Cycle 3 2020 Funding Cycle

PCORI Funding Announcements:
Suicide Prevention: Brief Interventions for Youth

Published September 1, 2020

This PCORI Funding Announcement (PFA) applies to the funding cycle that closes January 12, 2021, at 5 pm (ET). Submission Instructions, templates, and other resources are available at https://www.pcori.org/funding-opportunities/announcement/suicide-prevention-brief-interventions-youth-cycle-3-2020.
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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Follow us on Twitter: @PCORI
# Overview

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<th>Published</th>
<th>September 1, 2020</th>
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<tr>
<td><strong>Key Dates</strong></td>
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<tr>
<td>Online System Opens:</td>
<td>September 1, 2020</td>
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<tr>
<td>Town Hall:</td>
<td>September 10, 2020, 12 pm (ET)</td>
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<td>LOI Deadline:</td>
<td>September 29, 2020, by 5 pm (ET)</td>
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<td>LOI Status Notification:</td>
<td>October 27, 2020</td>
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<td>Application Deadline:</td>
<td>January 12, 2021, by 5 pm (ET)</td>
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<td>Merit Review:</td>
<td>April 2021</td>
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<td>Awards Announced:</td>
<td>July 2021</td>
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<td>Earliest Project Start Date:</td>
<td>November 2021</td>
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<tr>
<th>Maximum Project Budget (Direct Costs)</th>
<th>$10 million</th>
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<td>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. PCORI will not review submissions exceeding the stated maximum budget.</td>
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<tr>
<th>Maximum Research Project Period</th>
<th>5 years (60 months)</th>
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<td>PCORI will not review submissions exceeding the stated period of performance.</td>
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<th>Total Funds Available Up To</th>
<th>$30 million</th>
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<th>Eligibility</th>
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<td>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 United States 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.</td>
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<th>Review Criteria</th>
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<tr>
<td>1. Potential for the study to fill critical gaps in evidence</td>
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<td>2. Potential for the study findings to be adopted into clinical practice and improve delivery of care</td>
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<td>3. Scientific merit (research design, analysis, and outcomes)</td>
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<td>4. Investigator(s) and environment</td>
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<td>5. Patient-centeredness</td>
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<td>6. Patient and stakeholder engagement</td>
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<th>Contact Us</th>
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<td><strong>Programmatic Inquiries</strong>: Email (<a href="mailto:sciencequestions@pcori.org">sciencequestions@pcori.org</a>), phone (202-627-1884), or online (<a href="http://www.pcori.org/PFA/inquiry">http://www.pcori.org/PFA/inquiry</a>)</td>
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**Administrative, Financial, or Technical Inquiries**: Email (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 a Letter of Intent (LOI) or 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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PCORI Cycle 3 2020: Suicide Prevention PFA
I. **Introduction**

General Considerations for PCORI-Funded Research

The Patient-Centered Outcomes Research Institute (PCORI) funds patient-centered outcomes research (PCOR), a type of comparative clinical effectiveness research (CER) that focuses on outcomes that matter to patients, their caregivers, and their families. PCORI-funded studies compare two or more healthcare options and are designed to provide results that can inform critical healthcare decisions facing patients and caregivers, clinicians, policy makers, payers, and/or healthcare system leaders. These decisions must be consequential and occurring now, in the absence of sound evidence about the comparative effectiveness of alternative approaches.

The public entrusts PCORI to fund research that matters to patients, their caregivers, and other stakeholders (clinicians, clinician societies, hospitals and health systems, payers, purchasers, industry, researchers, policy makers, and training institutions). By emphasizing the role of diverse research teams that include varying perspectives, PCORI seeks to change the way research is conducted. Patients, caregivers, clinicians, payers, and the broader stakeholder community are actively engaged in all stages of PCORI research: generating research questions, reviewing research applications, conducting research, disseminating research findings, promoting the implementation of research findings, and using the results to understand and address patient and other stakeholder needs.

**Summary of Program**

This initiative seeks to fund high-quality studies that compare the effectiveness of brief interventions to prevent suicide in youth (ages 15–24).

**Topic Background**

Suicide continues to be a serious public health problem, with US suicide rates having increased by more than 35 percent between 1999 and 2018. Suicide rates for youth (ages 15–24) rose by 46 percent during this time period (from 9.9 to 14.5 per 100,000). There is growing concern that the COVID-19 pandemic will lead to even larger increases in suicide rates, due to the pandemic’s many psychological and sociological effects and expected sequelae.

