



Cycle 3 2021 Funding Cycle

PCORI Funding Announcement: Implementation of Effective Shared Decision-Making (SDM) Approaches in Practice Settings

Published September 7, 2021

This PCORI Funding Announcement (PFA) applies to the funding cycle that closes on December 7, 2021, at 5 pm (ET). Submission Instructions, templates, and other resources are available at <https://www.pcori.org/funding-opportunities/announcement/implementation-effective-shared-decision-making-cycle-3-2021>.



About PCORI

The Patient-Centered Outcomes Research Institute (PCORI) was authorized by Congress in 2010 and reauthorized for an additional 10 years in 2019 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.

Patient-Centered Outcomes Research Institute
1828 L St. NW, Suite 900
Washington, DC 20036
Phone: 202-827-7700
Fax: 202-355-9558
Email: info@pcori.org

Follow us on Twitter: [@PCORI](https://twitter.com/PCORI)



Overview

Summary	<p>This PFA promotes the targeted implementation and systematic uptake of shared decision making (SDM) in healthcare settings, in line with PCORI’s goal of supporting patients in making informed decisions about their care. This initiative will support projects that propose active, multicomponent approaches to implementing effective SDM strategies that address existing barriers and obstacles to uptake and maintenance, so that these interventions are effectively and sustainably integrated into practice. Projects must incorporate rigorous evaluation of the implementation of SDM approaches, as well as the impact of the SDM processes in the targeted settings.</p>														
Key Dates	<table border="0"> <tr> <td>Online System Opens:</td> <td>September 7, 2021</td> </tr> <tr> <td>LOI Deadline:</td> <td>September 28, 2021, by 5 pm (ET)</td> </tr> <tr> <td>LOI Screening Notification</td> <td>October 19, 2021</td> </tr> <tr> <td>Application Deadline:</td> <td>December 7, 2021, by 5 pm (ET)</td> </tr> <tr> <td>Merit Review:</td> <td>February 2022</td> </tr> <tr> <td>Large Awards Announced:</td> <td>July 2022</td> </tr> <tr> <td>Earliest Project Start Date:</td> <td>October 2022</td> </tr> </table>	Online System Opens:	September 7, 2021	LOI Deadline:	September 28, 2021, by 5 pm (ET)	LOI Screening Notification	October 19, 2021	Application Deadline:	December 7, 2021, by 5 pm (ET)	Merit Review:	February 2022	Large Awards Announced:	July 2022	Earliest Project Start Date:	October 2022
Online System Opens:	September 7, 2021														
LOI Deadline:	September 28, 2021, by 5 pm (ET)														
LOI Screening Notification	October 19, 2021														
Application Deadline:	December 7, 2021, by 5 pm (ET)														
Merit Review:	February 2022														
Large Awards Announced:	July 2022														
Earliest Project Start Date:	October 2022														
Maximum Project Budget (Direct Costs)	\$1.5 million total direct costs														
Maximum Project Period	Up to three years														
Funds Available Up To	\$6.5 million per cycle. The total amount awarded and the number of awards made will depend on the quality and costs of the applications received. Individual projects may not exceed \$1.5 million in direct costs, and the maximum project period is up to three years.														
Eligibility	<p>To be eligible for this PFA, applicants must do one of the following:</p> <ol style="list-style-type: none"> 1. Propose to implement an SDM strategy that was formally tested and demonstrated to be effective in the context of a PCORI-funded research award. 2. Propose an implementation project that will incorporate new PCORI-funded clinical comparative effectiveness research evidence into an existing and tested SDM strategy, then implement the updated strategy in a practice setting. <p>Applicants proposing to implement an SDM strategy that was formally tested and demonstrated to be effective in the context of a PCORI-funded research award must be the Principal Investigator (PI) of the original PCORI-funded research project or be a member of the original PCORI-funded research project team. PCORI strongly encourages applicants to include individuals with sufficient expertise in both SDM and implementation on their proposed project teams.</p> <p><i>Organization:</i> Applications may be submitted by private-sector research organizations, including any nonprofit or for-profit organization, and any 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. 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 clear and 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>Timing:</i> Applicants must propose to implement PCORI-funded results that are available at the time of the Letter of Intent (LOI) deadline. Specifically, (1) a draft final research report (DFRR) pertaining to the original PCORI-funded research award must have been accepted for entry into the peer-review process by PCORI or (2) a manuscript reporting the results of the PCORI-funded study being proposed for implementation must have been formally accepted for publication by a peer-reviewed scientific journal before the LOI deadline for this PFA.</p> <p>Applicants relying on submission of the DFRR to meet the above requirement should be aware that PCORI will administratively withdraw LOIs submitted prior to PCORI’s acceptance of the DFRR for entry into the peer-review process. Note that it typically takes six to eight weeks for processing, revision, and acceptance of high-quality DFRRs to enter PCORI’s peer-review process; applicants should plan accordingly.</p> <p>Applicants relying on publication of a peer-reviewed manuscript must include formal documentation of acceptance for publication of the manuscript with their LOI submission or PCORI will administratively withdraw the LOI.</p> <p>Applicants will have one opportunity to resubmit an application that was reviewed and not funded in a previous cycle. See the resubmission policy for more detail.</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. Importance of research results 2. Readiness for implementation 3. Technical merit of the proposed implementation project 4. Project personnel and environment 5. Patient-centeredness 6. Stakeholder engagement
Contact Us	<p>Programmatic Inquiries: Please contact the PCORI Dissemination & Implementation Helpdesk at disseminationquestions@pcori.org. PCORI will respond within two business days. However, we cannot guarantee that all questions will be addressed in two business days prior to an LOI or application deadline.</p> <p>Administrative, Financial, or Technical Inquiries: Please contact the PCORI Helpdesk at pfa@pcori.org. PCORI will respond within two business days. Please note that during the week of a deadline, response times may exceed two business days. Applicants may also call the PCORI Helpdesk (202-627-1885). It is the applicant’s responsibility to submit the application on or before the application deadline.</p>

