Cycle 2 2020 Funding Cycle

COVID-19 Targeted PCORI Funding Announcement

Published May 5, 2020

This PCORI Funding Announcement (PFA) applies to the funding cycle that closes May 26, 2020, at 5 pm ET. Submission Instructions, templates, and other resources are available at https://www.pcori.org/funding-opportunities/announcement/covid-19-targeted-pfa.

About PCORI

The Patient-Centered Outcomes Research Institute (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, caregivers, clinicians, policy makers, and other healthcare system stakeholders 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 and by promoting the dissemination and uptake of this evidence.

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 and other stakeholders.

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Overview

Published	May 5, 2020
Summary	The objectives of this funding announcement are to (1) strengthen the understanding of different approaches to improve the impact of COVID-19 on individuals, communities, healthcare providers, and healthcare systems; and (2) provide evidence to inform clinical and public health responses, decision making, and planning. This announcement has three targeted priority areas: (1) Adaptations to health care delivery, (2) Impact of COVID-19 on vulnerable populations, and (3) Impact of COVID-19 on healthcare workforce well-being, management, and training.
Applicant Resources	See https://www.pcori.org/funding-opportunities/announcement/covid-19-targeted-pfa
Key Dates	Online System Opens: May 5, 2020 Application Deadline: May 26, 2020, by 5 pm (ET) Merit Review: June 2020 Awards Announced: July 2020 Earliest Project Start Date: July 2020
Maximum Project Budget (Total Costs)	Small Studies: up to $2,500,000 Large Studies: up to $5,000,000 At the time of contract execution, PCORI sets aside all funds associated with an awarded project to be made available throughout the contract's period of performance. The maximum budget includes all research- and peer-review-related costs. This PFA does not consider exceptions to the budget. PCORI will not review submissions exceeding the stated maximum budget.
Maximum Research Project Period	2 years. However, investigators are encouraged to complete primary outcomes collection and provide actionable findings in no longer than 12 months. This PFA does not consider exceptions to period-of-performance limits. PCORI will not review submissions exceeding the stated period of performance.
Funds Available Up To	$30 million. This PFA may be re-issued if funds are available.
Eligibility	Applications may be submitted by any private-sector research organization, including any nonprofit or for-profit organization, and any public-sector research organization, including any university or college hospital or healthcare system; laboratory or manufacturer; or unit of local, state, or federal government. The Internal Revenue Service must recognize all US applicant organizations. Nondomestic components of organizations based in the US and foreign organizations may apply, as long as there is demonstrable benefit to the US healthcare system and US efforts in the area of patient-centered research can be shown clearly. Organizations may submit multiple applications for funding. Individuals are not permitted to apply.
Review Criteria	1. Potential to address an important and compelling clinical or care delivery question raised by COVID-19. 2. Potential for the study to generate actionable findings to inform clinical and/or public health responses, decision making, and planning 3. Scientific merit (research design, analysis, and outcomes) 4. Investigator(s) and environment 5. Patient centeredness 6. Patient and Stakeholder Engagement
Contact Us	**Programmatic Inquires:** sciencequestions@pcori.org, phone (202-627-1884), or online (http://www.pcori.org/PFA/inquiry).

Administrative, Financial, or Technical Inquiries: pfa@pcori.org or phone (202-627-1885).

PCORI will respond within two business days. However, we cannot guarantee that all questions will be addressed two business days prior to an application deadline. Applicants are asked to plan accordingly; it is the applicant's responsibility to submit the application on or before the application deadline.

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I. Introduction

PCORI was created to improve the evidence about what works in health care to better inform real, specific choices faced by patients, clinicians, healthcare administrators, and others in the healthcare community. With the dramatic increase in the number of patients infected with COVID-19, the US healthcare system faces an unprecedented challenge to adapt to meet new demands. Although the situation is rapidly evolving, these challenges provide an opportunity to learn about which strategies are most effective at improving patient-centered care.

