



Cycle 1 2019 Funding Cycle

PCORI Funding Announcement: Implementation of Findings from PCORI's Major Research Investments

Published January 3, 2019
Updated April 5, 2019

This PCORI Funding Announcement (PFA) applies to the funding cycle that closes on April 4, 2019, at 5 pm (ET). Application Guidelines, templates, and other resources are available at <https://www.pcori.org/funding-opportunities/announcement/implementation-findings-pcoris-major-research-investments-cycle-1>.



About PCORI

The Patient-Centered Outcomes Research Institute (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.

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."

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Overview

Published	January 3, 2019														
Letter of Intent Deadline	January 24, 2019, 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 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 14, 2019.														
Summary	The goal of this PFA is to move evidence emerging from major PCORI research funding initiatives, and findings from other selected PCORI-identified studies, toward practical use in improving health care and health outcomes. This PFA provides the opportunity for applicants to propose meaningful implementation projects that promote the uptake of peer-reviewed findings from these PCORI-funded studies—in the context of the body of related evidence—to make these findings more actionable and accessible to targeted decision makers and healthcare stakeholders at the point of care or in other decision settings. This is an Open Competition funding opportunity that seeks to draw on the expertise, creativity, and capacity of a broad applicant pool, including implementation experts and diverse stakeholder partners.														
Applicant Resources	See https://www.pcori.org/funding-opportunities/announcement/implementation-findings-pcoris-major-research-investments-cycle-1 .														
Key Dates	<table border="0"> <tr> <td>Online System Opens:</td> <td>January 3, 2019</td> </tr> <tr> <td>LOI Deadline:</td> <td>January 24, 2019, by 5 pm (ET)</td> </tr> <tr> <td>LOI Screening Notification</td> <td>February 14, 2019</td> </tr> <tr> <td>Application Deadline:</td> <td>April 4, 2019, by 5 pm (ET)</td> </tr> <tr> <td>Merit Review:</td> <td>June 2019</td> </tr> <tr> <td>Awards Announced:</td> <td>*November 2019</td> </tr> <tr> <td>Earliest Project Start Date:</td> <td>*February 2020</td> </tr> </table>	Online System Opens:	January 3, 2019	LOI Deadline:	January 24, 2019, by 5 pm (ET)	LOI Screening Notification	February 14, 2019	Application Deadline:	April 4, 2019, by 5 pm (ET)	Merit Review:	June 2019	Awards Announced:	*November 2019	Earliest Project Start Date:	*February 2020
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Maximum Project Budget (Total Costs)	Up to \$2,500,000 total costs														
Maximum Project Period	Up to three years														
Funds Available up to	\$8 million														
Eligibility	<p><i>Eligible Evidence:</i> Applicants must propose implementation projects that focus on the topics PCORI identifies in this PFA, which are drawn from published, peer-reviewed evidence emerging from selected areas of major PCORI investment in comparative clinical effectiveness research.</p> <p>For the Cycle 1 2019 PFA, PCORI has identified two areas of eligible evidence, each of which is the focus of an important PCORI-funded study.</p> <ol style="list-style-type: none"> 1. Use of narrow-spectrum versus broad-spectrum antibiotics to treat children’s acute respiratory tract infections 2. Informed use of self-monitoring of blood glucose for non–insulin requiring patients with type 2 diabetes. <p><i>Eligible Organizations:</i> 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</p>														



	<p>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.</p> <p><i>Eligible Applicants:</i> This is an Open Competition funding opportunity that seeks to draw on the expertise, creativity, and capacity of a broad applicant pool, including implementation experts and diverse stakeholder partners. As such, PCORI does not require applicants to have been associated with the PCORI-funded studies described above, nor does PCORI require them to have received any previous PCORI funding.</p>
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. Potential for uptake and impact of research results2. Technical merit of the proposed implementation project3. Project personnel and environment4. Patient-centeredness5. Patient and 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 5pm the following Monday or the next day after the federal holiday.</p>

**April 5, 2019 Update: The award announced date was moved to November 19, 2019, which pushed the earliest start date for projects to February 2020.*

