



## **Cycle 3 2020 Funding Cycle**

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

Published September 1, 2020

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This PCORI Funding Announcement (PFA) applies to the funding cycle that closes on December 1, 2020, at 5 pm (ET). Submission Instructions, templates, and other resources are available at <https://www.pcori.org/funding-opportunities/announcement/implementation-findings-pcori-major-research-investments-cycle-3-2020>.



## **About PCORI**

The Patient-Centered Outcomes Research Institute (PCORI) was authorized by Congress in 2010 as a nonprofit, nongovernmental organization. PCORI's purpose, as defined by our authorizing legislation, is to help patients, caregivers, clinicians, policy makers, and other healthcare system stakeholders make better-informed health decisions by advancing the quality and relevance of evidence about how to prevent, diagnose, treat, monitor, and manage diseases, disorders, and other health conditions, and by promoting the dissemination and uptake of this evidence.

PCORI is committed to transparency and a rigorous stakeholder-driven process that emphasizes patient engagement. PCORI uses a variety of forums and public comment periods to obtain public input to enhance its work. PCORI helps people make informed healthcare decisions and improves healthcare delivery and outcomes by producing and promoting high-integrity, evidence-based information that comes from research guided by patients and other stakeholders.

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## Overview

Summary	<p>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.</p>														
Key Dates	<table border="0"> <tr> <td>Online System Opens:</td> <td>September 1, 2020</td> </tr> <tr> <td>LOI Deadline:</td> <td>September 22, 2020, by 5 pm (ET)</td> </tr> <tr> <td>LOI Screening Notification:</td> <td>October 13, 2020</td> </tr> <tr> <td>Application Deadline:</td> <td>December 1, 2020, by 5 pm (ET)</td> </tr> <tr> <td>Merit Review:</td> <td>February 2021</td> </tr> <tr> <td>Awards Announced:</td> <td>July 2021</td> </tr> <tr> <td>Earliest Project Start Date:</td> <td>November 2021</td> </tr> </table>	Online System Opens:	September 1, 2020	LOI Deadline:	September 22, 2020, by 5 pm (ET)	LOI Screening Notification:	October 13, 2020	Application Deadline:	December 1, 2020, by 5 pm (ET)	Merit Review:	February 2021	Awards Announced:	July 2021	Earliest Project Start Date:	November 2021
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Maximum Project Budget (Total Costs)	Up to \$2,500,000 total costs														
Maximum Project Period	Up to 3 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 3 2020 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"> <li>Several kinds of therapy and medicines can reduce or stop symptoms for people with posttraumatic stress disorder (PTSD)</li> <li>The use of narrow-spectrum versus broad-spectrum antibiotics to treat children’s acute respiratory tract infections</li> </ol> <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 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</p>														



	have been associated with the PCORI-funded studies described above, nor does PCORI require them to have received any previous PCORI funding.
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"><li>1. Potential for uptake and impact of research results</li><li>2. Technical merit of the proposed implementation project</li><li>3. Project personnel and environment</li><li>4. Patient-centeredness</li><li>5. Stakeholder engagement</li></ol>
Contact Us	<p><b>Programmatic Inquiries:</b> Please contact the PCORI Dissemination &amp; Implementation Helpdesk at <a href="mailto:disseminationquestions@pcori.org">disseminationquestions@pcori.org</a>. PCORI will respond within two business days. However, we cannot guarantee that all questions will be addressed in two business days prior to a Letter of Intent (LOI) or application deadline.</p> <p><b>Administrative, Financial, or Technical Inquiries:</b> Please contact the PCORI Helpdesk at <a href="mailto:pfa@pcori.org">pfa@pcori.org</a>. 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>

**What Has Changed for the Cycle 3 2020 Funding Cycle:**

- The areas of [eligible evidence](#) under this PFA have changed for this cycle.
- The [merit review criteria](#) for this PFA has changed for this cycle.

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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.<sup>1</sup>

Promoting the uptake of research findings is part of the Patient-Centered Outcomes Research Institute's (PCORI's) 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 practices.

This PCORI Funding Announcement (PFA) supports meaningful implementation projects that promote the uptake of peer-reviewed findings from specific, high-priority PCORI initiatives in the context of the body of related evidence. These projects should have the goal of integrating 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 PFA 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 where implementation will occur.