In order to respond to the COVID-19 pandemic, PCORI is issuing a new research funding announcement with an accelerated timeline to support innovative, high-impact studies that fit clearly within our core mission of patient-engaged and patient-centered comparative clinical effectiveness research. The objectives of this announcement are to (1) strengthen the understanding of different approaches to mitigate the impact of COVID-19 on individuals, communities, healthcare providers, and healthcare systems; and (2) provide evidence to inform clinical and public health responses, decision making, and planning. PCORI will encourage the use of diverse methods, including interventional studies and the use of natural experiments, to conduct research on an accelerated timeline. Applicants are encouraged to complete primary outcomes collection and provide actionable findings in no longer than 12 months. Hybrid designs, which can provide insight into implementation approaches in the context of evidence generation, will also be welcome. Applicants should be prepared to work independently and/or with PCORI to expedite dissemination of results.

This funding announcement has three targeted priority areas. The research questions articulated in each of the priority areas below are not the only questions of interest; other relevant questions within these priority areas will also be considered. The priority areas are:

- **Adaptations to healthcare delivery**: What has been the impact on patient-centered outcomes of alternative healthcare delivery models (e.g., telehealth, hospital at home) that are being implemented in response to COVID-19? What has been learned about barriers and facilitators to their effective implementation?
- **Impact of COVID-19 on vulnerable populations**: What are effective clinical pathways to improve outcomes for the most vulnerable and higher risk patients? What are effective system- or organizational-level responses to prevent or mitigate the impact of COVID-19 in low-income and low-resource settings that serve vulnerable populations? Vulnerable populations include but are not limited to Native Americans or Alaskan Natives, African Americans, and other racial, ethnic, or sexual and gender minorities; rural communities; incarcerated populations; people who are homeless or unstably housed; individuals with intellectual, developmental, or physical disabilities; individuals with chronic conditions; and individuals facing increased exposure because they are unable to work remotely.
- **Impact of COVID-19 on healthcare workforce well-being, management, and training**: What policies, practices, or programs are effective in helping health systems quickly shift human resources, redeploy healthcare workers, and train current and new healthcare workers to fill certain healthcare delivery needs? What are effective strategies to protect the physical and/or mental well-being of the health care workforce?

Although PCORI will not fund basic science research, applications proposing COVID-19-related research in areas not covered by these priorities may also be submitted. Proposals responsive to the targeted priority areas will, however, be given preference. Innovative approaches that involve patients and communities in the development or implementation of research are encouraged. A portion of the award can be allocated for documentation of innovative engagement successes and challenges and effects on the project.

Specific Requirements

The proposed study should strive to meet the following requirements:

- Describe the potential for the study findings to improve the understanding of strategies that would mitigate the impact of COVID-19 and generate actionable findings to inform clinical and public health responses, decision making, and planning.

- Focus on a comparative clinical effectiveness question that is important to patients and other decision makers.

- Describe the pertinent evidence gaps and why the project questions are relevant for patients, caregivers, clinicians, policy makers, and other healthcare system stakeholders. Similarly, applicants should document why project outcomes are especially relevant and meaningful endpoints for patients and their families.

- Demonstrate consultation with patients and other stakeholders or their representative groups to determine if the study is answering a relevant question—one that, if adequately answered, would substantially inform clinical and public health responses, decision making, and planning.

- Propose a sample size that is sufficiently large to allow for precise estimation of hypothesized effect sizes or for clear demonstration of non-inferiority. The sample size must also support testing of *a priori* hypotheses related to potential differences in effectiveness among relevant patient subgroups (HTE).

- Examine diverse populations receiving care in real-world settings.

- For studies addressing the impact of COVID-19 on vulnerable populations, specify one or more target populations that will be the focus of the study. These include but are not limited to: Native Americans or Alaskan Natives, African Americans, and other racial, ethnic, or sexual and gender minorities; rural communities; incarcerated populations; people who are homeless or unstably housed; individuals with intellectual, developmental, or physical disabilities; individuals with chronic conditions; and individuals facing increased exposure because they are unable to work remotely. Studies should test the ability of interventions to improve outcomes and reduce disparities for vulnerable populations, including studies of maternal mortality.