Table of Contents

Introduction	1
Summary of Program	1
Proposing Shared Decision Making Projects	2
Specific Requirements	2
Use of Proprietary Decision Aids or Similar Tools.....	5
Multicomponent Implementation Approaches	6
Additional Guidance	6
Nonresponsiveness	6
Resubmissions.....	7
Protection of Human Subjects	8
Required Education of Key Personnel on the Protection of Human Subject Participants	8
Letter of Intent (LOI) Review	8
Merit Review	9
Preliminary Review	9
Application Review Criteria.....	10
In-Person Review	13
Post-Panel Review and Funding Recommendations	13
Summary Statements.....	13
PCORI Policies that Govern Awardees Related to Data Access, Privacy, and Public Reporting	14
PCORI Public Access Policy.....	14
Standards for Privacy of Individually Identifiable Health Information	14
Publication and Other Sharing of Information	14

Introduction

Even with comparative clinical effectiveness research (CER) evidence, many important healthcare decisions are not clear-cut; often, several reasonable alternatives exist among the available treatment options. In these instances, patients and their clinicians need to consider the available options, using the best existing evidence to support choices that reflect patient values and preferences. SDM is widely recognized as a key component of patient-centered health care and an important decision-making model in the context of uncertainty. Decades of research demonstrate the positive impact of SDM interventions on patient decision-making processes and care outcomes.¹

Recent commentary and research have emphasized the potential of SDM as an integral component of patient-centered, value-based care.^{2,3,4} The policy context surrounding SDM has also shifted in favor of its implementation and uptake. Washington State passed legislation incentivizing SDM as an alternative to traditional informed-consent procedures for preference-based treatment decisions, the National Quality Forum published certification standards for patient decision aids, the Centers for Medicare and Medicaid now require SDM as a precondition of payment for two preference-sensitive treatment choices, and the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) includes SDM as one of four performance categories used for determining clinicians' reimbursement under its Merit-Based Incentive Program.² Yet, despite research demonstrating the effectiveness of SDM, mounting policy momentum, and a wealth of available SDM interventions,^{1,5} uptake of SDM in clinical practice remains slow, and most clinicians and care settings have little or no experience with SDM. Some of the systemic barriers to the use of SDM include perceived time constraints associated with SDM; perceptions that SDM does not work well with certain patient groups; lack of training to equip clinicians with requisite education and skills necessary to facilitate SDM; and the perception among providers that they already conduct SDM with their patients, despite evidence to the contrary.⁶ Systematic reviews^{7,8} underscore the need for multicomponent implementation strategies that consider and target interventions to both the patient and the healthcare provider when incorporating SDM into routine clinical practice.

