



Cycle 1 2020 Funding Cycle

Limited PCORI Funding Announcement: Implementation of PCORI-Funded Patient-Centered Outcomes Research Results

Published January 7, 2020

This limited PCORI Funding Announcement (PFA) applies to the funding cycle that closes on April 7, 2020, at 5 pm ET. Submission Instructions, templates, and other resources are available at <https://www.pcori.org/funding-opportunities/announcement/limited-PFA-implementation-pcor-results-cycle1-2020>.



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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Overview

Published	January 7, 2020																
Letter of Intent Deadline	January 28, 2020, by 5 pm (ET) You must submit a Letter of Intent (LOI) to submit a full application. The Patient-Centered Outcomes Research Institute (PCORI) will screen LOIs for responsiveness to this limited PCORI Funding Announcement (PFA) and fit to program goals. Notification of denial or approval to submit a full application will occur no later than February 18, 2020.																
Summary	The intent of this limited PFA is to move evidence developed with PCORI research funding toward practical use in improving health care and health outcomes. PCORI will fund projects that aim to implement patient-centered clinical comparative effectiveness research (CER) results obtained from PCORI-funded studies in decision-making settings and, in selected cases, projects that focus on the dissemination of these findings. This limited PFA gives PCORI investigators the opportunity—following the generation of results from their PCORI-funded research award—to propose the next step(s) for making their research results more useful, actionable, accessible, and available to targeted end-users of these findings.																
Applicant Resources	See https://www.pcori.org/funding-opportunities/announcement/limited-PFA-implementation-pcor-results-cycle1-2020 .																
Key Dates	<table> <tr> <td>Online System Opens:</td> <td>January 7, 2020</td> </tr> <tr> <td>LOI Deadline:</td> <td>January 28, 2020, by 5 pm ET</td> </tr> <tr> <td>LOI Screening Notification</td> <td>February 18, 2020</td> </tr> <tr> <td>Application Deadline:</td> <td>April 7, 2020, by 5 pm ET</td> </tr> <tr> <td>Merit Review:</td> <td>May 2020</td> </tr> <tr> <td>Small Awards Announced:</td> <td>July 2020</td> </tr> <tr> <td>Large Awards Announced:</td> <td>September 2020</td> </tr> <tr> <td>Earliest Project Start Date:</td> <td>November 2020</td> </tr> </table>	Online System Opens:	January 7, 2020	LOI Deadline:	January 28, 2020, by 5 pm ET	LOI Screening Notification	February 18, 2020	Application Deadline:	April 7, 2020, by 5 pm ET	Merit Review:	May 2020	Small Awards Announced:	July 2020	Large Awards Announced:	September 2020	Earliest Project Start Date:	November 2020
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Maximum Project Budget (Direct Costs)	<p>Up to \$1 million total direct costs</p> <p>PCORI will accept applications requesting up to \$1 million in direct costs with clear and adequate justification. Applicants will indicate the funds requested from PCORI when submitting their LOI. PCORI will advise applicants that are invited to submit a full application as to the acceptability of the budget proposed in their LOI.</p> <p>In general, applications requesting budgets larger than \$500,000 in total costs are expected to demonstrably and significantly increase the reach (i.e., the total number of individuals expected to be reached through the proposed implementation project), generalizability (applicability of intervention across different groups, systems, or settings), uptake (use and adoption among more systems, settings, or sites), and overall impact of the evidence proposed for implementation.</p> <p>Note that applications proposing dissemination activities as the focus of the project will be allowed to request budgets up to \$300,000 in total costs. See pages 2-3 of this PFA for more information.</p>																
Maximum Project Period	Up to three years																
Funds Available up to	\$9 million per year																
Eligibility	<i>Evidence Readiness:</i> Applicants must propose a feasible and logical next step(s) that will facilitate real-world uptake and use of a clinically meaningful finding or findings																

associated with a PCORI-funded CER study. Only projects proposing to disseminate or implement findings from PCORI CER studies that (1) tested a research hypothesis and (2) evaluated comparative clinical effectiveness of two or more comparators will be considered responsive to this PFA. **NOTE:** *These requirements do not apply to methods studies.*

PCORI Research Awardees: Recipients of PCORI-funded research awards, including Broad PCORI Awards, Pilot Projects Program Awards, Targeted PCORI Awards, Pragmatic Clinical Study Awards, and PCORI-funded demonstration projects occurring within the National Patient-Centered Clinical Research Network (PCORnet®) infrastructure (e.g., ADAPTABLE and obesity trials) are eligible to respond to this PFA. Applications associated solely with Eugene Washington PCORI Engagement Awards and Pipeline to Proposal Awards are not eligible for this limited PFA. **NOTE:** *Although eligible to apply, Pilot Projects must still meet all of the PFA requirements to be considered responsive. Some of the requirements (e.g., evidence readiness) may be difficult for Pilot Projects to satisfy.*

Organization: Private-sector research organizations, including any nonprofit or for-profit organization; public-sector research organizations, including any university or college hospital or healthcare system; any laboratory or manufacturer; or any unit of local, state, or federal government may submit applications. 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. Organizations may submit multiple funding applications. Individuals may not apply.