Table of Contents

I. Introduction	1
Summary of Program	1
Background	2
Evidence Eligible as the Focus of Implementation under this PFA.....	2
Potential Approaches.....	5
Funds Available	5
II. Guidance for Preparing Applications	5
Specific Requirements	5
Nonresponsiveness	7
Protection of Human Subjects	8
Required Education of Key Personnel on the Protection of Human Subject Participants	9
III. How to Submit an Application	9
Letter of Intent.....	9
Letter of Intent Review	10
Submission Dates	10
PCORI Online	10
Applicant Resources.....	10
IV. Merit Review	10
Preliminary Review	11
Application Review Criteria.....	11
In-Person Review	13
Post-Panel Review and Funding Recommendations	14
Summary Statements.....	14

I. Introduction

Summary of Program

The Patient-Centered Outcomes Research Institute (PCORI) has launched this funding initiative to support meaningful implementation projects that promote the uptake of peer-reviewed findings from specific, high-priority PCORI studies in the context of the body of related evidence. The goal of these projects should be to integrate evidence developed through this research into practice, where it can inform the decisions of patients, clinicians, or other targeted decision makers and healthcare stakeholders at the point of care or in other decision settings. This funding initiative seeks to draw on the expertise, creativity, and capacity of a broad applicant pool, including implementation experts and diverse stakeholder partners embedded in the targeted settings in which implementation will occur.

PCORI seeks to fund implementation projects that incorporate active, multicomponent strategies that will lead to uptake and integration of PCORI-funded evidence into real-world practice settings. Relevant literature suggests that active, multicomponent implementation strategies that reflect comprehensive consideration of the barriers and facilitators in the proposed settings and that drive change among different stakeholders (e.g., patients, providers) at different levels (e.g., individual, clinical setting, community) are most likely to succeed.¹

Implementation strategies should target specific end-users with a clear interest in, and who are able to benefit from, using the evidence. Proposed implementation projects will adapt findings as needed to facilitate uptake in the proposed settings and accomplish scale-up (to reach larger numbers) and/or scale-out (to reach broader audiences, including diverse populations and settings). Applications must be guided by an established conceptual model or framework and, where possible, by evidence regarding effective strategies for implementing evidence-based practices and interventions. Additionally, applications must include a rigorous evaluation plan that documents the successful execution of the implementation strategy and the impact of the implementation project on health care and health outcomes as feasible and appropriate within the project scope. As a 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 and buy-in 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

¹ Powell BJ, McMillen JC, Proctor EK, et al. A compilation of strategies for implementing clinical innovations in health and mental health." *Med Care Res Rev.* 2012;69(2):123-157.

context and culture for undertaking the proposed project. Further, applicants will be expected to work with 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.

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.² 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.^{3,4} 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 and implementation are sometimes used interchangeably to describe activities aimed at bringing evidence into practice. For the purposes of this 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.⁵ The purpose of dissemination is to spread and sustain knowledge and the associated evidence-based interventions.
- *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.⁵

Successful applications for this PFA will propose 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 a workflow or other processes that support its use in a sustainable way.

Evidence Eligible as the Focus of Implementation under this PFA

Each release of this PFA will identify selected published, peer-reviewed, patient-centered clinical comparative effectiveness research (CER) evidence as the focus for implementation. We anticipate that selected findings will emerge regularly from PCORI’s targeted funding initiatives and pragmatic clinical studies, which address topics that have been identified as priority areas for PCORI research funding. In addition, PCORI may identify findings from PCORnet demonstration studies or from other selected

² 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.

³ 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

⁴ 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

⁵ See PCORI Dissemination & Implementation Mathematica framework. <http://www.mathematica-mpr.com/~media/publications/pdfs/health/pcori%20di%20framework%20draft.pdf>. Accessed January 3, 2019.

PCORI-funded studies as the focus of implementation efforts under this PFA.

For the Cycle 1 2019 PFA, PCORI has identified two areas of eligible evidence, each of which is the focus of an important PCORI-funded study. The goal of the proposed implementation projects under this PFA is to further awareness of this evidence and its use in practice.

