended solely for study-assessment purposes; capture PROs during office visits, electronically, or via phone)?
- Can the study design, as seamlessly as possible, be integrated with routine clinic or office operations?
- Is there an adequate plan for protection of human subjects participating in this study?
 - Does the project use efficient methods to obtain participant consent while still meeting ethical and legal requirements?
 - Is patient consent designed to be understandable to patients by detailing the risks and benefits of participating in the study in language non-scientists can comprehend?
 - Does the application adequately describe how potential risks to subjects appear reasonable in relation to anticipated benefits?

Criterion 3. 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:
 - Designing the study
 - 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?

Panel Discussion

After preliminary review is completed, reviewers meet in person for panel discussion and further review. During the panel discussion, panelists further clarify the merits of the proposed research and study protocol, and identify areas for improvement. Additionally, applications are re-scored based on the content of discussion. The panel discussion is led by a chairperson and a PCORI Merit Review Officer, who ensure a fair and thorough review informed by the standards outlined in the PFA.

Post-Panel Review

Following the panel discussion, applications are reviewed by PCORI program staff, who study merit review scores and comments and consider the fit within the programmatic vision. A single application 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 approve or reject a recommendation of funding based on merit review scores, programmatic balance and fit, and PCORI's strategic priorities. In this case, a single study application will be proposed to PCORI's Board of Governors for its consideration and final approval.

Funding Recommendations

This announcement is for a single award. An application that fits the programmatic needs and satisfactorily address reviewers' critiques, while adhering to PCORI's Methodology Standards, will be considered for funding by the PCORI Board of Governors.

Protocol Refinement

Following notice of funding status, applicants will begin refining the submitted protocol with a subcommittee of the PCORI Clinical Trial Advisory Panel (CTAP) inclusive of participants from the Merit Review.

Contract Execution and Activation

PCORI will issue a contract once it conducts a thorough programmatic and administrative review, and the awardee accepts PCORI's contract terms and conditions; among them is a fully agreed-upon study protocol as evaluated by the CTAP subcommittee for this trial. The study will only commence after PCORI and the awardee agree on the final protocol content.

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