Personnel: The Principal Investigator (PI) of the original PCORI-funded research project must write a Letter of Support if he or she is not the proposed PI of the current application. If the organization submitting an application in response to this PFA is not the original PCORI awardee institution, then the PI of the original PCORI-funded study—or another member of the original research team who played a significant role—must be involved as project personnel in the proposed implementation project.

Timing: Applicants must propose to disseminate or implement PCORI results that are available at the time of the LOI deadline. Specifically, (1) a draft final research report (DFRR) pertaining to the original PCORI-funded research award must have been accepted for entry into the peer-review process by PCORI, or (2) a manuscript reporting the results of the PCORI-funded study being proposed for implementation must have been formally accepted for publication by a peer-reviewed scientific journal before the LOI deadline for this PFA.

Applicants relying on submission of the DFRR to meet the above requirement should be aware that PCORI will administratively withdraw LOIs submitted before PCORI's acceptance of the DFRR for entry into the peer-review process. Note that it typically takes six weeks to process, revise, and accept **high-quality DFRRs** into PCORI's peer-review process; applicants should plan accordingly.

Applicants relying on publication of a peer-reviewed manuscript must include formal documentation of acceptance for publication of the manuscript with their LOI submission, or PCORI will administratively withdraw the LOI.

Applicants will have **one opportunity** to resubmit an application that was reviewed and not funded in a previous cycle. See the resubmission policy (page 3) for more detail.

Review Criteria	<p>Please note that the merit review criteria for this PFA are different from those PCORI uses when reviewing research applications. The following are the merit review criteria for this PFA:</p> <ol style="list-style-type: none"> 1. Importance of research results 2. Readiness for implementation 3. Technical merit of the proposed implementation project 4. Project personnel and environment 5. Patient-centeredness 6. Stakeholder engagement
Contact Us	<p>Programmatic Inquiries: Please contact the PCORI Dissemination & Implementation Helpdesk at disseminationquestions@pcori.org. PCORI will respond within two business days. However, we cannot guarantee that all questions will be addressed in two business days prior to an LOI or application deadline.</p> <p>Administrative, Financial, or Technical Inquiries: Please contact the PCORI Helpdesk at pfa@pcori.org. PCORI will respond within two business days. Please note that during the week of a deadline, response times may exceed two business days. Applicants may also call the PCORI Helpdesk (202-627-1885). It is the applicant's responsibility to submit the application on or before the application deadline.</p>
Other	<p>Deadlines are at 5 pm (ET). If deadlines fall on a weekend or a federal holiday, the deadline will be 5 pm the following Monday or the next day after the federal holiday.</p>

New or revised for the Cycle 1 2020 funding cycle:

- Revised the [merit review criteria](#) for this PFA.
- All policies and PCORI research requirements have been moved into a new section, called [PCORI Policies that Govern Awardees Related to Data Access, Privacy, and Public Reporting](#), at the end of this document.
- All instructional information related to templates or the submission process have been removed from the PFA and now only exist in the Submission Instructions (formerly known as the Application Guidelines).
- The [Submission Instructions](#) (formerly known as the Application Guidelines) for this PFA have been updated, including changes to templates.

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I. Introduction

Summary of Program

The Patient-Centered Outcomes Research Institute (PCORI) launched this funding initiative to support the investigator-initiated implementation of patient-centered, comparative clinical effectiveness research (CER) findings obtained from PCORI-funded studies.

This funding opportunity gives PCORI awardees the chance, following the generation of results from their PCORI-funded research award, to propose next steps to move their findings into practice, drawing on the knowledge and experience they gained during their PCORI-funded research award.

PCORI seeks to fund implementation projects that incorporate active strategies that will lead to uptake and integration of evidence into real-world practice settings. Strategies must address adaptation of findings to facilitate uptake in the specific proposed settings, scale-up (to reach larger numbers), and scale-out (to reach broader audiences, including diverse populations and settings), as applicable. Applications must include a rigorous evaluation plan that documents successful execution of the implementation strategy and the impact of the implementation activities on health care and health outcomes as feasible and appropriate within the project scope. As part of these strategies, implementation activities may include the development of tools and materials for actively implementing evidence, but these should not be the primary activities proposed.