1. Use of narrow-spectrum versus broad-spectrum antibiotics to treat children’s acute respiratory tract infections

Current guidelines generally recommend the use of narrow-spectrum antibiotics, such as amoxicillin, as first-line treatment for ARTIs in children, subject to local conditions regarding antibiotic resistance.^{6,7} A recently published [PCORI-funded study](#) (Principal Investigator [PI]: Jeffrey Gerber) highlights the benefits of using narrow-spectrum antibiotics when possible. Gerber and colleagues looked at records for more than 30,000 children, aged 6 months to 12 years, taking narrow- or broad-spectrum antibiotics for ear, nose, or throat infections in 31 pediatric primary care practices in New Jersey and Pennsylvania. Their analysis found no difference in symptom resolution or treatment failure between children taking narrow-spectrum antibiotics versus those taking broad-spectrum antibiotics. However, the risk of side effects, including diarrhea, candidiasis, allergic reaction, and vomiting, was significantly lower for children taking narrow-spectrum antibiotics.⁸

Available evidence suggests that approximately 80 percent of children’s diagnoses for common ARTIs should be treated with narrow-spectrum antibiotics, yet roughly 50 percent of children are still prescribed broad-spectrum antibiotics as first-line treatment.^{9,10} In addition, studies have shown that there is significant variation in antibiotic prescribing behavior. For example, one study found that children seen at a high-antibiotic-use practice were four times as likely to receive a broad-spectrum antibiotic than children visiting a low-antibiotic-use practice, as well as twice as likely to receive antibiotics overall.¹¹

Consistent prescription of narrow-spectrum antibiotics as first-line treatment has the potential to improve the quality of life for children, lowering the incidence of treatment-associated side effects, and for their caregivers. Inappropriate prescribing of broad-spectrum antibiotics can also contribute to antibiotic resistance, a growing problem that contributes to at least two million antibiotic-resistant infections each year. The problem of antibiotic resistance, as well as the larger goal of improving appropriate use of antibiotics, has been highlighted by the Centers for Disease Control and Prevention (CDC) as an important priority for improving patient safety

⁶ Wald ER, Applegate KE, Bordley C, et al. Clinical practice guideline for the diagnosis and management of acute bacterial sinusitis in children aged 1 to 18 years. *Pediatrics*. 2013;132:e262-e280.

⁷ See <https://www.cdc.gov/antibiotic-use/community/for-hcp/outpatient-hcp/pediatric-treatment-rec.html>. Accessed January 3, 2019.

⁸ Gerber JS, Ross RK, Bryan M, et al. Association of broad- vs narrow-spectrum antibiotics with treatment failure, adverse events, and quality of life in children with acute respiratory tract infections. *JAMA*. 2017;318(23):2325-2336.

⁹ Hersh AL, Shapiro DJ, Pavia AT, Shah SS. Antibiotic prescribing in ambulatory pediatrics in the United States. *Pediatrics*. 2011;128(6):1053-1061.

¹⁰ Hersh AL, Fleming-Dutra KE, Shapiro DJ, Hyun DY, Hicks LA. Frequency of first-line antibiotic selection among US ambulatory care visits for otitis media, sinusitis, and pharyngitis. *JAMA Intern Med*. 2016;176(12):1870-1872.

¹¹ Gerber JS, Prasad PA, Localio AR, et al. Variation in antibiotic prescribing across a pediatric primary care network. *J Pediatric Infect Dis Soc*. 2015;4(4):297-304.

and public health.¹²

PCORI-Funded Study: [Comparing Broad- and Narrow-Spectrum Antibiotics for Children with Ear, Sinus, and Throat Infections](#) (PI: Jeffrey Gerber)

Publication: Gerber JS, Ross RK, Bryan M, et al. [Association of broad- vs narrow-spectrum antibiotics with treatment failure, adverse events, and quality of life in children with acute respiratory tract infections.](#) *JAMA.* 2017;318(23):2325-2336.

For additional reference, see [PCORI Evidence Update for Patients and Caregivers](#), and [PCORI Evidence Update for Clinicians](#) on this topic.