While suicide rates have risen across different race/ethnicity, gender, and geographical groups, rates remain higher for boys and males, and for LGBTQ, homeless, rural, disability, and American Indian/Native Alaskan populations. Although rates for Black and Latinx populations have historically been lower than those for white populations, specific concern has been raised more recently about the

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increasing rate for Black and Latina teenagers.5,6,7

Brief interventions are often the first intervention patients receive when concern about suicidality develops or increases. Designed to reduce acute suicide risk and to direct patients to appropriate long-term mental health treatment, these interventions generally take up to an hour during a single encounter, and they may include follow-up outreach. Several brief interventions are in use (e.g., Safety Planning, Teachable Moment Brief Intervention, Motivational Interviewing). Although provision of an evidence-based brief intervention is considered usual care for patients with suicidality, implementation varies, and comparative effectiveness has not been examined.

Brief interventions are used for youth with suicidality, and benefits have been suggested for hospitalized adolescents specifically, including reduced suicidality and increased connection to follow-up treatment.8,9,10,11 Evidence for effectiveness for underserved populations among youth, such as American Indian/Alaska Native, Black, Latinx, LGBTQ, homeless, rural, and disability populations, is sparse.

Brief interventions may be administered by a range of healthcare workers, including physicians, physician assistants, school counselors, nurses, mental health professionals, and others. They may be administered where patients present with suicidality, including emergency departments, schools, primary care settings, mental health settings, mobile crisis units, inpatient psychiatric units, residential programs, correctional facilities, and various community settings. Providers have recently greatly increased the use of telehealth for suicide prevention due to the restrictions associated with the COVID-19 pandemic.

Cultural adaptation (cultural centering, tailoring) of interventions for specific populations is associated with improved outcomes for a range of conditions including smoking cessation, diabetes self-management, weight loss, medication adherence, and others,12,13,14,15 and is considered important for

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suicide prevention.\textsuperscript{16,17,18,19}

Cultural adaptation may include but is not limited to such elements as specific language, icons, family involvement, or rituals; specific settings or staff providing interventions; involvement of people with lived experience; and telehealth (apps, text-based, web-based, phone call, video calls). Elements are included based on identified barriers for target populations and input and endorsement from that population. Preliminary studies of culturally adapted suicide prevention interventions have reported positive results.\textsuperscript{20,21,22,23} Applicants should justify the types of adaptations they propose, including evidence for effectiveness and acceptability to youth and other stakeholders.

Specific Requirements for This Funding Announcement

All applications must address the following priority research question:

What is the comparative effectiveness of different evidence-based and/or widely used brief interventions to reduce suicidality and improve outcomes for youth ages 15 to 24?

PCORI is interested in culturally adapted approaches for underserved subpopulations with increased rates of suicidality (LGBTQ, American Indian/Native Alaskan, Black, Latina, rural, individuals with disabilities).

PCORI invites applications proposing head-to-head comparisons of evidence-based or widely used brief interventions and/or of culturally adaptations of such brief interventions for specific populations of youth. Comparisons of culturally adapted and nonadapted interventions, and of different approaches to cultural adaptation, will be considered responsive. Applicants should clearly specify the comparisons to be included.

- **Multicomponent approaches** (e.g., outreach, screening, identification, brief intervention, care coordination, and follow-up) may be proposed. If the multicomponent approach does not have evidence and is not in widespread use, applicants should describe evidence and/or use for the components and address why the proposed combination of components is expected to be more effective than single components. Applicants also should address the dissemination and sustainability of the multicomponent approach.

\textsuperscript{18} The Congressional Black Caucus - Emergency Taskforce on Black Youth Suicide and Mental Health. \textit{Ring the Alarm: The Crisis of Black Youth Suicide in America.} 2019.
• **Populations of interest** are youth ages 15 to 24 or a subset of ages in this range. Specific youth populations of interest include Black, Latinx, American Indian/Alaska Native, LGBTQ, rural, homeless, and disabilities populations. PCORI is interested in Heterogeneity of Treatment Effects (HTE), and applicants are encouraged to include such analyses when appropriate.

• **Settings:** Study interventions should be administered in settings where patients receive care and should be incorporated into clinical care.