Applicants will be expected to work closely with relevant patient and healthcare stakeholder groups, as well as with implementation experts, to propose implementation strategies that address barriers and obstacles to evidence uptake, integration into practice, and maintenance of the changes as implemented. Proposed implementation strategies should incorporate the perspectives and experiences of patients and stakeholders, including individuals living with the disease or condition of interest.

Stakeholder involvement in the proposed projects will be critical to their success. Applicants will need to demonstrate commitment from proposed implementation sites, including frontline staff critical to the success of the project, to improve healthcare quality and a willingness to invest in the evidence being implemented. This commitment from the sites and frontline staff provides a supportive context and culture for undertaking the proposed project. Further, applicants will be expected to work with relevant regional and national stakeholder organizations, as their support will be critical to extending the impact of PCORI-funded evidence to broader venues based on the experience gained in these projects.

In some cases, applicants may choose dissemination activities, rather than implementation activities, as the focus of their project. PCORI will fund dissemination projects when these activities comprise a logical and direct next step to promoting the uptake of evidence by specific target audiences.

Background

US healthcare organizations and agencies in the public and private sectors spend billions of dollars on research and service delivery programs each year, yet patients and stakeholders often lack sufficient information to make decisions regarding the most effective treatment strategies for their particular

circumstances.¹ The gap between what is known to optimize healthcare delivery and what is actually implemented in everyday practice remains one of the most important issues hindering the healthcare system and public health.^{2,3} Finding ways to enhance awareness and knowledge of useful and relevant information to help people and organizations make decisions (dissemination) and put them into practice (implementation) is essential to improving health care and health outcomes.

The concepts of Dissemination & Implementation (D&I) are sometimes used interchangeably to describe activities aimed at bringing evidence into practice. For the purposes of this limited PCORI Funding Announcement (PFA), PCORI makes the following distinction between dissemination and implementation:

- *Dissemination* is the intentional, active process of identifying target audiences and tailoring communication strategies to increase awareness and understanding of evidence and to motivate its use in policy, practice, and individual choices.⁴
- *Implementation* is the deliberate, iterative process of integrating evidence into policy and practice by adapting evidence to different contexts and facilitating behavior change and decision making based on evidence across individuals, communities, and healthcare systems.⁴

This PFA has the primary focus of funding projects aligned with the above definition of *implementation*—that is, to adapt evidence as appropriate for specific contexts, incorporate that evidence to inform decisions, and integrate the evidence into workflow or other processes that support its use in a sustainable way. Selected projects focusing on *dissemination* may also support the goals of this initiative.

Dissemination and implementation share the ultimate goal of encouraging the use of evidence in individual decision making, policy, and practice. These processes involve stakeholder engagement and partnerships with people and organizations, and are improved by ongoing evaluation.

For Cycle 1 2020, this PFA will consider projects aligned with the above definition of *dissemination* – that is, to spread knowledge and awareness of evidence from PCORI-funded CER studies and increase motivation and ability to use it, in cases where dissemination activities, rather than implementation, comprise the most logical next step for promoting the uptake of evidence. For example, a dissemination project may be appropriate when clinicians and patients would benefit from increased awareness of evidence but when no change in practice is warranted.

- Consistent with this definition of dissemination as an active process, this PFA will not support projects primarily dependent on passive dissemination strategies (sometimes called research diffusion), such as untargeted mass mailings, publication of study findings, or untargeted

¹ Grimshaw JM, Eccles MP, Lavis JN, Hill SJ, Squires JE. Knowledge translation of research findings. *Implementation Sci.* 2012;(7):50. doi:10.1186/1748-5908-7-50

² Meissner HI, Glasgow RE, Vinson CA, et al. The U.S. training institute for dissemination and implementation research in health. *Implementation Sci.* 2013;(8):12. doi:10.1186/1748-5908-8-12

³ Green LW, Ottoson JM, Garcia C, Hiatt RA. Diffusion theory and knowledge dissemination, utilization, and integration in public health. *Annu Rev Public Health.* 2009;(30):151-174. doi:10.1146/annurev.publhealth.031308.100049

⁴ PCORI Dissemination & Implementation Mathematica Framework. <http://www.mathematica-mpr.com/~media/publications/pdfs/health/pcori%20di%20framework%20draft.pdf>.

presentations to heterogeneous groups.

- Dissemination-focused projects should not exceed \$300,000 in total project costs. These projects undergo internal PCORI programmatic review and are approved for funding by PCORI's Chief Engagement and Dissemination Officer (see pages 4 and 10).