### Summary of Program

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.<sup>2</sup>

Implementation strategies should target specific end-users with a clear interest in—and who are able to benefit from—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

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<sup>1</sup> 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.

<sup>2</sup> 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.

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 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.

### Defining Dissemination and Implementation

The concepts of dissemination and implementation are sometimes used interchangeably to describe activities aimed at bringing evidence into practice. For the purposes of this 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.<sup>3</sup> 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.<sup>5</sup>

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 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 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

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

addition, PCORI may identify findings from PCORnet<sup>®</sup> Demonstration studies or from other selected PCORI-funded studies as the focus of implementation efforts under this PFA.

For the Cycle 3 2020 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. Several kinds of therapy and medicines can reduce or stop symptoms for people with posttraumatic stress disorder (PTSD).**

PTSD affects about 6 percent of US adults.<sup>4</sup> It is more common in certain groups, including women, younger people, and those who did not complete high school or who have lower incomes.<sup>5</sup> PTSD can affect military personnel serving in combat, but it may also develop after many other types of traumatic events, including after a person experiences or witnesses intimate partner violence, sexual violence, other physical abuse or assault, or natural disasters. PTSD is also common among survivors of critical care illnesses, with one-fifth of patients reporting PTSD symptoms within one year of their discharge from the intensive care unit<sup>6,7</sup>—adding to the current salience of this condition for the many patients recovering from serious cases of COVID-19.<sup>8</sup> Experience from past disease outbreaks and pandemics suggests that caregivers of these patients, healthcare workers, first responders, and critical infrastructure personnel may also experience PTSD.<sup>9,10,11</sup>

A recent update to a systematic review, supported by PCORI through a research partnership with Agency for Healthcare Research and Quality (AHRQ), summarizes evidence from nearly 200 studies on psychological and pharmacological treatments for people with PTSD. Findings indicate that cognitive behavioral therapy (CBT) can improve PTSD symptoms to the point where the PTSD diagnosis is no longer substantiated. Specifically, the review found that exposure therapy, a specific form of CBT, and a group of other treatments that included elements of CBT had high strength of evidence (SOE) of effectiveness for improving PTSD symptoms. Recent studies included in the systematic review update increased the SOE supporting this finding. Although the harms of CBT were not well studied, they are likely minimal. Other forms of CBT (cognitive processing therapy, cognitive therapy, and narrative exposure therapy) and eye

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<sup>4</sup> Kessler RC, Chiu WT, Demler O, Merikangas KR, Walters EE. Prevalence, severity, and comorbidity of 12-month DSM-IV disorders in the National Comorbidity Survey Replication. *Arch Gen Psychiatry*. 2005;62(6):617-627.

<sup>5</sup> Goldstein RB, Smith SM, Chou SP, et al. The Epidemiology of DSM-5 Posttraumatic Stress Disorder in the United States: results from the National Epidemiologic Survey on Alcohol and Related Conditions-III. *Soc Psychiatry Psychiatr Epidemiol*. 2016;51(8):1137-1148.

<sup>6</sup> Parker AM, Sricharoenchai T, Rappala S, Schneck KW, Bienvenu OJ, Needham DM. Posttraumatic stress disorder in critical illness survivors. *Critical Care Medicine*. 2015;43(5):1121-1129.

<sup>7</sup> Bienvenu OJ, Gellar J, Althouse BM, et al. Post-traumatic stress disorder symptoms after acute lung injury: a 2-year prospective longitudinal study. *Psychol Med*. 2013;43(12):2657-2671.

<sup>8</sup> Khullar D. The challenges of post-COVID-19 care. *New Yorker*. 2020 Apr 23. [https://www.newyorker.com/science/medical-dispatch/the-challenges-of-post-covid-19-care?itm\\_content=footer-recirc&sfns=mo](https://www.newyorker.com/science/medical-dispatch/the-challenges-of-post-covid-19-care?itm_content=footer-recirc&sfns=mo). Last retrieved May 21, 2020.

<sup>9</sup> Lin CY, Peng YC, Wu YH, Chang J, Chan CH, Yang DY. The psychological effect of severe acute respiratory syndrome on emergency department staff. *Emerg Med J*. 2007;24(1):12-17.

