Cycle 2 2020 Funding Cycle

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

Published May 5, 2020

This limited PCORI Funding Announcement (PFA) applies to the funding cycle that closes on August 31, 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-cycle2-2020.
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.
Overview

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<tr>
<th>Published</th>
<th>May 5, 2020</th>
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<tr>
<td>Summary</td>
<td>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.</td>
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<td>Key Dates</td>
<td>Online System Opens: May 5, 2020</td>
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<td>LOI Deadline: June 18, 2020, by 5 pm (ET)</td>
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<td>LOI Screening Notification: July 13, 2020</td>
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<td>Application Deadline: August 31, 2020, by 5 pm (ET)</td>
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<td>Merit Review: October 2020</td>
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<td>Small Awards Announced: January 2021</td>
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<td>Large Awards Announced: February 2021</td>
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<td>Earliest Project Start Date: April 2021</td>
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<td>Maximum Project Budget (Direct Costs)</td>
<td>For implementation projects: Up to $1 million in total direct costs, with clear and adequate justification. Applicants will indicate the funds requested from PCORI when submitting their Letter of Intent (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 are expected to demonstrably and significantly increase the reach of the evidence.</td>
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<td>Maximum Project Period</td>
<td>Up to three years</td>
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<td>Funds Available Up To</td>
<td>$9 million per year</td>
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<td>Eligibility</td>
<td>Evidence Readiness: 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.</td>
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<td>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.</td>
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PCORI Cycle 2 2020 Limited PFA: Implementation of PCORI-Funded Patient-Centered Outcomes Research Results
**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 for more detail.

<table>
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<tr>
<th>Review Criteria</th>
<th>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:</th>
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<td>1. Importance of research results</td>
<td>2. Readiness for implementation</td>
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<td>3. Technical merit of the proposed implementation project</td>
<td>4. Project personnel and environment</td>
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<td>5. Patient-centeredness</td>
<td>6. Stakeholder engagement</td>
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**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.

**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.

New or revised for the Cycle 2 2020 funding cycle:

- Updated guidance for applicants proposing dissemination-focused projects.
- Updated merit review criteria
- Updated LOI and Project Plan Template, see the Submission Instructions (formerly the Application Guidelines) for this PFA for more information
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I. Introduction

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

Promoting the uptake of research findings is part of the Patient-Centered Outcomes Research Institute’s (PCORI) mission to improve the quality and relevance of evidence available to help patients, caregivers, clinicians, and others make better-informed health decisions. PCORI dissemination and implementation programs and activities are designed to promote awareness of findings from PCORI-funded research and to facilitate the uptake of these findings in real-world practice settings.

This funding announcement supports the investigator-initiated implementation of patient-centered, comparative clinical effectiveness research (CER) findings obtained from PCORI-funded studies.

Summary of Program

The intent of this limited PCORI Funding Announcement (PFA) is to move evidence developed with PCORI research funding toward practical use in improving health care and health outcomes. 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 implementation 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 implemented, the population(s) being targeted, and the goals of the proposed project. Implementation projects will include rigorous evaluation plans that document both the successful performance of the proposed 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).

Applicants are expected to work closely with the appropriate stakeholders, including implementation experts and relevant patient and healthcare stakeholder groups, to identify appropriate implementation strategies that address barriers and obstacles to evidence uptake, integration into practice, and maintenance of the changes as implemented. Applicants are also expected to have engaged with proposed implementation sites and obtained evidence of buy-in and commitment (both at the leadership level and from the frontline staff who will be responsible for delivering the intervention) prior to the start of the project.

In cases in which applicants can justify that heightened knowledge and awareness is essential to or will

accomplish uptake of evidence, applicants may propose projects that focus on dissemination of findings from PCORI-funded CER studies rather than on implementation.

Defining Dissemination and Implementation

The concepts of dissemination and implementation (D&I) are sometimes used interchangeably to describe activities aimed at bringing evidence into practice. Based on the predominant definitions in the literature and for the purposes of this limited 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.

- **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.  

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.

This PFA is primarily focused on 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—that is, the active spread and increase in knowledge and use of evidence—that are consistent with the goals of this initiative may also be considered for funding.

II. Proposing Implementation Projects

PCORI seeks to fund implementation projects that incorporate active strategies that will lead to uptake and integration of evidence into real-world practice among the targeted end-users and settings.