• **Study design:** Randomized controlled trials (RCTs) are preferred; however, well-designed observational studies will also be considered if an RCT is not possible and the proposed approach appropriately controls for confounding. Thoughtful use of new study designs, such as hybrid designs, could speed the translation of research findings into routine practice, identify more effective implementation strategies, and provide more useful information for stakeholders. For this PFA, one of the primary aims must be focused on a CER question, so hybrid type 1 and hybrid type 2 designs may be appropriate. Hybrid type 3 designs, for which the primary aim is implementation research, will not be considered responsive.

• **Interventions:** Evidence-based and/or widely used brief interventions appropriate for youth (age range 15–24) with suicidality should be included. Interventions may include telehealth and/or mHealth with appropriate justification; applicants should describe the evidence or current use of the telehealth and/or mHealth approaches they propose, along with appropriate safeguards.

• **Cultural adaptations:** Cultural adaptation may include elements such as specific language, icons, family involvement, or rituals; specific settings or staff providing interventions; involvement of people with lived experience; and telehealth (apps, text-based, web-based, phone call, video calls). Applicants should describe input and endorsement from the target community.

• **Outcomes of interest** should include suicidal ideation, self-harm, suicide attempts, and deaths from suicide; mental health treatment initiation, engagement in such treatment, satisfaction with treatment, and access to means; coping skills/skills to manage ideation, sense of belonging/connectedness, sense of purpose, hope, and reasons for living; quality of life; autonomy; and daily functioning. Parent/caretaker outcomes are encouraged when appropriate. Applicants should minimally include suicidal ideation and attempts, access to means, and entering and staying in treatment as outcomes with one-year follow-up.

• **Data analysis:** Applicants should present power analyses that include justification of the estimates used. PCORI is specifically interested in HTE. Applicants should clearly describe any planned HTE analyses as well as approaches to handling missing data.

• **Patient safety:** Youth at risk of suicide are an especially vulnerable population, and the protection of youth who participate in these studies are an important consideration in this initiative. Applicants should propose appropriate measures to protect and monitor patient safety, including a Data and Safety Monitoring Board, independent medical monitor, standard clinical protocols for risk, and appropriate study inclusion/exclusion criteria.

• **Stakeholders:** Applicants should demonstrate endorsement of and participation in the project by
patients and other stakeholders who represent the target community.

II. General Requirements for PCORI Research
This section includes information intended to be useful for preparing applications. This guidance explains PCORI’s requirements for scientific and programmatic responsiveness under this funding announcement. For information related to administrative and technical requirements for Letter of Intent and application submission, please consult the PCORI Submission Instructions.

Research Priorities
To be considered responsive, applications must:

- **Describe comparators.** Regardless of the approach being studied, all proposed research projects must compare at least two alternatives. If the applicant proposes “usual care” as a rational and important comparator in the proposed study, then it must be described in detail, coherent as a clinical alternative, and properly justified as a legitimate comparator (e.g., “usual care” is guidelines based). It must also be accompanied by an explanation of how the care given in the “usual care” group will be measured in each patient and how appropriate inferences will be drawn from its inclusion. “Usual care” must be described as mentioned above to ensure that it accounts for geographic and temporal variations and that it has wide interpretability, applicability, and reproducibility.

- **Describe research that compares two or more alternatives, each of which has established efficacy or widespread use.** The application must provide information about the efficacy of the interventions that will be compared; pilot data may be appropriate. If the efficacy or evidence base is insufficient, then data need to be provided to document that the intervention is used widely. Projects aiming to develop new interventions that lack evidence of efficacy or effectiveness will be considered out of scope.

- **Describe research that studies the benefits and harms of interventions and strategies delivered in real-world settings.** PCORI is interested in studies that provide practical information that can help patients and other stakeholders make informed decisions about their health care and health outcomes.

- **Describe consultation with patients and other stakeholders about how the study is answering a critical question.** Explain the pertinent evidence gaps and why the project questions represent decisional dilemmas for patients, caregivers, clinicians, policy makers, and other healthcare system stakeholders. Describe why project outcomes are especially relevant and meaningful endpoints to patients and other stakeholders.

Categories of Nonresponsiveness
PCORI discourages proposals in the following categories and will deem them nonresponsive:

- Instrument development, such as new surveys, scales, etc.