2. Informed use of self-monitoring of blood glucose for non–insulin requiring patients with type 2 diabetes.

According to the CDC, there are approximately 30 million adults with non–insulin treated type 2 diabetes.¹³ Many of these patients monitor their blood sugar level daily using testing strips and glucose meters, as prescribed by their clinicians. However, research has not established benefit from self-monitoring of blood glucose (SMBG). Some studies have reported that daily SMBG improves glycemic control in certain populations,¹⁴ but most have found no benefit, or benefit that was not clinically meaningful or limited to the first six months of monitoring.^{15,16,17,18,19}

A recently published [PCORI-funded study](#) (PI: Katrina Donahue) adds to the evidence on this topic from a relatively large pragmatic trial. Donahue and colleagues looked at 450 people with non–insulin treated type 2 diabetes in 15 community-based primary care practices in central North Carolina. The study compared people who performed once-daily SMBG with those who didn't test every day. After one year, researchers found no differences in blood sugar control or health-related quality of life between the groups. The lack of effect held true even for a subgroup of people who received real-time text messages explaining their testing results.²⁰

Proponents of SMBG have argued that testing keeps patients engaged and promotes better awareness of blood sugar levels, leading to improvements in diet and lifestyle. Others say that testing supplies are costly, that testing may be inconvenient and cause discomfort, and that patients' attention to blood sugar levels could be more productively focused on diet and lifestyle changes that have a demonstrable impact on health. At a minimum, it is clear that patients need

¹² See <https://www.cdc.gov/antibiotic-use/healthcare/implementation/core-elements.html>. Accessed January 3, 2019.

¹³ See <https://www.cdc.gov/diabetes/basics/type2.html>. Accessed January 3, 2019.

¹⁴ Poolsup N, Suksomboon N, Rattanasookchit S. Meta-analysis of the benefits of self-monitoring of blood glucose on glycemic control in type 2 diabetes patients: an update. *Diabetes Technol Ther.* 2009;11(12):775-84.

¹⁵ Malanda UL, Welschen LM, Riphagen II, Dekker JM, Nijpels G, Bot SD. Self-monitoring of blood glucose in patients with type 2 diabetes mellitus who are not using insulin. *Cochrane Database Syst Rev.* 2012;1:CD005060.

¹⁶ Farmer AJ, Perera R, Ward A, et al. Meta-analysis of individual patient data in randomised trials of self monitoring of blood glucose in people with non-insulin treated type 2 diabetes. *BMJ.* 2012;344:e486.

¹⁷ Clar C, Barnard K, Cummins E, Royle P, Waugh N; Aberdeen Technology Assessment Group. Self-monitoring of blood glucose in type 2 diabetes: systematic review. *Health Technol Assess.* 2010;14(12):1-140.

¹⁸ Franciosi M, Pellegrini F, De Berardis G, et al. Self-monitoring of blood glucose in noninsulin-treated diabetes: a systematic review. *SBU Systematic Review Summaries.* Stockholm, Sweden: Swedish Council on Health Technology Assessment; 2009. SBU yellow report 194.

¹⁹ Towfigh A, Romanova M, Weinreb JE, et al. Self-monitoring of blood glucose levels in patients with type 2 diabetes mellitus not taking insulin: a meta-analysis. *Am J Manag Care.* 2008;14(7):468-475.

²⁰ Young LA, Buse JB, Weaver MA, et al. Glucose self-monitoring in non-insulin-treated patients with type 2 diabetes in primary care settings: a randomized trial. *JAMA Intern Med.* 2017;177(7):920-929.

support as well as accurate information about SMBG in order to make informed decisions about whether SMBG is right for them. Further, clinicians and diabetes educators require adequate preparation to meaningfully engage their patients, including those who currently perform SMBG as well as new patients initiating management of their type 2 diabetes, in discussions about SMBG.

PCORI-Funded Study: [Does Daily Self-Monitoring of Blood Sugar Levels Improve Blood Sugar Control and Quality of Life for Patients with Type 2 Diabetes Who Do Not Use Insulin?](#) (PI: Katrina Donahue)

Publication: Young LA, Buse JB, Weaver MA, et al. [Glucose self-monitoring in non-insulin treated patients with type 2 diabetes in primary care settings: a randomized trial.](#) *JAMA Intern Med.* 2017;177(7):920-929.