Summary of Program

This PFA promotes the targeted implementation of shared decision making (SDM) in healthcare settings, in line with PCORI's goal of supporting patients in making informed decisions about their care. It supports projects that propose active, multicomponent implementation approaches that address existing barriers and obstacles to uptake and maintenance of effective SDM strategies, with the goal of

¹ Stacey D, Légaré F, Lewis K, et al. Decision aids for people facing health treatment or screening decisions. *Cochrane Database Syst Rev*. 2017;(4):CD001431. doi:10.1002/14651858.CD001431.pub5

² Spatz E, Krumholz H, Moulton B. Prime time for shared decision making. *JAMA*. 2017;317(13):1309-1310. doi:10.1001/jama.2019.0616

³ Oshima Lee E, Emanuel EJ. Shared decision making to improve care and reduce costs. *N Engl J Med*. 2013;(368):6-8.

⁴ Barry MJ, Edgman-Levitan S. Shared decision making—pinnacle of patient-centered care. *N Engl J Med*. 2012;366(9):780-781.

⁵ Gayer CC, Crowley MJ, Lawrence WF, et al. An overview and discussion of the Patient-Centered Outcomes Research Institute's decision aid portfolio. *J Comp Eff Res*. 2016;5(4):407-415.

⁶ Légaré F, Witteman HO. Shared decision making: examining key elements and barriers to adoption into routine clinical practice. *Health Aff (Millwood)*. 2013;(32):276-284.

⁷ Légaré F, Ratte S, Stacey D, et al. Interventions for improving the adoption of shared decision making by healthcare professionals. *Cochrane Database Syst Rev*. 2010;(5):CD006732. doi:10.1002/14651858.CD006732.pub2

⁸ Légaré F, Politi MC, Drolet R, Desroches S, Stacey D, Bekker H; SDM-CPD Team. Training health professionals in shared decision-making: an international environmental scan. *Patient Educ Couns*. 2012;(88):159-169.

effectively and sustainably integrating these interventions into practice.

For this PFA, PCORI defines an SDM strategy as an intervention or approach that draws on and presents available evidence to inform patients of available treatment options and their risks and benefits, and either engages patients in a decision-making process with their clinician that reflects their values or promotes their ability to engage in such a process.

Proposing Shared Decision Making Projects

Proposed projects should integrate SDM strategies into real-world settings, demonstrating the ability of the proposed implementation strategy to bring evidence to targeted end-users in ways that are sustainable and scalable.⁶ Applicants may take either of two approaches:

1. Propose to implement an SDM strategy that was formally tested and demonstrated to be effective in the context of a PCORI-funded research award.
2. Propose an implementation project that will incorporate new PCORI-funded clinical comparative effectiveness research evidence into an existing and tested SDM strategy, then implement the updated strategy in a practice setting.

For applicants incorporating new PCORI-funded clinical comparative effectiveness research evidence into an existing and tested SDM strategy, it is important to consider the body of existing evidence relevant to the PCORI-funded research finding that is the focus of the proposed shared decision-making project. Applicants should explain how the current finding supports, augments, or differs from related evidence and how the proposed SDM strategy and its implementation take account of the full body of related information.

Specific Requirements

Applications are expected to do the following:

- Propose to implement an SDM strategy consistent with the above definition.
- Demonstrate that the proposed SDM strategy has been developed and tested in alignment with existing quality standards (please see the [SDM Submission Instructions](#) and [Shared Decision Making Approach Template](#) under Applicant Resources for more detail).
- Describe efforts undertaken to eliminate bias in how the evidence is presented in the SDM approach.
- Document that the proposed SDM strategy has demonstrated effectiveness on patient, caregiver, or healthcare provider decision making using well-accepted metrics:
 - At a minimum, the intervention should have demonstrated efficacy or effectiveness related to patient-centered decisional outcomes (e.g., decision conflict, decision confidence, the process of shared decision making, decision congruence with preferences). PCORI will not consider as sufficient interventions for which testing has been limited to tool validation, usability, or satisfaction.