- Have strong interest from and support of host delivery systems and clinical care settings.

- Specify broad and simple eligibility criteria that will allow for wide generalization of results while attending appropriately to ethical concerns of excess risk in some patient subgroups.

- Feature near-term outcomes and patient-reported outcomes (PROs) as primary outcomes, when appropriate.

- Plan to collect patient-centered outcome data efficiently and periodically during follow-up.

- Provide preliminary evidence of the potential for efficient recruitment, high participation rates, and appropriate oversight by local or centralized Institutional Review Boards (IRBs), including plans for streamlining or waiving individual informed consent in cases of low-risk interventions (if applicable). PCORI believes that the intensity of oversight and the complexity of informed consent procedures should be closely related to the degree of risk from study participation. Applicants must address this issue and present evidence that the study will not encounter significant recruitment or participation barriers. The relevant IRBs make the final determination of the adequacy of informed-consent procedures and participant protections.

- Adhere to all applicable PCORI Methodology Standards. Applicants selected for funding will be required to identify the standards appropriate to the proposed study and to describe how the study team plans to address each standard.

To carry out studies that allow for adoption of the findings in a real-world setting, and to maximize the efficient use of resources, take care to prevent these trials from becoming more complex and onerous than necessary. We encourage the applicant to be creative and consider innovative strategies as appropriate and feasible:

- Innovative approaches for involvement of patients and communities in the design, conduct, and/or dissemination of the project are encouraged, particularly given current and anticipated limits on in-person interactions and the need for speed of research. PCORI encourages allocation of funds for documentation of innovative engagement approaches, engagement successes and challenges, and effects on the project (e.g., design decisions, study feasibility and acceptability to participants, etc.).
- Minimize disruption to participants' daily routines (e.g., minimize participant visits intended for study-assessment purposes and capture PROs during office visits, electronically, or via phone). Use efficient methods to obtain participant consent while still meeting ethical and legal requirements.
- Capitalize on existing electronic health records (EHRs) and other computerized information to identify and recruit eligible patients, monitor study conduct and patient safety, and collect study outcomes information. PCORI specifically encourages applications that use the infrastructure of PCORnet®, the National Patient-Centered Clinical Research Network.
- If data standardization and interoperability across study sites have not already been accomplished, develop methods that will enhance the standardization of data that are accessed from different EHR systems.

Budget and Duration of Project

Applicants may request up to $2.5 million in total costs for a small project or $5 million in total costs for a large project, with a project period not to exceed two years in duration (not including peer review). The maximum budget includes all research *and* peer review related costs (please refer to the Submission

Instructions for further details). **Applicants should submit a realistic budget and timeline reflective of the scope and requirements of the proposed study. PCORI expects that project budgets and duration will vary depending on the proposed design, needs for recruitment and/or primary data collection, and analytic complexity.** PCORI seeks efficient studies that use existing resources to enhance contracting, IRB approval, recruitment, and data collection.

II. General Requirements for PCORI Research

This section includes language that is specific to PCORI's requirements for programmatic responsiveness under this funding announcement. Applicants should use this section as guidance when preparing applications. For information related to administrative and technical requirements the application submission, please consult the PCORI Submission Instructions.

Categories of Non-responsiveness

Consistent with PCORI's authorizing law,[1] PCORI does not fund research whose findings will include:

- Coverage recommendations

- Payment or policy recommendations

- Creation of clinical practice guidelines or clinical pathways

- Establishment of efficacy for a new clinical strategy

- Pharmacodynamics

- Study of the natural history of disease

- Basic science or the study of biological mechanisms

Studies of Cost-Effectiveness

PCORI will consider an application nonresponsive if the proposed research:

- Conducts a formal cost-effectiveness analysis of alternative approaches to providing care

- Directly compares the costs of care between two or more alternative approaches to providing care

Proposals that include studies of these issues may measure and report utilization of any or all health services, but may not employ direct measurements of care costs. For further information, please reference our cost-effectiveness analysis FAQs.