Potential Approaches

PCORI is seeking projects that propose feasible and well-informed strategies that integrate evidence from one of the two PCORI-funded studies identified in this PFA (see Evidence Eligible as the Focus of Implementation section) into real-world settings, with the aim of increasing its accessibility, usefulness, uptake, and 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 implementation effort. Strategies focused on de-implementation are encouraged where appropriate. As noted earlier, successful applications will include multiple component strategies reflecting the opportunities and challenges specific to implementation to the proposed audiences and settings.

PCORI encourages applicants to work closely with relevant individuals and stakeholder groups to identify appropriate implementation strategies in advance of developing a proposal. This may include those embedded in the targeted implementation settings who are closely familiar with specific sites, as well as those with experience and demonstrated success implementing change across practice settings.

See below for additional guidance on proposed implementation approaches.

Funds Available

PCORI has devoted up to \$8 million in total costs under this PFA. The total amount awarded and the number of awards made will depend on the quality and costs of the applications received. Total costs, including prime and subcontractor indirect costs, may not exceed \$2.5 million for any individual or collaborative project. The maximum project period is up to three years.

II. Guidance for Preparing Applications

Specific Requirements

Applications must meet the following requirements:

- Propose to implement findings from one of the two PCORI-funded studies identified in this PFA in the context of related evidence (see Evidence Eligible as the Focus of Implementation section).

- Provide a summary of the evidence that will be the focus of this project, accurately describing the strength of the evidence in a way that addresses its readiness for the type of implementation project proposed.
- Provide a thoughtful description of the decision-making contexts in which this evidence is relevant.
- Target patients, clinicians, or other specific 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.
- Propose implementation sites that have a demonstrable commitment to improving healthcare quality and a willingness to invest in the implementation 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.
- Propose a well-justified and feasible plan for improving the uptake and impact of the eligible evidence among the targeted end-users and settings.
 - Propose a comprehensive, multicomponent implementation strategy that addresses barriers and obstacles to evidence uptake, integration into practice, and maintenance of the changes as implemented.
 - The proposed strategy should be guided by an established conceptual model or framework and, where possible, by evidence regarding effective strategies for implementing evidence-based practices and interventions.
 - Propose an implementation strategy that incorporates the perspectives and experiences of patients and stakeholders, including individuals living with the disease or condition of interest.
 - The proposed strategy should have potential for use and scalability beyond the targeted implementation 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 implementation project), generalizability (i.e., applicability of intervention across different groups, systems, or settings), uptake (i.e., 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 this implementation initiative in terms of the following:
 - Absolute Number: Total number of individuals (whose care experience and health outcomes you expect to ultimately change) who will be reached with this implementation initiative
 - Proportion: Expected reach of this implementation initiative relative to the broader population of individuals who stand to benefit from the results being implemented

- Representativeness: Consideration of how those being targeted by this implementation initiative are similar to or different from the broader population of individuals who stand to benefit from the results being implemented. Address the potential of the proposed project to inform future implementation efforts, leading to broader uptake of the PCORI findings.
- 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 implementation activities, to participate as meaningful partners throughout the implementation project.
 - Demonstrate involvement of relevant regional and national stakeholder organizations whose support will be critical to extending the impact of the evidence being implemented to broader venues beyond the proposed project.
- Propose a rigorous evaluation plan focusing 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). Evaluation activities should start at the beginning of the project.
 - Evaluation activities are 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. In general, evaluation plans that exclusively reflect impacts on setting characteristics and/or implementation process outcomes will not be considered sufficient.

We provide selected references below that may be of use in developing your application.^{21,22,23,24,25,26}

Nonresponsiveness

PCORI will consider Letters of Intent (LOIs) and applications nonresponsive to this PFA, and will

²¹ 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.

²² 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.

²³ 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.

²⁴ 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.

²⁵ Brownson RC, Colditz GA, Proctor EK. *Dissemination and Implementation Research in Health: Translating Science to Practice.* New York, NY: Oxford University Press; 2012.