Potential Approaches

PCORI is seeking projects that propose feasible and well-informed strategies that actively integrate evidence from PCORI-funded CER studies into real-world settings, with the aim of increasing its accessibility, usefulness, uptake, and/or impact among targeted end-users. Specific strategies will vary based on a host of factors, including the finding being disseminated/implemented, the population(s) being targeted, and the goals of the proposed project. PCORI encourages applicants to work closely with relevant stakeholder groups to identify appropriate D&I strategies. Examples of appropriate project activities include, among others, efforts to do the following:

- Adapt the content, format, or vehicle for delivering CER research evidence to improve its penetration and use at the policy, health system, clinical practice, caregiver, and patient levels.
- Incorporate results of PCORI-funded research into decision-making settings for patients, providers, policy makers, and other stakeholders.
- Demonstrate the capacity and ability to take CER research evidence to scale, promoting broader uptake in diverse settings and populations.
- De-implement or reduce the use of interventions that are not evidence based, have been widely adopted prematurely, or are harmful or wasteful.

While recognizing that adapting evidence is usually a critical component of successful implementation projects, note that the primary focus, including allocation of time and resources, of the proposed project should be on activities that directly support the integration and use of the evidence in practice. Applications proposing to adapt a finding or product without a plan to actively implement it will be considered nonresponsive.

Collaborations

Applicants may consider proposing projects that involve collaboration to implement the results of multiple related PCORI-funded research studies. Collaborative implementation projects may take different forms. At a minimum, a collaborative project must involve the partnership of two or more PCORI-funded investigators partnering to implement the collective results of two or more PCORI-funded research studies that address a single or closely related condition, population, decision dilemma, or evidence gap. Collaborative projects must have demonstrated support from the Principal Investigator (PI) of each PCORI-funded study whose findings are being implemented in the collaborative implementation project. Please note that participation in a collaborative project does not preclude individual investigators from submitting a separate, individual implementation application through this mechanism; however, investigators will be expected to provide a strong justification that their individual implementation projects do not duplicate activities proposed in the collaborative implementation project.

Resubmissions

Applicants will have **one opportunity** to resubmit an application that completed the merit review process (i.e., for which the applicant received a summary statement) and was not funded in a previous cycle. Applicants may not resubmit an application for a previously submitted and reviewed application until they have received merit review feedback (a summary statement) from the initial submission. All resubmitted applications require submission of a new Letter of Intent (LOI); applicants are responsible for ensuring their LOI is administratively and programmatically responsive to the current PFA.

Resubmitted applications must include a Resubmission Letter. PCORI will deem applications that do not meet these requirements as nonresponsive and will withdraw them from merit review. LOIs that are not invited to submit a full application by PCORI do not count as a submission or resubmission.

Funds Available

PCORI has devoted up to \$9 million in total annual costs under this limited PFA. The total amount awarded and the number of awards made will depend on the quality, duration, and costs of the applications received. The maximum proposed budget for individual implementation projects is \$1,000,000 in direct costs, and the maximum project period is up to three years. PCORI will accept applications requesting up to \$1,000,000 in direct costs with clear and adequate justification. Applicants will indicate the funds requested from PCORI when submitting their LOI. PCORI will advise applicants that are invited to submit a full application as to the acceptability of the budget proposed in their LOI.

In general, applications requesting budgets larger than \$500,000 in total costs are expected to demonstrably and significantly increase the reach (i.e., the total number of individuals expected to be reached through the proposed implementation project), generalizability (i.e., the applicability of intervention across different groups, systems, or settings), uptake (i.e., the use and adoption among more systems, settings, or sites), and overall impact of the evidence proposed for implementation.

Note that applications proposing dissemination activities as the focus of the project will be allowed to request budgets up to \$300,000 in total costs. See pages 2-3 of this PFA for more information.

II. Guidance for Preparing Applications

In developing an implementation strategy and corresponding PCORI application, applicants should pay attention to four fundamental concepts: evidence context, setting, engagement, and evaluation.^{5,6,7,8,9}

- *Evidence context* refers to the body of existing evidence relevant to the PCORI-funded research finding. It is seldom the case that a single finding warrants implementation independent from

⁵ Pentland D, Forsyth K, Maciver D, et al. Key characteristics of knowledge transfer and exchange in healthcare: integrative literature review. *J Adv Nurs*. 2011;67(7):1408-1425.

⁶ Greenhalgh T, Robert G, Macfarlane F, Bate P, Kyriakidou O. Diffusion of innovations in service organizations: systematic review and recommendations. *Milbank Q*. 2004;82(4):581-629.

⁷ Glasgow RE, Vinson C, Chambers D, Khoury MJ, Kaplan RM, Hunter C. National Institutes of Health approaches to dissemination and implementation science: current and future directions. *Am J Public Health*. 2012;102(7):1274-1281.

⁸ Brownson RC, Colditz GA, Proctor EK. *Dissemination and Implementation Research in Health: Translating Science to Practice*. New York, NY: Oxford University Press; 2012.