- Note that, although this initiative does not support developing new SDM strategies, those with demonstrated effectiveness may be adapted for broader implementation audiences and contexts with appropriate justification.
- This initiative does not support research to establish efficacy or effectiveness of SDM strategies or to study the comparative clinical effectiveness of multiple SDM strategies. Projects proposing to compare the effectiveness of two or more SDM strategies should consider applying to PCORI's Communication and Dissemination Research Program PFA.
- Propose to implement an SDM strategy informing a preference-sensitive decision.
- Propose a multicomponent implementation strategy that does the following:
 - Comprehensively addresses barriers and obstacles to SDM uptake, integration into practice, and maintenance of the intervention
 - Is guided by an established conceptual model or framework and, where possible, by evidence regarding the implementation of evidence-based practices and interventions
 - Has potential for use and scalability beyond the targeted implementation settings
- Describe the project team's
 - Experience and successful track record with the proposed implementation activities
 - Complementary expertise in SDM and implementation science sufficient to guide these central aspects of the proposed project
- Demonstrate comprehensive and meaningful stakeholder engagement and buy-in:
 - Describe how the relevant frontline staff, care providers, and leadership of host delivery settings informed the development of the proposal.
 - Describe how personnel at the implementation sites have demonstrated their interest in, as well as commitment to use, the SDM approach at the level of the frontline staff responsible for delivering the intervention or directly supporting the project activities. Did these staff provide input on, or endorse, the activities they will undertake during the proposed project, and will they continue to provide input throughout the proposed project? How so?
 - Demonstrate that the leadership—specifically, the relevant decision makers—at the healthcare systems and settings in which implementation will occur are committed to the project goals as well as have the organizational influence and authority to ensure immediate and long-term implementation success.
 - Describe the specific criteria these individuals will use to make decisions regarding the ongoing maintenance of the program being implemented and the extent to which the project evaluation will inform them.
 - Describe site/system leadership commitment to sustaining the SDM approach/intervention beyond the proposed project.

- What specific work will site/system leadership undertake during the proposed project to ensure continued long-term use of the intervention beyond the immediate project?
- Describe the relevant regional and/or national stakeholders who can contribute to the implementation strategy's sustainability in the target setting and whose support will be critical to extending the impact of the SDM approach to broader venues beyond the proposed project. Describe your relationship and past involvement with these organizations.
- Describe the specific sites and settings where implementation will occur:
 - Propose implementation sites and settings that have a demonstrable commitment to improving healthcare quality and a willingness to invest in SDM, such that they provide a supportive context and culture for undertaking the proposed project.
 - Propose implementing SDM 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 staff who will be involved at each site (i.e., those who will be trained and expected to participate in delivery of the intervention), including numbers and roles. 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: For projects designed to reach a significant proportion of the relevant target population regionally or nationally, please elaborate.
 - Representativeness: Describe 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 SDM approach being implemented.
 - Racial/ethnic, geographic, or other (e.g., insurance, socioeconomic status) diversity.
- Consider the sustainability of the implementation strategies in the context of sustainable payment models in both fee-for-service and non-fee-for-service environments.
- Describe how you envision further scale-up will occur beyond the proposed project. Describe the relevant educational or implementation materials/resources (or other implementation infrastructure/supports) used in the proposed project that will be important for supporting further scale-up. How do you anticipate the relevant individuals/organizations will access and use these resources moving forward?
- Include a rigorous evaluation plan that does the following:
 - Assesses the fidelity of the SDM approach as implemented; the effectiveness of the

implementation approach; and the impact of the SDM strategy on relevant decisional, clinical, and healthcare utilization outcomes

- Includes an appropriate balance of process measures, proximal healthcare utilization outcomes and health outcomes, and more distal utilization and health outcomes as appropriate within the project scope
- Includes the CollaboRATE measure for SDM

PCORI also encourages applicants to review recently published standards for reporting implementation studies (e.g., STaRI), which provide helpful guidance related to project planning, execution, evaluation, and reporting.^{9,10,11} These standards promote using a dual-strands approach to describe both the strategies used to promote implementation and the intervention being implemented. This approach is particularly relevant to this funding opportunity.

Use of Proprietary Decision Aids or Similar Tools

Applicants may propose to use proprietary decision aid(s) that meet the above requirements for efficacy, as part of their SDM strategy. PCORI recognizes that commercially available products may offer advantages in terms of assured maintenance and sustainability.

Applicants proposing to use proprietary decision aids must provide clear rationale for their choice of the specific proposed decision aid(s). Justification should include relevance to implementation sites and advantages vis-à-vis other available decision aids, as well as any other important considerations.