<sup>10</sup> Wu P, Fang Y, Guan Z, Fan B, Kong J, Yao Z, Liu X, Fuller CJ, Susser E, Lu J, Hoven CW. The psychological impact of the SARS epidemic on hospital employees in China: exposure, risk perception, and altruistic acceptance of risk. *Can J Psychiatry*. 2009;54(5):302-311.

<sup>11</sup> Lee SM, Kang WS, Cho AR, Kim T, Park JK. Psychological impact of the 2015 MERS outbreak on hospital workers and quarantined hemodialysis patients. *Compr Psychiatry*. 2018;87:123-127.



movement desensitization and reprocessing (EMDR) had moderate SOE for effectiveness of treating PTSD, as did three medications: fluoxetine, paroxetine, and venlafaxine.<sup>12</sup>

PTSD imposes a significant burden on patients, their families, and caregivers. People affected by PTSD have high rates of psychiatric comorbidity and may have problems with work, family, and social functioning. They may suffer a range of adverse consequences over their life course, such as difficulties with educational attainment, work earnings, marriage attainment, and child rearing. Despite the extent of these health and other impacts, almost half (43 percent) of adults with PTSD do not get mental health treatment; among those who do, only 40 percent get minimally adequate treatment.<sup>13</sup> Although studies have shown that about 92 percent of adults with lifetime PTSD eventually achieve remission, the median time to remission is 14 years.

The SOE for specific treatment approaches for PTSD, outlined in the recent systematic review update, underscores the potential for improving patient-centered outcomes through the implementation of effective treatment. This potential may be particularly great for nonmilitary populations, among whom PTSD often goes unrecognized or undertreated.<sup>14</sup> Evidence suggests that undertreatment may be a particular concern for minority populations, who are also at higher risk for experiencing certain traumatic events but who have been found to seek treatment less often.<sup>15</sup>

PCORI-Funded Study: Psychological and Pharmacological Treatments for Adults with Posttraumatic Stress Disorder (PTSD): A Systematic Review Update

*Publication:* Hoffman V, Middleton JC, Feltner C, Gaynes BN, Weber RP, Bann C, Viswanathan M, Lohr KN, Baker C, Green J. Psychological and Pharmacological Treatments for Adults with Posttraumatic Stress Disorder: A Systematic Review Update. Comparative Effectiveness Review No. 207. (Prepared by the RTI International-University of North Carolina at Chapel Hill Evidence-Based Practice Center under Contract No. 290-2015-00011-I for AHRQ and PCORI.) AHRQ Publication No. 18-EHC011-EF. PCORI Publication No. 2018-SR-01. Rockville, MD: Agency for Healthcare Research and Quality; May 2018. Posted final reports are located on the Effective Health Care Program search page.

For additional reference,<sup>15</sup> see [PCORI Evidence Updates for Healthcare Consumers](#), and for [Clinicians](#) on this topic.

## 2. The use of narrow-spectrum versus broad-spectrum antibiotics to treat children’s acute respiratory tract infections (ARTIs)

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

<sup>12</sup> Brand names for Fluoxetine include Prozac®, Prozac®weekly, Rapiflux®, Sarafem®, and Selfemra®. Brand names for Paroxetine include Brisdelle®, Paxil®, Paxil® CR, and Peveva®. Brand names for Venlafaxine include Effexor® and Effexor® XR.

<sup>13</sup> Wang PS, Lane M, Olfson M, Pincus HA, Wells KB, Kessler RC. Twelvemonth use of mental health services in the United States: results from the National Comorbidity Survey Replication. *Arch Gen Psychiatry*. 2005 Jun;62(6):629-40.

<sup>14</sup> Lehavot K, Katon JG, Chen JA, Fortney JC, Simpson TL. Post-traumatic stress disorder by gender and veteran status [published correction appears in *Am J Prev Med*. 2019 Oct;57(4):573]. *Am J Prev Med*. 2018;54(1):e1-e9.

<sup>15</sup> Roberts AL, Gilman SE, Breslau J, Breslau N, Koenen KC. Race/ethnic differences in exposure to traumatic events, development of post-traumatic stress disorder, and treatment-seeking for post-traumatic stress disorder in the United States. *Psychol Med*. 2011;41(1):71-83.

antibiotic resistance.<sup>16,17</sup> 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, ages 6 months to 12 years, who took 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.<sup>18</sup>

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.<sup>19,20</sup> 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, and were twice as likely to receive antibiotics overall.<sup>21</sup>

By lowering the incidence of treatment-associated side effects, consistent prescription of narrow-spectrum antibiotics as first-line treatment has the potential to improve the quality of life for children and 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 as an important priority for improving patient safety and public health.<sup>22</sup>

[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.