⁹ Neta G, Glasgow RE, Carpenter CR, et al. A framework for enhancing the value of research for dissemination and implementation. *Am J Public Health*. 2015;105(1):49-57.

other research findings. Applicants should explain how the current finding supports, augments, or differs from related evidence and how the proposed implementation plan takes account of the full body of related information.

- *Setting*. The proposed project should carefully consider the setting in which the implementation will take place (e.g., health system, organization, or community). The focus of investigators' efforts should be the logical next implementation steps associated with PCORI-funded research results. At a minimum, the project should move findings out of a controlled research setting to a more general setting, demonstrating the proposed strategy's ability to bring PCORI-funded research findings to the targeted end-users in ways that promote uptake.⁶ Successful project designs will consider existing clinical workflows and reflect relationships and roles among the stakeholders within the setting.
- *Engagement* involves incorporating into project design the perspectives and experiences of interested patients and stakeholders, including individuals living with the disease or condition of interest, as well as the host delivery systems and settings in which applicants intend to implement their work. Implementation efforts will not succeed without the active involvement of those central to the implementation activities, including the targeted end-users. Stakeholders should be appropriately engaged in both planning and executing the implementation strategy, and particularly in ensuring that evidence and strategies are tailored appropriately to the setting. Plans for engaging stakeholders should reflect a spirit of partnership and reciprocity.
- *Evaluation* is essential to understanding how and why implementation activities are or are not successful, as a basis for future replication, adjustment, or reconsideration of strategies. Evaluation is also critical for documenting the continued effectiveness (i.e., in the new setting or among a new population) of the intervention being implemented. Evaluation activities should start at the beginning of the project and should assess an appropriate balance of measurable outcomes that document both the successful performance of implementation activities in getting the intervention into practice (i.e., reach, adoption, and fidelity) and the impact of these activities on end-users in the immediate and longer term (i.e., changes in knowledge, satisfaction, behavior, healthcare utilization, and health outcomes). In general, evaluation plans that exclusively reflect impact on setting characteristics and/or implementation process outcomes will not be considered sufficient. The following resources may be helpful for identifying an appropriate evaluation strategy.¹⁰

Specific Requirements

Applications must meet the following requirements:

- Propose to disseminate or implement findings from PCORI CER studies that (1) tested a research hypothesis and (2) evaluated comparative clinical effectiveness of two or more comparators. (**Note:** These requirements do not apply to methods studies.)

¹⁰ Tabak RG, Khoong EC, Chambers DA, Brownson RC. Bridging research and practice: models for dissemination and implementation research. *Am J Prev Med.* 2012;43(3):337-350.

- Restate the hypotheses from your original PCORI-funded research study, the primary outcomes, and the differences the study was powered to detect. Then clearly describe the key findings as they relate to these hypotheses, supported by the required tables and figures. Investigators should discuss how the study findings relate to the body of evidence in the existing literature and current state of knowledge on the particular questions. Further, the investigator should identify the decision-making context in which the research findings are relevant, beyond the study setting. The findings must be applicable and generalizable to this context.
- Target patients, clinicians, or other decision makers and healthcare stakeholders who can benefit directly from using the evidence that is the focus of the project or who are a critical link to achieving changes in health outcomes or health care.
- Describe why the findings proposed for D&I are relevant to these targeted end users and describe the investigator's relationship to these end users (and/or to partnering organizations able to reach them), as well as experience and track record in bringing evidence to them.
- Propose logical and feasible next step(s) for dissemination/implementation of clinically meaningful CER finding(s) to improve CER finding accessibility, usefulness, uptake, and/or impact among targeted end-users. (**Note:** For the purposes of this limited PFA, a research finding includes any tools or other products that may have been developed or refined as part of the original PCORI-funded study.)
- Propose sites and settings, in which dissemination/implementation will occur, that have a demonstrated commitment to improving healthcare quality and a willingness to invest in the proposed strategy, such that they provide a supportive context and culture for undertaking the proposed project.
- Propose dissemination/implementation in diverse geographical and practice settings, including, but not limited to, networks of primary care, specialty care, acute care, and community-based care settings.
- Propose a well-justified and feasible plan for improving the uptake and impact of the PCORI-funded research findings among the targeted end-users and settings. Propose an implementation strategy that:
 - Addresses barriers and obstacles to evidence uptake, integration into practice, and maintenance of the changes as implemented.
 - Is guided by an established conceptual model or framework and, where possible, by evidence regarding effective strategies for implementing evidence-based practices and interventions.
 - Incorporates the perspectives and experiences of patients and stakeholders, including individuals living with the disease or condition of interest.
 - Has the potential for use and scalability beyond the targeted sites/settings. The strategy

should be sustainable in the context of relevant payment models.