²⁶ 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.

administratively withdraw them, if the project proposes to do any of the following:

- Conduct new research, as opposed to implementing eligible evidence (see Evidence Eligible as the Focus of Implementation section) 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.
- Translate or adapt an intervention or evidence without actively implementing it.
- Develop or validate a new tool for patients or clinicians without the primary purpose of actively implementing eligible evidence. 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 in the implementation project.
- Conduct activities **primarily** aimed at spreading knowledge and awareness of eligible evidence. These activities fall under PCORI’s definition of “dissemination” rather than “implementation.”
 - Please see the PCORI [Engagement Award: Dissemination Initiative](#) funding opportunity, which focuses on giving organizations and communities the opportunity to propose meaningful dissemination projects aimed at spreading awareness and increasing knowledge of new evidence.
- 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.

Protection of Human Subjects

If applicable, applicants should describe the protection of human subjects involved in their proposed research. If human subject protection is not applicable, applicants should provide a justification that such protection is not necessary for their project. 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](#),²⁷ 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.

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](#).²⁸

III. How to Submit an Application

Letter of Intent

Applicants should download the [Letter of Intent Template](#) for the PFA from the PCORI Funding Opportunities page on the PCORI website. The LOI has a three-page limit. References should be numbered in the text and full citations provided on a separate page following the LOI. PCORI suggests including all references as in-text citations using American Medical Association citation style, but other citation styles are acceptable. Complete the document and convert it to a PDF file. Do not upload additional documents as part of your LOI, including Letters of Endorsement or Support, because they are not requested at this stage. Inclusion of additional documents will result in LOI rejection without review. Please visit the PCORI Funding Opportunities page for additional applicant resources, including the PFA and required templates. LOIs are a mandatory prerequisite for submission of a full application. Applicants that fail to submit an LOI will not be permitted to submit a full application to the corresponding award cycle.

Responsive applicants must thoroughly address all LOI fields according to the instructions in the LOI Template and then upload the document into PCORI Online. **The deadline for LOI submission is 5 pm (ET) January 24, 2019.**

Note: A PI can submit only one LOI per PFA. However, an individual listed as a PI on one LOI may be listed as and serve in another non-PI role (e.g., co-investigator or consultant) on other LOIs within the same PFA, during the same cycle. A PI's project concept may undergo review in only one PFA at a time. A

²⁷ See <http://grants.nih.gov/sites/default/files/supplementalinstructions.docx>. Accessed January 3, 2019.

²⁸ See <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-08-054.html>. Accessed January 3, 2019.

PI wishing to submit an LOI to a particular PFA, and who already has a similar project under review in any PFA, *will need to strongly demonstrate that the project being proposed in the new LOI submission is clearly distinct from the application already under review.* This justification must be included in the LOI submission. If a strong enough case is not made during the competitive LOI review process, the LOI will be administratively withdrawn and the application to the other PFA will remain under review.

Similarly, a PI can submit multiple LOIs to different PFAs in a single cycle, but *the PI must strongly demonstrate that the projects are distinct in their aims and approaches.* If a PI submits a single project concept to multiple program PFAs, PCORI reserves the right to administratively withdraw LOIs deemed as duplicate submissions. PIs are encouraged to speak with PCORI staff well in advance of the LOI submission deadline regarding concerns related to potential LOI duplication. This applies to single- and dual-PI submissions.

Letter of Intent Review

All applicants are required to submit an LOI. PCORI will screen all LOIs for programmatic responsiveness to this PFA and to ensure compliance with administrative guidelines. PCORI invites only applicants whose LOIs are most responsive to this 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 Application Guidelines, to submit a full application. PCORI will notify applicants of denial or approval to submit an application no later than February 14, 2019. Please refer to the [Application Guidelines](#) for information on how to submit your LOI via PCORI Online.

Submission Dates

You must submit your LOI and application in accordance with the published dates and times listed in the Overview section of this document and in the PCORI Funding Opportunities.