Responsive applications will propose projects to implement findings from PCORI-funded 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.)

Proposed implementation projects should represent a logical and feasible next step for implementing a clinically meaningful CER finding(s) in ways that will significantly increase the reach (i.e., the total number of individuals expected to be reached through the proposed dissemination or implementation project), generalizability (i.e., the applicability of the 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. (For the purposes of this limited PFA, a research finding

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includes any tools or other products that may have been developed or refined as part of the original PCORI-funded study.)

At a minimum, proposed implementation projects should move findings out of a controlled research setting into 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. Successful project designs will consider existing clinical workflows and reflect relationships and roles among the stakeholders within the setting. Implementation proposals should also consider the fundamental concepts of evidence context, setting, engagement, and evaluation,\(^3,4,5,6,7\) which are discussed in greater detail below.

Examples of appropriate implementation 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.

**Specific Requirements**

Applicants proposing implementation projects are expected to do the following:

- Describe the evidence from PCORI-funded research proposed for implementation:
  - Restate the hypotheses from your original PCORI-funded research study and describe the study design and PICOTS—(1) population, (2) intervention, (3) comparators, (4) outcomes, and (5) timeline—associated with the study. Then clearly describe the key findings you aim to implement, supported by the required tables and figures.
  - Describe the strength of the results being proposed for implementation, including their clinical meaningfulness and statistical significance. Indicate whether the findings being implemented in this project have been published in a peer-reviewed journal.
  - Discuss how the study findings relate to the body of evidence in the existing literature. A single finding seldom warrants implementation independent from other research findings;

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explain how the findings being implemented support, augment, or differ from related evidence—and how they improve on currently available information.

- 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.
- Describe the audience (e.g., patients, clinicians, other decision makers and healthcare stakeholders) targeted for implementation who can benefit directly from using the evidence or who are a critical link to achieving changes in health outcomes or health care.
- Describe why the findings proposed for implementation are relevant to these targeted end-users and describe the project team’s relationship to these end-users (and/or to partnering organizations able to reach them).
- Describe the potential impact of uptake of these findings by the targeted end-users in the immediate implementation project.

- Demonstrate comprehensive and meaningful stakeholder engagement:
  - Describe how the relevant frontline staff, care providers, and leadership of host delivery settings informed the development of the proposal.
  - Demonstrate the commitment of implementation sites, including those at the leadership level and frontline staff responsible for delivering the intervention or directly supporting the project activities, to use the intervention and support the implementation activities. Have site personnel provided input on, or endorsed, the activities they will undertake during the project?
  - 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 well-justified and feasible implementation plan for improving the uptake and impact of the PCORI-funded research findings among the targeted end-users and settings:
  - Describe the implementation framework or conceptual model that will be used to anchor and inform the project design, outcomes, and evaluation plan. Consider including a logic pathway showing how the proposed implementation approach is likely to lead to meaningful changes in knowledge, behavior, and practice.
  - Describe the proposed implementation activities and how these activities are likely to result in successful uptake of the evidence; these activities should be guided by evidence regarding effective strategies for implementing evidence-based practices and interventions.
  - Describe the project team’s experience and successful track record with the proposed implementation activities.
  - Describe and justify any adaptations needed to facilitate uptake of the research finding(s) in the targeted implementation setting(s), scale-up (to reach larger numbers), and scale-out
(to reach broader audiences, including diverse populations and settings), as applicable. Justify that the adapted intervention preserves the core elements of the original tested intervention.

- **NOTE:** While recognizing that adapting evidence is usually a critical component of successful implementation projects, the primary focus of the proposed project, including allocation of time and resources, 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.

  - Describe how the proposed implementation activities will address potential barriers and obstacles to evidence uptake, integration into practice, and maintenance of the changes as implemented.
  - Describe the potential for sustainability of this implementation effort at the project sites and the potential for scalability to other audiences and settings, including a clear path for future efforts to bring these research results into wider use.