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

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

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[1] Available at http://www.pcori.org/sites/default/files/PCORI_Authorizing_Legislation.pdf/.

- 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

Coverage of Intervention Costs

In general, PCORI will not cover costs for study interventions that constitute the procedures, treatments, interventions, or other standard clinical care ("patient care") that are being proposed for comparison in the research project ("patient care costs").

Methodological Considerations

The PCORI Methodology Standards represent minimal requirements for the design, conduct, analysis, and reporting of scientifically valid, patient-centered outcomes research. Regardless of study design, applications must adhere to all relevant PCORI Methodology Standards, and all deviations need to be justified.

Patient-Centered Outcome Measures and Core Outcome Sets

- PCORI encourages investigators to design their research using validated outcome measures. We encourage investigators to consider those measures described in the Patient-Reported Outcomes Measurement Information System[2] (PROMIS).

- PCORI also encourages researchers to consider the inclusion of relevant core outcome sets (COS). There are efforts to develop COS specific to COVID-19 (http://www.comet-initiative.org/Studies/Details/1538). The inclusion of COS facilitates evidence synthesis and helps to ensure that COVID-19 studies address the impacts of disease and treatment that are meaningful and of high priority to people affected or at risk of COVID-19, and those involved in their care.

Leveraging Existing Resources, Including PCORnet

PCORI is interested in new research that derives data from a wide variety of sources and that uses study designs appropriate for the goals of the proposed project. PCORI encourages investigators to propose studies that leverage existing resources, such as adding PCOR to an existing large clinical trial or analyzing existing large databases that contain valuable, relevant information that may be used to answer important CER questions. Another possible resource is established patient outcomes registries, especially when such registries can be linked to electronic medical record (EMR) data from healthcare delivery systems or administrative claims data from public or commercial insurers. In circumstances where randomized control trials are not practical or ethically acceptable, studies leveraging established patient-outcomes registries can have meaningful and complementary roles in evaluating patient outcomes. PCORI does not intend for this PFA to support the development of new data networks or patient registries, but rather to support the effective utilization of existing data resources for proposed new CER studies.

For some proposed projects, the data resources of PCORnet may be particularly appropriate. Over the

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[2] Available at http://www.healthmeasures.net/explore-measurement-systems/promis.

past six years, PCORI has made a major commitment to create the infrastructure of PCORnet, which was designed to improve the nation's capacity to conduct efficient large-scale clinical research and to learn from the healthcare experiences of millions of Americans. This large clinical research network represents patients, clinicians, health systems, and health plans across the country, and it supports research that will improve health care and health outcomes. The network currently includes nine clinical research networks (CRNs), representing more than 100 health systems, two health plan research networks (HPRNs), and a coordinating center. PCORnet provides access to large longitudinal datasets that enhance the capture of relevant outcomes and provide more detail on specific procedures or treatments, disease severity, and the presence of comorbid illness. Contact the PCORnet Front Door to learn more about PCORnet and how the network resources might assist in one or more aspects of your proposed research study.

The following elements are central to the rationale for and the sustainability of PCORnet:

- Preexisting, standardized, curated, and research-ready clinical data on large numbers of persons with specific clinical conditions and illnesses

- Actively engaged patients who join in governing the research uses of these data

- Distributed (rather than centralized) data platforms that maximize the security and local control of all data

- A readiness among network members to collaborate and a willingness to share data in pursuit of worthy research aims

- The capacity to link data across data sources at the individual patient level

Applicants are encouraged to consider whether using PCORnet might assist in one or more aspects of their proposed research study. Examples include, but are not limited to, the following:

- Background to the research question or feasibility of study

- Document the importance of the research question

- Estimating the size of the potentially eligible population

- Determining the range of current treatment practices and sequencing

- Assessing the duration of continuous treatment and care

Studies in Rare Diseases

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

Patient and Stakeholder Engagement

In PCORI-funded research, patients and other healthcare stakeholders are viewed as partners who leverage their lived experience and/or professional expertise to influence research to be more patient-centered, relevant, and useful. Engagement approaches and practices vary by project based on the

patient population, setting, and needs of a study. Within the context of the COVID-19 pandemic, PCORI recognizes that forming and sustaining conventional partnerships may be challenging, and encourages the use of novel, creative, and flexible engagement approaches that facilitate the inclusion of stakeholder perspectives in key decisions that may influence study design, conduct, and dissemination of findings. For example, rapid structured methods (e.g., surveys, virtual community forums) to gather input from members of stakeholder groups quickly may be combined with ongoing involvement of patient and stakeholder advisors. Recognizing that plans for engagement with stakeholders may be evolving, applicants should submit their most current ideas for identifying and soliciting input from representatives of stakeholder groups most affected by COVID-19 and the decision points for which they will be consulted. A detailed engagement plan will be required if an award is made.

Populations Studied and Recruited

PCORI seeks to fund research that includes diverse populations with respect to age, gender, race, ethnicity, geography, or clinical status, so that possible differences in outcomes may be examined in defined subpopulations. PCORI recognizes that some proposed studies might represent important PCOR opportunities, even in the absence of a broadly diverse study population. However, the burden is on the applicant to justify the study's importance in the absence of diversity, to discuss which subgroups are most important, and to discuss how the subgroups will be analyzed, including whether the study will be powered to examine the question of effectiveness in subgroups.

PCORI is particularly interested in including vulnerable populations for whom effectiveness information is especially needed. Thus, comparisons should examine the impact of the strategies in various subpopulations, with attention to the possibility that the strategy's effects might differ across subpopulations.

Regardless of the population studied, investigators are expected to provide evidence-based estimates regarding the representativeness of the potential pool of participants from which recruitment will occur; the target sample size; and recruitment and retention rates, reflecting the study's inclusion and exclusion criteria as well as factors that may impact the final sample size (e.g., loss to follow-up).

Protection of Human Subjects

PCORI follows the Federal Policy for the Protection of Human Subjects (45 CFR part 46), including the Common Rule. For more detailed information, please see Section 5, titled "Human Subjects Research Policy," in the Supplemental Grant Application Instructions for All Competing Applications and Progress Reports, [3] which is issued by the US Department of Health and Human Services (HHS). In referencing the HHS Supplemental Grant Application Instructions, note that PCORI does not require that applicants comply with sections of that policy that refer to requirements for federal-wide assurance and the inclusion of women, minorities, and children in the proposed studies. Instead, PCORI expects applicants to address diversity in study participants in the research plan, through a focus on subpopulations, as described in the above section on Populations Studied and Recruited. Awardees must also comply with appropriate state, local, and institutional regulations and guidelines pertaining to the use of human

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[3] See http://grants.nih.gov/sites/default/files/supplementalinstructions.docx

subjects in research.

PCORI requires awardees to ensure that there is a Data and Safety Monitoring Plan, which may include the need to appoint a Data and Safety Monitoring Board, as provided in the PCORI Policy on Data and Safety Monitoring Plans for PCORI-Funded Research.[4]

PCORI merit reviewers will examine plans for protection of human subjects in all applications and may provide comments regarding the plans (see How To Evaluate Human Subjects Protections[5]). Reviewers' comments on human subject research are not reflected in the overall application score, but PCORI staff might use them during potential funding negotiations. Final determinations about the adequacy of human subject protections rest with the Institutional Review Board or international equivalent that have jurisdiction for the study.