- Significantly increase the reach (i.e., the total number of individuals expected to be reached through the proposed dissemination/implementation project), generalizability (i.e., the applicability of intervention across different groups, systems, or settings), uptake (i.e., the use and adoption among more systems, settings, or sites), and overall impact of the evidence proposed for implementation.
- Applications should describe the projected reach of their D&I initiatives in terms of the following:
 - *Absolute Number*: Total number of individuals (whose awareness and knowledge will be meaningfully increased and whose care experience and health outcomes you expect to ultimately change) who will be reached in the immediate dissemination/implementation initiative.
 - *Proportion (where relevant)*: Expected reach of this initiative relative to the broader population of individuals who stand to benefit from the results being disseminated/implemented. (This measure is particularly relevant for proposals designed to reach a significant proportion of the relevant target population regionally or nationally.)
 - *Representativeness*: Consideration of how those being targeted by this initiative are similar to or different from the broader population of individuals who stand to benefit from the results being disseminated/implemented. Address the potential of the proposed project to inform future D&I efforts, leading to broader uptake of the PCORI-funded research findings.
- Describe the potential impact of uptake of these findings by the targeted end users.
- Demonstrate comprehensive and meaningful involvement of relevant stakeholders.
 - Describe how frontline staff, care providers, and leadership of host delivery settings have been included in the development of the proposal. Demonstrate the commitment of those at the leadership level, as well as those responsible for delivering the intervention or directly supporting the project activities, to participate as meaningful partners throughout the proposed project. For projects focusing on dissemination, describe how the project is leveraging trusted sources of information.
 - Demonstrate involvement of relevant regional and national stakeholder organizations whose support will be critical to extending the impact of the PCORI-funded research findings to broader venues beyond the proposed project.
- Propose a rigorous evaluation plan
 - Implementation projects should include an evaluation plan that focuses on an appropriate balance of measurable outcomes that document both the successful performance of implementation activities in getting the intervention into practice (i.e., reach, adoption, and fidelity) and the impact of these activities on end-users in the immediate and longer

term (i.e., changes in knowledge, satisfaction, behavior, healthcare utilization, and health outcomes).

- Dissemination projects should, at a minimum, document the reach (in absolute numbers) among the targeted end users and settings, as well as include metrics to assess the extent to which project goals were accomplished using validated measures whenever available.

Nonresponsiveness

PCORI will consider LOIs and applications nonresponsive to this PFA, and will administratively withdraw them, if the project proposes to do any of the following:

- Conduct new research, as opposed to implementing research findings obtained from completed PCORI-funded studies and evaluating the success of those implementation efforts. Projects proposing to perform CER are **not of interest** under this PFA and will cause an LOI or application to be considered nonresponsive.
- Disseminate or implement findings that are not associated with a PCORI-funded CER or methods study.
- Translate or adapt a finding without actively disseminating/implementing it.
- Develop or validate a new tool or system for patients or clinicians without the primary purpose of actively implementing evidence from the PCORI-funded study. PCORI will consider modification or adaptation of tools and systems previously found to be effective and proposed as the primary mechanism for actively implementing evidence, as long as the modification/adaptation is not the primary activity proposed.
- Use contract funds to pay for the cost of the interventions being implemented in the project. In general, PCORI does not pay for the cost of the interventions being implemented in the projects it funds. Intervention costs include, but are not limited to, salary and time compensation for personnel who are delivering the intervention, as well as equipment and other material costs associated with delivering the intervention. These are considered direct patient care costs, and PCORI expects these costs to be covered by the healthcare delivery system or other interested payers. PCORI encourages all applicants to find support from sites, payers, stakeholders, and so on, in the payment or cost sharing of the interventions. Only under special circumstances will PCORI consider, as an exception, coverage of patient care intervention costs. If you are requesting the use of PCORI funds for any portion of these costs, this should be clearly described in your LOI. Invited applications must include a detailed justification (in the Budget Justification Template) outlining the importance of the request to the project's overall success and to the sustainability and implementation once the project is completed (i.e., how these costs will be covered in the future, post-PCORI funding, for implementing the interventions not only at the sites participating in the study but also in other communities and healthcare settings). Such a justification, however, will not guarantee that PCORI will approve the costs.

For information related to administrative and technical requirements for Letter of Intent and application

submission, please consult the PCORI [Submission Instructions](#) for this PFA.

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](#),¹¹ issued by the US Department of Health and Human Services. Awardees must also comply with appropriate state, local, and institutional regulations and guidelines pertaining to the use of human subjects in research.

Applicants should consult the [PCORI Policy on Data and Safety Monitoring Plans for PCORI-Funded Research](#)¹² to determine whether a Data and Safety Monitoring Plan, as well as Data and Safety Monitoring Board, may be needed for their proposed implementation project. Applicants may be asked to submit a full data and safety monitoring plan upon award, depending on the nature of the proposed project.