- **Describe the specific sites and settings** where implementation will occur:
  - Propose implementation sites and settings 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 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.
  - Describe the participants who will be involved at these sites, including the number of individuals participating (e.g., number of clinical sites, number of health workers trained), how they have been or will be selected, and how these sites resemble (are representative of) or differ from potential future implementation sites. Be as specific as possible.
  - Specify the total number of individuals (whose care experience and health outcomes you expect to ultimately change) who will be reached with this implementation initiative. Please also describe the projected reach of this implementation initiative in terms of the following:
    - Proportion (where relevant): Expected reach of this implementation initiative relative to the broader population of individuals who stand to benefit from the results being 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 with this implementation initiative are similar to or different from the broader population of individuals who stand to benefit from the results being implemented

- Include a rigorous evaluation plan that focuses on an appropriate balance of measurable
outcomes. Evaluation activities should start at the beginning of the project and document both of the following:

- The successful performance of implementation activities in getting the intervention into practice (i.e., reach, adoption, and fidelity)
- The impact of these activities on end-users in the immediate and longer term, as feasible and appropriate within the project scope (i.e., changes in knowledge, satisfaction, behavior, healthcare utilization, and health outcomes)

III. Proposing Dissemination Projects

While this funding initiative is designed primarily to support implementation projects that meet the requirements above, PCORI will consider supporting dissemination projects with the primary goal of spreading knowledge and awareness of evidence from PCORI-funded research studies and increasing targeted end-users’ motivation and ability to use it. Applicants proposing dissemination-focused projects must make a compelling case that proposed project activities are a logical and necessary step for promoting the uptake of evidence by specific target audiences.

Research has shown that passive dissemination strategies, which simply make information available, are not sufficient for promoting evidence uptake. As such, applicants proposing dissemination-focused projects are expected to use an intentional, active process for identifying target audiences and tailoring communication strategies to increase awareness and understanding of the evidence, and to motivate its use.

Research supports the use of multicomponent dissemination approaches. Examples of appropriate dissemination strategies that may comprise a successful overall approach include, among others, the following:

- Focused trainings at seminars and workshops, including train-the-trainer approaches, to increase knowledge of the evidence among practitioners
- Outreach efforts through different learning environments, including learning collaboratives, to promote awareness of evidence among frontline public health or community center staff
- Incorporation of evidence into existing materials and systems used to educate and train patients and practitioners
- Development and distribution of new dissemination materials (e.g., print and electronic

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materials, videos) tailored for specific audiences

- Targeted symposia at conferences and professional meetings to reach specialized clinicians
- Development and distribution of summary materials to increase awareness and understanding of the relevance of evidence to decision makers at the local, state, and federal levels
- Targeted media and marketing campaigns to promote awareness of the evidence across trusted channels accessed by specific patient, caregiver, or other end-user audiences
- Efforts to share information with specific audiences using social media, web forums, or existing websites

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 Post-Panel Review and Funding Recommendations).

Specific Requirements

Applicants proposing dissemination projects are expected to do the following:

- Describe the evidence from PCORI-funded research proposed for dissemination:
  - Restate the hypotheses from your original PCORI-funded research study and describe the study design and PICOTS – (1) population, (2) intervention, (3) comparators, (4) outcomes, and (5) timeline – associated with the study. Then clearly describe the key findings you aim to disseminate, supported by the required tables and figures.
  - Describe the strength of the results being proposed for dissemination, including their clinical meaningfulness and statistical significance. Indicate whether the findings being disseminated in this project have been published in a peer-reviewed journal.
  - Discuss how the study findings relate to the body of evidence in the existing literature and body of evidence. Explain how the finding being disseminated augment or differ from related evidence—and how it improves on currently available information.
- Justify why proposed dissemination activities—rather than implementation—are an essential and appropriate next step for progress toward near-term or eventual uptake of the evidence.
- Describe the audience targeted for dissemination (e.g., patients, clinicians, other decision makers and healthcare stakeholders). Justify why these individuals require the evidence and what decisions the evidence will inform.
- Specify the number of individuals you will reach through your proposed dissemination project. Describe your reach relative to the broader population of individuals who stand to benefit from the evidence being disseminated.
- Describe the project team's relationship to the targeted audience. If partnering with other organizations to reach the targeted audience, describe (1) the relationship between the partnering organization and the project team and (2) the relationship between the partnering
Describe the **stakeholders you engaged** in developing your proposal and explain why engaging these individuals or groups is critical to the success of your project. Describe how these stakeholders have endorsed and/or provided input on your overall approach and specific project activities. Provide Letters of Support as needed.

- **NOTE:** Applicants that do not yet have a dissemination plan—informed and supported by the necessary stakeholders—should consider applying for a Capacity Building Award through PCORI’s Eugene Washington Engagement Award Program.