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

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

PCORI requires that all applicants adhere to the National Institutes of Health (NIH) policy on education in the protection of human subject participants in the conduct of research. This applies to all individuals listed as key personnel in the application. The policy and FAQs are available on the NIH website.[6]

III.   Merit Review

PCORI's merit review process is designed to support the following goals:

- Identify applications that have the strongest potential to help patients, caregivers, clinicians, policy makers, and other healthcare system stakeholders make informed decisions to improve patient outcomes

- Implement a transparent, fair, objective, and consistent process to identify these applications

- Elicit high-quality feedback that reflects a diversity of perspectives to ensure that the PCORI-funded research reflects the interests and views of patients and other stakeholders and those who care for them, and that it meets the criteria for scientific rigor

- Identify projects that fill important evidence gaps and have strong implementation potential

- Regularly evaluate and continually improve the merit review process and policies in support of PCORI's mission

Administrative Screening

Note that PCORI may eliminate applications from the review process for administrative or scientific reasons (e.g., non-responsiveness). An application may be administratively withdrawn if it is incomplete; submitted past the stated due date and time; or does not meet the formatting criteria outlined in the Submission Instructions, in the PCORI templates, and in PCORI Online. An application may be withdrawn

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[4] See http://www.pcori.org/sites/default/files/PCORI-Policy-Data-Safety-Monitoring-Plans.pdf

[5] See http://www.pcori.org/sites/default/files/PCORI-Checklist-for-Evaluating-Human-Subjects-Protections.pdf/.

[6] See http://grants.nih.gov/grants/guide/notice-files/NOT-OD-08-054.html.

if it is not responsive to the guidelines described in this PFA, describes research that is not comparative, includes a cost-effectiveness analysis, or otherwise does not meet PCORI programmatic requirements.

Programmatic Screening

After administrative screening, senior PCORI staff will screen all complete, responsive applications. Applications will be screened and scored in light of the following considerations:

- Does it address a compelling clinical or care delivery question raised by the COVID-19 crisis?
- At the completion of the study, will there be actionable findings that could immediately be implemented?
- Does the applicant propose an appropriate and sound methodological approach to address the research question?
- Does the study have appropriate partnerships and adequate infrastructure to a) ensure timely commencement and completion, and b) support downstream uptake of the findings?

Only a subset of the best-scoring applications will be advanced for Panel Review by external reviewers.

Panel Review

PCORI Merit Review Officers (MROs) recruit each review panel based on the number and topic areas represented by the applications to be reviewed. MROs recruit the panel chair, scientist reviewers who are subject matter experts, patient representatives, and representatives of other stakeholder groups. All panel members receive training during the review cycle to ensure that they understand the programmatic and organizational goals of review.

Applications are evaluated and scored by external reviewers based on PCORI's merit review criteria during an online review phase. After this preliminary review, PCORI program staff members evaluate panel scores and written critiques to identify a subset of applications for merit reviewers to discuss at the review panel meeting. Not all applications move forward for discussion at the panel review meeting.

During the panel meeting, merit reviewers discuss applications and clarify further the merits of the proposed research. They also identify areas for improvement. Each application is re-scored based on the content of discussion. The Panel Chair and PCORI MRO lead the panel meeting and ensure that all applications receive a fair and thorough review according to the standards outlined in the PFA.

PCORI Merit Review Criteria

Below are PCORI's merit review criteria for this funding announcement. PCORI's merit reviewers use these criteria during the preliminary online and panel discussion review phases to evaluate and score applications and to ensure consistency and fairness in how applications are evaluated.

Criterion 1. Potential to address an important and compelling clinical or care delivery question raised by COVID-19.

The following questions should be addressed:

- Would the study findings significantly contribute to understanding strategies that would mitigate the impact of COVID-19 on patients, communities, healthcare providers, or healthcare systems?

- Does the application demonstrate that the research question is important to relevant stakeholders?
- Would the study findings be a novel or compelling contribution to the field of COVID-19 research?