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<sup>16</sup> 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.

<sup>17</sup> See <https://www.cdc.gov/antibiotic-use/community/for-hcp/outpatient-hcp/pediatric-treatment-rec.html>. Accessed January 3, 2019.

<sup>18</sup> 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.

<sup>19</sup> Hersh AL, Shapiro DJ, Pavia AT, Shah SS. Antibiotic prescribing in ambulatory pediatrics in the United States. *Pediatrics*. 2011;128(6):1053-1061.

<sup>20</sup> 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.

<sup>21</sup> 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.

<sup>22</sup> See <https://www.cdc.gov/antibiotic-use/healthcare/implementation/core-elements.html>. Accessed January 3, 2019.

## Potential Approaches

PCORI is seeking implementation projects that propose feasible and well-informed strategies that integrate evidence 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 before developing a proposal. This may include those individuals or groups 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 specific requirements for proposed implementation projects.

## 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 eligible findings 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 your proposed project, and explain why this evidence is relevant and important to the audience and settings targeted in the proposed implementation project.
  - Provide a thoughtful description of the decision-making contexts in which this evidence is relevant.
- Describe the audience (e.g., patients, clinicians, or other specific decision makers and healthcare stakeholders) targeted for implementation who can benefit directly from using the evidence that is the focus of the project or who are a critical link to achieving changes in health outcomes or health care.
- Describe why the evidence is relevant to these targeted end-users and describe the project team's relationship to them (and/or to partnering organizations able to reach them).
- 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 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.
- 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.
- Propose a well-justified and feasible **implementation plan** for improving the uptake and impact of the eligible evidence 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 proposed—for example, to facilitate uptake of the evidence proposed for implementation 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 or approach. (How will you ensure fidelity?) Describe the potential for sustainability of this 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.

- 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.
- Demonstrate comprehensive and meaningful **stakeholder engagement and buy-in**:
  - Describe how relevant frontline staff, care providers, and leadership of host delivery settings informed the development of the proposal.
  - Demonstrate how personnel at the implementation sites have demonstrated their interest in, as well as commitment to use, the evidence, both at the leadership level and at the level of frontline staff responsible for delivering the intervention or directly supporting the implementation activities. Have site personnel provided input on, or endorsed, the project activities they will undertake?
  - Demonstrate that decision makers at the healthcare systems and settings in which implementation will occur are committed to the project goals as well as to sustaining the implementation activities as appropriate.
  - Describe the relevant regional or national stakeholder organizations whose support will be critical to extending the impact of the evidence being implemented to broader venues beyond the proposed project. Describe your relationship and past involvement with these organizations.
- 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); and
  - The impact of these activities on end-users in the immediate and longer term (i.e., changes in knowledge, behavior, healthcare utilization, and health outcomes).

We provide selected references below that may be of use in developing your application.<sup>23,24,25,26,27,28</sup>

### Nonresponsiveness

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

- Conduct new research, as opposed to implementing 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.
- Implementing evidence not specified in the [Evidence Eligible as the Focus of Implementation section](#).
- 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

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<sup>23</sup> 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.

<sup>24</sup> 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.

<sup>25</sup> 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.

<sup>26</sup> 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.

<sup>27</sup> Brownson RC, Colditz GA, Proctor EK. *Dissemination and Implementation Research in Health: Translating Science to Practice.* New York, NY: Oxford University Press; 2012.

<sup>28</sup> 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.

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 LOI and application submission, please consult the [PCORI Submission Instructions for This PFA](#).

### Protection of Human Subjects

PCORI follows the Federal Policy for the Protection of Human Subjects (45 CFR part 46), including the Common Rule. For more detailed information, please see Section 5, "Human Subjects Research Policy," in the [Supplemental Grant Application Instructions for All Competing Applications and Progress Reports](#),<sup>29</sup> issued by the US Department of Health and Human Services (HHS). 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](#)<sup>30</sup> 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 requirement applies to all individuals listed as key personnel in the application. The policy and frequently asked questions are available on the [NIH website](#).<sup>31</sup>

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<sup>29</sup> See <http://grants.nih.gov/sites/default/files/supplementalinstructions.docx>. Accessed January 3, 2019.