- Development, testing, and validation of new decision aids and tools, or clinical prognostication tools
• Pilot studies intended to inform larger efforts
• Studies that compare patient characteristics rather than clinical strategy options

Consistent with its authorizing law,24 PCORI does not fund research whose findings will include the following:
• Coverage, payment, or policy recommendations
• Creation of clinical practice guidelines or clinical pathways
• Establishment of efficacy. NOTE: Multicomponent approaches for which efficacy has not been established but that include evidence-based or widely used components will be considered responsive.
• Pharmacodynamics
• Natural history of disease
• Basic science or biological mechanisms

Cost Effectiveness and Cost

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 that lead to high costs to individuals or 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
• Address cost-related issues, such as the resources needed to replicate or disseminate a successful intervention
• Evaluate interventions to reduce health system waste or increase health system efficiency

PCORI’s authorizing law was amended by reauthorization legislation25 to include a new mandate to consider the full range of outcomes data, including cost and economic impact outcomes relevant to patients and stakeholders. PCORI is developing principles that will serve as a point of reference for providing guidance to potential applicants on what is included in “the full range of clinical and patient-

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center outcomes relevant to, and that meet the needs of, patients, clinicians, purchasers, and policy makers,” consistent with our authorizing law. Final principles and guidance, informed by robust stakeholder input, are forthcoming.

**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”).

**Avoiding Redundancy**

PCORI encourages potential applicants to review funded research at pcori.org. We intend to balance our funded portfolio to achieve synergy and avoid redundancy where possible.

**Methodological Considerations**

The PCORI Methodology Standards represent minimal requirements for the design, conduct, analysis, and reporting of scientifically valid PCOR. Regardless of study design, applications must adhere to all relevant PCORI Methodology Standards, and all deviations need to be justified. Applicants should address additional best practices for the proposed research approach in the application for PCORI funding.

**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 they can be linked to electronic medical record data from healthcare delivery systems or administrative claims data from public or commercial insurers. In circumstances in which RCTs 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, the National Patient-Centered Clinical Research Network, may be particularly appropriate. Over the 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 supports research that will improve health care and health outcomes. The network currently includes nine clinical research networks, representing more than 100 health systems, two health plan research networks, a coordinating center, and a central office. PCORnet provides access to large longitudinal data sets that enhance the capture of relevant outcomes and provide more detail on specific procedures or treatments, disease severity, and the presence of comorbid illness.
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 patients 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 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 the study
- Documenting 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

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 from project to project based on the patient population, the setting, and the needs of a study. PCORI encourages study teams to be creative in their methods for engaging with research partners. Effective involvement of patients and other stakeholders requires a well-considered engagement plan that includes the goals for engagement and information on who will be involved, what preparation will be provided, points and intensity of involvement, and the decision-making process.

Populations Studied and Recruited

PCORI seeks to fund research that includes diverse populations regarding 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 significance in the absence of diversity; to discuss which subgroups are most important; and to explain 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 previously understudied populations for whom effectiveness information is especially needed, such as hard-to-reach populations or patients with multiple conditions.
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. PCORI has developed the following list of populations of interest to guide our efforts in research and engagement:

- Racial and ethnic minority groups
- Low-income groups
- Women
- Children (0–17 years of age)
- Older adults (65 years of age 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 or numeracy, or limited English proficiency
- Gender and sexual minorities
- Veterans and members of the Armed Forces and their families

Regardless of the population studied, investigators are expected to provide evidence-based estimates regarding the representativeness of the potential pool of participants on which the study will be based, the target sample size, and data availability in light of 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, “Human Subjects Research Policy,” in the Supplemental Grant Application Instructions for All Competing Applications and Progress Reports, 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 the 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 subjects in research.

PCORI requires awardees to ensure that there is a Data and Safety Monitoring Plan, which may include

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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.27

PCORI merit reviewers will examine plans for protection of human subjects in all applications and may provide comments about the plans (see How to Evaluate Human Subjects Protections28). 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 has jurisdiction over 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.29

III. LOI Review

Applying for funding from PCORI is a two-stage process. An LOI must be submitted and an applicant must be invited to submit an application.

LOIs are evaluated based on the following:

- Importance and relevance of the proposed comparison, as evidenced by the rationale presented including the critical evidence gaps identified
- Clarity and credibility of responses to the LOI questions
- The investigators’ prior relevant experience
- Programmatic fit and balance, considering whether the LOI overlaps with previously funded studies or concurrent LOIs and/or applications to a significant degree or, conversely, whether the application fills a gap in the portfolio with certain characteristics, including priority population, methodologies, and other variables

Only applicants whose LOIs are deemed most responsive to this PFA will be invited to submit a full application. A minimum of two PCORI staff members review the LOIs, which are not scored during review.