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](#)). Reviewers’ comments on human subject research are not reflected in the overall application score, but PCORI staff may use them during potential funding negotiations. Final determinations about adequacy of human subject protections rest with the Institutional Review Board(s) that has jurisdiction over the study.

The awardee institution or organization, 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

For those projects requiring human subject protection, 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 frequently asked questions are available on the [NIH website](#).¹³

III. Letter of Intent (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.

Responsive applicants must thoroughly address all LOI fields according to the instructions in the LOI Template. PCORI will screen all LOIs for programmatic responsiveness and to ensure compliance with the [PCORI Submission Instructions](#). A minimum of two PCORI staff review the LOIs, which are not scored during review. PCORI invites only applicants whose LOIs are most responsive to this limited PFA to submit a full application. PCORI will not invite nonresponsive LOIs, including those submitted using an

¹¹ See <http://grants.nih.gov/sites/default/files/supplementalinstructions.docx>. Accessed January 3, 2019.

¹² See <http://www.pcori.org/sites/default/files/PCORI-Policy-Data-Safety-Monitoring-Plans.pdf>

¹³ See <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-08-054.html>. Accessed January 3, 2019.

incorrect LOI template and those not adhering to the [Submission Instructions](#), to submit a full application. Please refer to the [Submission Instructions](#) for due dates and 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 lead to increased use and uptake of evidence from PCORI-funded studies and, ultimately, lead to improved health care and health outcomes.
- Ensure 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 implementation projects reflect the interests and views of patients and other stakeholders and those who care for them, and have strong technical merit.

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 (based on the preliminary review and program priorities), and programmatic review and recommendation to the Office of the Chief Engagement and Dissemination Officer for funding approval. Projects with total budgets of \$500,000 and over are presented to the Engagement, Dissemination, and Implementation Committee for endorsement and to the Board of Governors for funding 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 programmatic reasons (e.g., nonresponsiveness) or for administrative reasons. An application may be administratively withdrawn if it is incomplete; is 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. Note that applications proposing dissemination-focused projects undergo internal PCORI programmatic review (i.e., these applications do not undergo the PCORI Merit Review process) and are approved for funding by PCORI's Chief Engagement and Dissemination Officer. Funding decisions for dissemination-focused applications will be announced no later than September 2020.

All other responsive applications will undergo PCORI's Merit Review process. PCORI Merit Review Officers (MROs) recruit each merit review panel based on the number and type of topic areas represented by 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.

Application Review Criteria

Below are PCORI's merit review criteria for this limited PFA. PCORI's review panels use these criteria

during the preliminary and in-person phases to score and evaluate all submitted applications. **Please note that the merit review criteria for this PFA are different from those used to review applications for other PFAs.**

Criterion 1. Importance of research results

- Does the application sufficiently describe the original evidence gap that the PCORI-funded research addressed, and how the findings from this research address this gap?
- Are the research results proposed for implementation clearly described? Does the application describe the clinical relevance and strength of the findings from the PCORI-funded study proposed for implementation?
- Does the application sufficiently discuss how the PCORI-funded research results augment, strengthen, or complement the existing body of evidence? If the results contradict the existing evidence base, does the application address and justify the appropriate next steps, whether further research, dissemination, or changes in practice?

Criterion 2. Readiness for implementation

- Does the application describe how further uptake of these results, beginning with the project proposed, will lead to a change in practice and improved health care and health outcomes?
- Is the proposed implementation project an appropriate next step toward integrating and using the evidence in real-world settings? What will this next step accomplish, e.g., adapting an intervention or incorporating evidence to promote uptake in practice settings, reaching larger numbers of end-users, and/or reaching broader audiences including diverse populations and settings?
- Have the proposed implementation sites been identified? If not, has the applicant provided a rationale for why this is not possible and acceptable assurances that all implementation sites can be activated within the initial project phase?
- Does the application sufficiently address the relevance of the PCORI-funded evidence proposed for implementation to the targeted end-users and implementation settings?
 - Does the application sufficiently describe the group that will be the target of the proposed implementation activity? Does it describe the setting in which the implementation will take place? Are the PCORI-funded results generalizable to these targeted users and settings?
 - Are these targeted end-users and settings representative of additional audiences beyond this proposed implementation project?

Criterion 3. Technical merit of the proposed implementation project (project design and evaluation)

- Does the application provide a clear approach for implementing the described PCORI-funded research results?
- Are the chosen implementation strategies appropriate for this effort? Consider the extent to

which they are tested, evidence based, and consistent with principles and findings from implementation science.