<sup>30</sup> See <http://www.pcori.org/sites/default/files/PCORI-Policy-Data-Safety-Monitoring-Plans.pdf>.

<sup>31</sup> See <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-08-054.html>. Accessed January 3, 2019.

### III. Letter of Intent Review

Applying for PCORI funding 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 members 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.

### IV. Merit Review

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

- Identify applications that have the strongest potential to lead to increased use and uptake of evidence from PCORI-funded studies and, ultimately, lead to improved health care and health outcomes.
- Ensure a transparent, fair, objective, and consistent process to identify these applications.
- Elicit high-quality feedback that reflects a diversity of perspectives to ensure that the PCORI-funded implementation projects reflect the interests and views of patients and other stakeholders and those who care for them, and have strong technical merit.

PCORI merit review is a multiphase process that includes the review panel's preliminary assessment of full applications and an in-person panel discussion of a subset of applications (based on the preliminary review and program priorities), and programmatic review and recommendation to the Office of the Chief Engagement and Dissemination Officer for funding approval. Projects with total budgets of \$500,000 and over are presented to the Engagement, Dissemination, and Implementation Committee for endorsement and to the Board of Governors for funding approval.

#### Preliminary Review

PCORI conducts rigorous merit review of the full applications it receives. Note that PCORI may eliminate applications from the review process for programmatic reasons (e.g., nonresponsiveness) or for administrative reasons. An application may be administratively withdrawn if it is incomplete; is submitted past the stated due date and time; or does not meet the formatting criteria outlined in the [Submission Instructions](#), in the PCORI templates, and in PCORI Online.

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



organizational goals of review.

### Application Review Criteria

Below are PCORI's merit review criteria for implementation applications proposed 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 sufficiently describe the target group of the proposed implementation activity? Does it describe the setting(s) in which the implementation will take place?
- Does the application sufficiently address the relevance and importance of the evidence to the end-users and implementation settings targeted in this proposed project? Is the eligible evidence generalizable to these targeted users and settings? Will its uptake improve health care and/or health outcomes for the targeted end-users in these settings?
- Have the specific implementation sites been identified? If so, has the applicant demonstrated the readiness of the implementation sites, including the commitment of key decision makers?
- Are the targeted end-users and settings representative of additional audiences who stand to benefit beyond this proposed implementation project?
- Does the application describe how further uptake of the evidence, beginning with the project proposed, will lead to a change in practice and improved health care and health outcomes?

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

- Does the application provide a clear approach for implementing the eligible evidence? Are all components of this approach well described?
- 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.
- Are the proposed implementation strategies likely to result in successful uptake of this 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?
  - The successful execution of implementation activities (i.e., reach, site-level adoption, and fidelity); and
  - The impact of these activities on end-users in the immediate and longer term (i.e., changes in knowledge, behavior, healthcare utilization, and health outcomes).

- Does the application use a Dissemination & Implementation (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?
- Do the proposed strategies consider factors that may help or hinder successful integration of the eligible evidence in the proposed project, including specific barriers to implementation and how to mitigate them?
- 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?
- Are the project timeline and specific project milestones realistic?

### **Criterion 3. 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 project 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 4. 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 5. 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? 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 eligible evidence to broader venues? Does the application describe how the project will engage or work directly with these stakeholders?

### In-Person Review

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

During the in-person review, merit reviewers meet to discuss and clarify further the merits of the proposed application and identify areas for improvement. In addition, each application is rescored 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 to the 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, 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, and accepted by, 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.

## V. PCORI Policies that Govern Awardees Related to Data Access, Privacy, and Public Reporting

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

### PCORI Public Access Policy

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

### Standards for Privacy of Individually Identifiable Health Information

On August 14, 2002, 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](#)<sup>32</sup> 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](#).<sup>33</sup>

### Publication and Other Sharing of Information

In accordance with its authorizing legislation, PCORI is committed to publishing and disseminating all information and materials developed using PCORI funding. All recipients of PCORI contracts must agree to these principles and take steps to facilitate data availability.

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<sup>32</sup> Available at <https://www.hhs.gov/ocr/index.html>.

<sup>33</sup> Available at <https://grants.nih.gov/grants/guide/notice-files/NOT-OD-03-025.html>.