The LOI Template provides guidance on responding to each item. Please refer to the Submission Instructions for information on how to submit an LOI via PCORI Online.

IV. 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.
- Fund 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.

PCORI merit review is a multiphase process that includes the review panel's preliminary review of full applications and an in-person panel discussion of a subset of applications (identified by PCORI’s program staff and based on the preliminary review and program priorities). After merit review, key steps include post-panel review of the applications by PCORI staff; the Selection Committee’s 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. Note that PCORI may eliminate applications from the review process for administrative or scientific reasons (e.g., nonresponsiveness). 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 scientifically withdrawn 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.

PCORI Merit Review Officers (MROs) recruit each review panel based on the number of invited LOIs and topic areas represented by the invited LOIs. 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.

The table below is designed to help applicants understand how the PCORI merit review criteria align with criteria from other funding organizations with which applicants might be familiar (e.g., NIH). Though PCORI’s criteria do map to most NIH criteria, there are areas where we ask for different information (i.e., PCORI does not include a criterion that tracks to NIH’s innovation criterion but does include criteria evaluating patient-centeredness and engagement), reflecting PCORI’s unique approach.
Below are PCORI’s merit review criteria. PCORI’s merit review panels use these criteria during the preliminary and in-person review phases to evaluate and score all submitted applications and to ensure consistency and fairness in how applications are evaluated.

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

The application should address the following questions:

- Does the application convincingly describe the clinical burden for the population(s) of interest?
- Does the application identify a critical gap in current knowledge as noted in systematic reviews, guideline development efforts, previous research prioritizations, published research, or stakeholder input?
- Does the application identify a critical gap in current knowledge, evidenced by inconsistency in clinical practice and decision making?
- Would research findings from the study have the potential to fill these evidence gaps?

**Criterion 2. Potential for the study findings to be adopted into clinical practice and improve delivery of care**

The application should describe how evidence generated from this study could be adopted into clinical practice and delivery of care by others. The application should also address the following questions:

- Does the application identify who will make the decision (i.e., the decision maker) or use (i.e., the end-user) the study findings (not the intervention) this study produces, such as local and national stakeholders?
- Does the application identify potential end-users of study findings—such as local and national stakeholders—and describe strategies to engage these end-users?
- Does the application provide information that supports a demand for this kind of a study from end-users?
• Would this study’s research findings have the potential to inform decision making for key stakeholders? If so, provide an example. How likely is it that positive findings could be reproduced by others, resulting in improvements in practice and patient outcomes? Identify the potential barriers that could hinder adoption of the intervention by others.

• Does the application describe a plan for how study findings will be disseminated beyond publication in peer-reviewed journals and at national conferences?

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

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

• Does the application describe a clear conceptual framework anchored in background literature that informs the design, key variables, and relationship between interventions and outcomes being tested?

• Does the Research Plan describe rigorous methods that demonstrate adherence to the PCORI Methodology Standards?

• Is the overall study design justified to answer the research question(s)?

• Are the patient population(s) and study setting appropriate for the proposed research question?

• Does the application provide justification that the outcome measures are validated and appropriate for the population?

• Are each of the comparators (e.g., active intervention arm and comparator arm) described clearly and well justified? If “usual care” is one of the arms, is it adequately justified, and will it be sufficiently measured?

• Are the sample sizes and power estimates appropriate? Is the study design (e.g., cluster randomized design, randomized controlled trial, or observational study) accounted for, and is the anticipated effect size adequately justified?

• Is the study plan feasible? Is the project timeline realistic, including specific scientific and engagement milestones? Is the strategy for recruiting participants feasible? Are assumptions about participant attrition realistic, and are plans to address patient or site attrition adequate?

Criterion 4. Investigator(s) and environment

This criterion should assess the appropriateness (e.g., qualifications and experience) of the investigator(s)/team and the environment’s capacity (e.g., resources, facilities, and equipment) to support the proposed project. It should not be an assessment of the institution’s quality.

The application should also address the following questions:

• How well qualified are the Principal Investigators (PIs), collaborators, and other researchers to conduct the proposed activities? Is there evidence of sufficient clinical or statistical expertise (if applicable)?
• Does the investigator or co-investigator have demonstrated experience conducting projects of a similar size, scope, and complexity?