Criterion 2. Potential for the study to generate actionable findings to inform clinical practice and/or public health responses, decision making, and planning.

The following questions should be addressed:

- Does the application describe how the study would result in actionable findings and identify potential end-users of the study findings?
- Are potential barriers to uptake of the study findings identified and addressed?

Criterion 3. Scientific merit (research design, analysis, and outcomes)

The research design should show sufficient technical merit to ensure that the study goals will be met. The following questions should be addressed:

- Does the application describe a clear causal framework that informs the research design, key variables, and relationships being examined?
- Are the study design, study setting, and selected comparators adequately described and justified?
- Does the proposed project demonstrate a rigorous methodological approach, and will the research strategy address the research question? (For example: Are sample sizes and power estimates appropriate? Are outcome measures appropriate and validated? Is the analytic plan well described and justified?)
- Is the project feasible in the proposed timeline?

Criterion 4. Investigator(s) and environment

The following questions should be addressed:

- Do members of the research team have track records demonstrating that they are qualified and capable of successfully completing the proposed project?
- Are the relevant necessary areas of expertise represented on the research team?
- Are the levels of effort for team members appropriate for the proposed work?
- Is the research environment appropriate to support proposed project and will the team have access to the resources necessary for success?

Criterion 5. Patient centeredness

(Note: A study can be patient centered even if the end user is not the patient, as long as patients will benefit from the study findings.)

The following question should be addressed:

- Does the application describe which outcomes (potential benefits and harms) are important to patients and relevant stakeholders?

- Is the burden to research participants reasonable, given the research question?

Criterion 6. Patient and Stakeholder Engagement

The following questions should be addressed:

- Does the application describe involvement with the stakeholder groups that are most relevant and appropriate?
- Does the application describe a process for engagement and the decision points at which engagement activities will occur?
- Does the application describe dissemination to those who could use the study findings to inform healthcare decisions? Does the project engage the stakeholder organizations ultimately needed for effective dissemination?

Post-Panel Review

After the panel meeting, PCORI program staff review final panel scores and comments, identify duplication or synergy among funded projects, and consider the fit of applications within the programmatic vision. Program staff then recommend projects to a Selection Committee, which is a subcommittee of the Board of Governors. The Selection Committee considers recommendations and works with staff to identify a slate of applications for possible funding based on merit review scores, programmatic balance and fit, and PCORI's strategic priorities. For this PFA, the Board of Governors has delegated the approval authority to the Executive Director.

In addition, PCORI evaluates applicant risk before issuing a PCORI award. Factors considered include financial stability, quality of management systems, audit findings, and past performance on PCORI awards (e.g., compliance with PCORI reporting requirements, conformance to PCORI terms and conditions on previous awards, and timely achievement of milestones). Based on the risk assessment, PCORI may impose special terms and conditions on awardees or withhold contract issuance until such business risks are mitigated. PCORI will not award new contracts to current awardees with overdue reports (progress, interim, final, etc.) until the overdue reports have been submitted.

Summary Statements and Funding Recommendations

Applications that do not advance to Panel Review by external reviewers will receive a brief summary based on the Programmatic Screening.

Applications that do advance to Panel Review by external reviewers, but are not discussed at the panel meeting, will receive the preliminary reviewer critiques.

If an application progresses to panel discussion, the applicant will receive a summary statement that will include:

- Panel discussion notes
- Final average overall score
- 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 the PCORI Methodology Standards. Programs also consider the funds allotted for the current funding announcement when deciding which applications to recommend for approval. Applicants to this current cycle's PFA will receive summary statements and notification of the funding status of their application no later than July 2020.

IV. PCORI Policies That Govern Awardees Related to Data Access, Privacy, and Public Reporting

Applicants should be aware that all PCORI awardees are required to comply with the following requirements:

Registering Research Projects

PIs are required to use the naming convention *PCORI-PCORI application number* (i.e., PCORI-XXXX-XXXXX). Clinical trials must be registered before enrollment of the first patient. All trials that meet the definition on the NIH database[7] (see Data Element Definitions) are required to register, if funded.