- Propose a well-justified and feasible **dissemination plan**, drawing on evidence-based strategies that have a high likelihood of success in improving knowledge and leading to changes in behavior and practice for the audience targeted in your project:
  - Describe specific project activities that will occur, including the project team’s experience and successful track record in reaching the targeted audience through these activities.
  - Describe the implementation framework or model you will use to anchor and inform the project design, outcomes, and evaluation plan. Consider including a logic pathway showing how the proposed dissemination approach is likely to lead to meaningful changes in knowledge, behavior, and practice.

- Clearly state the **messaging related to the evidence** that this project will disseminate. Messaging should be clearly supported by the findings from the PCORI-funded study, in the context of the larger body of relevant evidence.

- Describe the **dissemination materials** (e.g., printed or electronic materials, videos) that you will use in your dissemination effort:
  - If you are developing these materials as part of your project, specify who on your project team will develop these materials, and describe their experience and successful track record performing this kind of work. If partnering with a vendor, describe your previous collaborations, including the types of materials the vendor developed, how these materials were used, and what evidence you have that these materials accomplished their purpose. Include citations or provide sample materials.
  - Describe how will you verify that materials you will use in your proposed dissemination effort (whether those you have created or existing materials) are high quality and appropriately tailored for the targeted audience. Will you leverage existing evidence-related materials already developed by PCORI (e.g., Results Summaries, Professional Abstracts, Evidence Updates)?

- Describe the **dissemination channels or mechanisms** you will use to reach your targeted audience (e.g., social media, webinars, online learning systems, in-person meetings). When your approach leverages stakeholder organizations’ channels or mechanisms—such as their existing contact lists or learning collaboratives—describe these specifically. Explain why the channels
you have selected are the best ones to reach your target audience. In addition, describe the project team’s, or your collaborators’, experience and successful track record using the proposed channels and mechanisms to reach your target audience.

- Include a suitable evaluation plan. Your evaluation should do the following:
  - Document the performance and completion of your proposed dissemination activities.
  - Document the reach you accomplish among your targeted audience.
  - Assess changes in knowledge, awareness, and motivation to use the evidence that are the goal of dissemination activities.
  - Whenever possible, capture changes in behavior that occur as a result of dissemination activities.

- Describe the need and potential for broadened dissemination following this dissemination project. Should future efforts extend reach among your target audience, or among additional audiences or settings? Will existing project partners or other stakeholders take up further dissemination after the proposed project has been completed?

IV. Additional Guidance

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 disseminating or implementing research findings obtained from completed PCORI-funded studies and evaluating the success of those implementation efforts. Projects proposing to perform CER are not eligible for funding 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 or 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 modification or 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 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.

Collaborations

Applicants may propose projects that involve collaboration of multiple related PCORI-funded research studies. Collaborative projects may take different forms. At a minimum, a collaborative project must involve the partnership of two or more PCORI-funded investigators partnering to incorporate 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 of each PCORI-funded study whose findings are being disseminated or implemented in the collaborative project. Please note that participation in a collaborative project does not preclude individual investigators from submitting a separate, individual application through this mechanism; however, investigators will be expected to provide a strong justification that their individual projects do not duplicate activities proposed in the collaborative 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 (i.e., a summary statement) from the initial submission. All resubmitted applications require submission of a new Letter of Intent; 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.

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,\textsuperscript{13} 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\textsuperscript{14} 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 that require 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.\textsuperscript{15}

**V. 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 will review the LOIs, which are not scored during review. PCORI will invite 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 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.

**VI. 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 implementation 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.

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.

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 January 2021.

**Application Review Criteria**

Below are PCORI’s merit review criteria for implementation applications proposed 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, as well as 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, reaching broader audiences including diverse populations and settings)?

- Have the proposed implementation sites been identified? If so, has the applicant demonstrated the readiness of the implementation sites, including the identification of site champions and key decision makers? If not, has the applicant provided a rationale for why this is not possible, along with 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 target group 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 who stand to benefit 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 of the following?
  o The successful execution of implementation activities (i.e., reach, site-level adoption, and fidelity)
  o 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 that shows 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, 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 where 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 further clarify 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, 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.

**VII. 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 (HHS) 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.

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.

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16 Available at https://www.hhs.gov/ocr/index.html.