• If the project is collaborative or dual-PI, do the investigators have complementary and integrated expertise? Are the leadership, governance, and organizational structures appropriate for the project?
  o (Dual-PI Option Only) Does the Leadership Plan adequately describe and justify PI roles and areas of responsibility?

• Is the level of effort for each team member appropriate for successfully conducting the proposed work?

• Does the application describe adequate availability of and access to facilities and resources (including patient populations, samples, and collaborative arrangements) to carry out the proposed research?

• Is the institutional support appropriate for the proposed research?

Criterion 5. Patient-centeredness

The application should demonstrate that the study focuses on improving patient-centered outcomes and employs a patient-centered research design (i.e., a design informed or endorsed by patients). (Note: The study can be patient centered even if the end-user is not the patient, as long as patients will benefit from the information.)

The application should also address the following questions:

• Does the application include a thorough description about which outcomes (both benefits and harms) are important to patients, and are those outcomes included in the study plan?

• Does the application provide information that indicates that closing the evidence gap is important to patients and other stakeholders?

• Are the interventions being compared in the study available to patients now, or can they be made available immediately following the study (sustainability)?

• Are the interventions being compared the best options for comparison (including whether they would be chosen by patients and their healthcare providers for managing the condition being studied)?

Criterion 6. Patient and stakeholder engagement

The application should demonstrate the engagement of relevant patients and other stakeholders (i.e., patients, caregivers, clinicians, policy makers, hospital and health system representatives, payers [insurance], purchasers [business], industry, researchers, and training institutions) in the conduct of the study. Quality of engagement should be evaluated based on scope, form, and frequency of patient and stakeholder involvement throughout the research process.

The application should also address the following questions:
• Does the application provide a well-justified description of how the research team incorporates stakeholder involvement? Does the study include the right individuals (e.g., patients, caregivers, clinicians, policy makers, hospital and health system representatives, payers, purchasers, industry, researchers, and training institutions) to ensure that the projects will be carried out successfully?

• Does the application show evidence of active engagement among scientists, patients, and other stakeholders throughout the research process (e.g., formulating questions, identifying outcomes, monitoring the study, disseminating, and implementing)? Is the frequency and level of patient and stakeholder involvement sufficient to support the study goals?

• Is the proposed Engagement Plan appropriate and tailored to the study?

• Are the roles and the decision-making authority of all study partners described clearly?

• Are the organizational structure and resources appropriate to engage patients and stakeholders throughout the project?

In-Person Review

During preliminary review, all administratively and scientifically compliant applications are evaluated and scored by panels of external reviewers based on PCORI’s merit review criteria, including evaluation of adherence to the PCORI Methodology Standards. After preliminary review, PCORI program staff members evaluate panel scores and critiques to identify a subset of applications for merit reviewers to discuss at the in-person review meeting. Not all submitted applications move forward to in-person review.

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

Post-Panel Review

After the in-person meeting, PCORI program staff evaluate final merit review panel scores and comments, identify duplication or synergy among funded projects, and consider the fit of applications within the programmatic vision. Program staff members then recommend projects to a selection committee, which includes members of the Board. 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. This slate is then proposed to the Board for consideration and approval.

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, 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 to PCORI.**

**Summary Statements and Funding Recommendations**

Summary statements are provided to applicants approximately two weeks before funding decisions are announced. **If an application progresses to in-person discussion,** the applicant will receive a summary statement that will include the following:

- In-person panel discussion notes
- Final average overall score
- Preliminary reviewer critiques
- Application quartile, to help applicants understand how their application compared with other discussed applications, as appropriate

Summary statements for applications that do not progress to in-person discussion include only the preliminary reviewer critiques.

Funding recommendations are made by identifying meritorious applications that fit the programmatic needs and that satisfactorily address the merit review criteria while adhering to the PCORI Methodology Standards. Programs also consider the funds allotted for the current funding announcement when deciding which applications to recommend to the Board 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 2021.

**V. 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[^30] (see Data Element Definitions) are required to register, if funded.

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

Any patient registries used in this study 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.

[^30]: Available at https://prsinfo.clinicaltrials.gov/.
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 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 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.

Data Management and Data-Sharing Plan

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

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31 Available at http://www.hhs.gov/ocr/.
In summary, awardee institutions are required to submit to PCORI for peer review a draft final research report that provides the methodological details, describes the main study results, and 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 draft final research report 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.