Funded clinical trials or observational outcomes studies must be registered at ClinicalTrials.gov.

Funded evidence-synthesis studies must be registered at PROSPERO.[8] Funded patient registries must be registered at https://patientregistry.ahrq.gov/.

PCORI Public Access Policy

PCORI requires all awardees to adhere strictly to PCORI's publication policies, which will be shared with awardees within the research contract.

Standards for Privacy of Individually Identifiable Health Information

On August 14, 2002, the Department of Health and Human Services issued a final modification to the Standards for Privacy of Individually Identifiable Health Information, the "Privacy Rule." The Privacy Rule is a federal regulation under the Health Insurance Portability and Accountability Act (HIPAA) of 1996 that governs the protection of individually identifiable health information and is administered and enforced by the Department of HHS Office for Civil Rights.

Decisions about the applicability and implementation of the Privacy Rule reside with the researcher and his or her institution. The Office for Civil Rights[9] provides information on the Privacy Rule, including a complete Regulation Text and a set of decision tools related to "Am I a covered entity?" Information on the impact of the HIPAA Privacy Rule on NIH processes involving the review, funding and progress monitoring of grants, cooperative agreements, and research contracts is available from NIH.[10]

Data Management and Data Sharing

PCORI is committed to publishing and disseminating all information and materials developed using PCORI funding, in accordance with its authorizing legislation. All recipients of PCORI contracts must

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[7] Available at https://prsinfo.clinicaltrials.gov/.
[8] Available at http://www.crd.york.ac.uk/prospero/.
[9] Available at http://www.hhs.gov/ocr/.
[10] Available at http://grants.nih.gov/grants/guide/notice-files/NOT-OD-03-025.html.

agree to these principles and take steps to facilitate data availability.

PCORI encourages openness in research and making research data available for purposes of replication and reproducibility. As such, if an award is made, the awardee will be expected to adhere to PCORI's Policy for Data Management and Data Sharing. The Policy articulates PCORI's requirement that certain Awardees make the underlying data and data documentation (e.g., study protocol, metadata, and analytic code) from their PCORI-funded research projects available to third-party requestors.

A full data management and data sharing plan is not required at the time of application. If an award is made, the Awardee is required to develop and maintain such a plan, which is described in detail in the PCORI Methodology Standards for Data Integrity and Rigorous Analyses, specifically Standard IR-7. This plan must be appropriate for the nature of the research project and the types of research project data, and consistent with applicable privacy, confidentiality, and other legal requirements. The policy includes details about what data certain Awardees will be expected to deposit into a PCORI-designated data repository and when that data would be available for third-party requests.

The information here is meant for informational purposes only and does not attempt to be an exhaustive representation of the Policy for Data Management and Data Sharing. Please refer to the policy in its entirety for additional information.

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. Accordingly, the PCORI Board of Governors adopted the Process for Peer Review of Primary Research and Public Release of Research Findings.[11]

In summary, Awardee Institutions are required to submit to PCORI for peer review a Draft Final Research Report (DFRR) that provides the methodological details, describes the main study results, and interprets the findings in clinical or other decisional contexts. After Awardee Institutions have responded to reviewers' comments to PCORI's satisfaction, the report will be accepted and considered final. PCORI will then prepare two 500-word standardized abstracts summarizing the study results (as detailed below), which the Awardee Institution will review and approve.

No later than 90 days after the DFRR is accepted, PCORI will post the following materials on its website: (1) a 500-word abstract for medical professionals; (2) a 500-word standardized abstract summarizing the study results for patients and the general public; (3) a link to the study record on ClinicalTrials.gov (as applicable); and (4) ancillary information, including conflict of interest disclosures. 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.

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[11] See http://www.pcori.org/sites/default/files/PCORI-Peer-Review-and-Release-of-Findings-Process.pdf.