PCORI Online

To submit an application, you must create an account in [PCORI Online](#) and submit both an LOI and an application, if invited, for each cycle to which you are applying. Please be sure that you are applying to the PFA titled “Implementation of Findings from PCORI’s Major Research Investments.”

Applicant Resources

PCORI Funding Opportunities	https://www.pcori.org/funding-opportunities/announcement/implementation-findings-pcoris-major-research-investments-cycle-1
PCORI Online	https://pcori.force.com/engagement
PCORI Funding Awards	http://www.pcori.org/research-results-home

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 PCORI program staff evaluation of LOIs, preliminary review of full applications by review panels, in-person panel discussion of a subset of full applications (based on the preliminary review and program priorities), and programmatic review and recommendation 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. PCORI may administratively withdraw an application if it is incomplete; is submitted past the stated due date and time; or does not meet the formatting criteria outlined in the [Application Guidelines](#), in the PCORI templates, and in PCORI Online.

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 implementation and 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

The following are PCORI's merit review criteria for this 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. Potential for uptake and impact of research results

- Does the application address the extent to which the evidence proposed for implementation aligns or conflicts with current practice and decision making among the targeted implementation settings and end-users?
- If the applicant is proposing to adapt an effective intervention, is the adaptation well justified? Does the applicant provide adequate assurance that the adapted intervention captures the core elements of the original and, as such, will be ready for implementation?
- Does the application consider factors that may help or hinder successful integration of the eligible evidence into practice, including specific barriers to user implementation and how to mitigate them within the context of the proposed project?
- Does the application address scalability, including a clear path for future efforts to move this

evidence toward yet wider use across more systems, settings, or sites?

Criterion 2. Technical merit of the proposed implementation project (project design, outcomes, and evaluation)

- 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?
- Does the application sufficiently address the relevance of the evidence proposed for implementation to the targeted end-users and implementation settings?
- Are these targeted end-users and settings representative of additional audiences beyond this proposed implementation project?
- Does the application use an implementation framework or model to anchor and inform the project design, outcomes, and evaluation plan?
- 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 describe a clear, multicomponent approach for implementing the eligible evidence?
 - Are the implementation activities appropriate for this effort? Consider the extent to which they are tested, evidence based, and consistent with principles and findings from implementation science.
 - Are the proposed project 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?
- 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 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)?
- Are the project timeline and specific project milestones realistic?

Criterion 3. Project personnel and environment

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

- Does the application describe the project team's expertise and demonstrated success in moving evidence toward practical use in improving health care and health outcomes?
- How well qualified is the project team (e.g., PIs, collaborators, and other stakeholders) to conduct the proposed project activities?

- 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?
- Does the application describe adequate availability of and access to facilities and resources (e.g., collaborative or partnering arrangements) to carry out the proposed project?
- Is the institutional support appropriate for the proposed project?

Criterion 4. Patient-centeredness

- Does the application demonstrate a clear link between the proposed implementation project and the ultimate benefit/value to patients as a direct result of this project?

Criterion 5. Patient and stakeholder engagement

- Does the application demonstrate that the necessary stakeholder perspectives, including those of patients and their representatives central to the proposed project, have informed the development of the proposal and that the necessary stakeholders will be meaningfully engaged throughout the project?
- Does the application demonstrate the principles of reciprocal relationships, co-learning, partnership, trust, transparency, and honesty?
- 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 phases?
- Does the application demonstrate that personnel (e.g., those delivering the intervention or directly supporting the implementation activities) at the proposed implementation sites are clearly interested in the evidence proposed for implementation and are committed to participating as active partners in the project?
- Does the application demonstrate sufficient commitment to the project from the decision makers in the healthcare systems and settings in which implementation will occur to promote the use of the evidence that is the focus of the project as well as to plan for sustaining the implementation approach?
- Does the application propose to work with relevant regional or national stakeholder organizations whose support will be critical to extending the impact of the eligible evidence to broader venues?

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 to the Engagement, Dissemination, and Implementation Committee, which is a subcommittee of PCORI's Board of Governors, and then Board of Governors itself.

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 receive summary statements 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.

Applicants to this current cycle's PFA will receive summary statements and notification of the funding status of their application in **November** 2019.