- Do the proposed strategies consider factors that may help or hinder the integration of the PCORI-funded research results in the proposed project, including specific barriers to user implementation and how to mitigate them?
- Are the proposed project activities clearly described, and are these activities likely to result in successful uptake of the evidence and lead to meaningful changes in practice and improvements in health care and health outcomes?
- If the applicant is proposing to adapt an effective intervention, is the adaptation well justified? Does the adapted intervention capture the core elements of the original tested intervention?
- Does the application propose appropriate measures and describe the plan for evaluating success in sufficient detail, including an appropriate balance of measurable outcomes that document both:
 - the successful execution of implementation activities (i.e., reach, site-level adoption, and fidelity), and
 - the impact of these activities on end-users in the immediate and longer term (i.e., changes in knowledge, satisfaction, behavior change, healthcare utilization, and health outcomes)?
- Does the application use a D&I framework or model to inform the project design and evaluation outcomes? Alternatively, does the application adequately describe a logic pathway showing how the proposed implementation approach is likely to lead to meaningful changes in knowledge, behavior, and practice?
- Does the application address scalability, including a clear path for future efforts to bring these research results toward yet wider use across more systems, settings, or sites?
- Are the proposed timeline and specific project milestones realistic?

Criterion 4. Project personnel and environment

This criterion should assess the appropriateness (e.g., qualifications and experience) of the project personnel/team and the capacity of the environment to support the proposed project.

- How well qualified is the project team (e.g., PIs, collaborators, and other stakeholders) to conduct the proposed activities? Does the application describe the project team's expertise relevant to moving evidence into practice?
- Does the investigator (or co-investigator) have demonstrated experience conducting projects of a similar size, scope, and complexity?
- (Dual-PI option only) Does the Leadership Plan adequately describe and justify roles and areas of responsibility of the PIs? Specifically, do the investigators have complementary and integrated expertise? Further, are the leadership, governance, and organizational structures

appropriate for the project?

- Is the level of effort for each team member appropriate for successful conduct of the proposed work?

Criterion 5. Patient-centeredness

- Does the application describe how the proposed implementation project has the potential to help people make more informed healthcare decisions or to improve healthcare delivery and/or health outcomes?

Criterion 6. Stakeholder engagement

- Does the application demonstrate that the relevant stakeholder perspectives—including those of the relevant patients or caregivers—have informed the development of the proposal and describe how these stakeholders will be meaningfully engaged throughout the project?
- Does the application demonstrate that decision makers at the proposed healthcare systems and settings in which implementation will occur are sufficiently committed to the proposed implementation project, as well as sustaining successful interventions beyond the PCORI-funded project? Does the application describe how these decision makers will be meaningfully engaged throughout the project?
- Does the application demonstrate that personnel (e.g., the frontline staff delivering the intervention or directly supporting the implementation activities) at the proposed implementation sites are clearly interested in the proposed implementation project and are committed to participating as active partners in the project? Have these staff provided input on, or endorsed, the activities they will undertake during the proposed project?
- Does the application indicate the relevant regional or national stakeholder organizations whose support will be critical to extending the impact of the PCORI-funded research findings to broader venues? Does the application describe how the project will engage or work directly with these stakeholders?

In-Person Review

During preliminary review, PCORI merit review panels evaluate all administratively compliant applications and score them based on PFA-specific merit review criteria. After completing the preliminary review, PCORI program staff evaluate panel scores and written application critiques to identify the applications with the strongest potential to promote and facilitate the uptake and use of PCORI evidence in real-world settings; these applications will be discussed by merit reviewers at the in-person review meeting. Not all submitted applications move on to in-person review.

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

Post-Panel Review and Funding Recommendations

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. PCORI program staff also consider the funds allotted for the current PFA when deciding which applications to recommend for funding. PCORI program staff then recommend the most meritorious projects to the Office of the Chief Engagement and Dissemination Officer for funding approval. Projects with total budgets of \$500,000 and over are presented to the Engagement, Dissemination, and Implementation Committee (EDIC) for endorsement and to the Board of Governors for funding approval. The EDIC, a subcommittee of PCORI's Board of Governors, governs the D&I program (including its funded projects portfolio).

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 to PCORI.**

Summary Statements

Applicants whose proposals undergo PCORI's Merit Review process receive summary statements at least one month before funding decisions are announced. **If an application progresses to in-person discussion**, the applicant will receive a summary statement that includes the following:

- In-person panel discussion notes
- Final average overall score
- Preliminary reviewer critiques

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

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:

PCORI Public Access Policy

PCORI requires all awardees to adhere strictly to PCORI's publication policies, which will be shared with awardees within the 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](#)¹⁴ 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](#).¹⁵

Publication and Other Sharing of Information

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

¹⁴ Available at <http://www.hhs.gov/ocr/>.

¹⁵ Available at <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-03-025.html>.