Applicants should specify how costs associated with the decision aid(s) will be covered during the project, for example, by sites or through agreements between the applicant and the decision aid developer or vendor. (Note that PCORI funds cannot be used to cover or offset costs associated with accessing or using the decision aid during the proposed project, including purchasing, licensing, or subscribing fees.)

In addition, applicants must describe how both participating and future sites (e.g., hospitals or other healthcare settings) will access the decision aid beyond the PCORI-funded project, such as by subscription or purchase. For decision aids that will be made available to future users through a vendor, applicants must provide a letter of support from the vendor confirming the vendor's intention to:

- 1) Maintain the availability of the decision aid for a minimum of 5 years
- 2) Offer the decision aid as a standalone subscription or purchase and not exclusively through a larger package
- 3) Offer the decision aid at a subscription or purchase price that future sites can reasonably be expected to bear. (The vendor should confirm the reasonableness of this cost to sites with an

⁹ Pinnock H, Epiphaniou E, Sheikh A, et al. Developing Standards for Reporting Implementation studies (StaRI): an e-Delphi. *Implement Sci.* 2015;(10):42.

¹⁰ Pinnock H, Barwick M, Carpenter C, et al; StaRI Team. Standards for Reporting Implementation Studies (StaRI) statement. *BMJ.* 2017;(356):i6795.

¹¹ Pinnock H, Barwick M, Carpenter CR, et al; StaRI Group. Standards for Reporting Implementation Studies (StaRI): explanation and elaboration document. *BMJ Open.* 2017;(7):e013318. doi:10.1136/bmjopen-2016-013318

explicit statement that the subscription or purchase price is currently and will continue to be consistent with that of similar decision aids available on the market.)

- 4) Update the decision aid to maintain its currency, particularly with respect to new evidence

Applicants intending to commercialize the decision aid following completion of their proposed implementation project—for example, a decision aid that was developed and tested in a PCORI-funded research study but is not yet publicly available—must commit to ensuring that future commercialization or partnerships with vendors will satisfy requirements (1) - (4) above. While applicants may work toward commercializing their decision aid concurrently with their PCORI-funded implementation project, applicants may not use PCORI funds to support these activities.

Applicants must disclose in their proposals potential conflicts of interest related to use of the decision aid during the proposed project, or its use at future sites thereafter. PCORI may require applicants being considered for funding to provide documentation that all relevant conflicts of interest have been appropriately disclosed and managed by the applicant’s relevant institutional official.

Multicomponent Implementation Approaches

Multicomponent implementation approaches reflecting a comprehensive view of the barriers and facilitators to using SDM in the proposed setting(s) are generally required to ensure a proposed project’s success. Using combinations of different implementation strategies to drive change among varied stakeholders (e.g., patients, providers) at different levels (e.g., individual, clinical setting, or community) enhances the likelihood of implementation success.¹² Applicants are encouraged to include regional or national stakeholder groups, such as physician specialty groups, patient advocacy groups, large payers, or policy makers, as meaningful team members, partners, or advisors in the project. Involving these types of stakeholders will help ensure continued implementation of the shared decision-making approach beyond the immediate project, should it be successful. The implementation science literature has identified dozens of implementation strategies that fall into six main domains of strategic focus: (1) planning, (2) education, (3) finance, (4) restructuring, (5) quality management, and (6) attention to policy context.⁹ For the purposes of this PFA, PCORI is open to diverse, well-considered approaches to sustainable implementation of SDM. Proposed multicomponent implementation approaches should reflect the selected SDM approach, target settings, and other contextual factors.

Additional Guidance

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:

- Establish efficacy or effectiveness of SDM strategies or to study the comparative clinical effectiveness of multiple SDM strategies.
 - Applicants interested in conducting CER should consider applying to PCORI’s

¹² 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.

Communication and Dissemination Research Program using the appropriate application materials. PCORI will not refer projects proposing to perform CER under this PFA and will withdraw them as nonresponsive.

- Implement evidence that does not include a PCORI-funded CER or methods study result.
- Translate or adapt an SDM approach without actively implementing it.
- Develop or validate a new tool or system for patients or clinicians without the primary purpose of actively implementing 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 their development is not the primary activity proposed.
- Use contract funds to incentivize or compensate sites (or site personnel) for completing training; participating in proposed implementation activities; or identifying, recruiting, or enrolling patients receiving the intervention that is the focus of the proposed project.
- Use contract funds to pay the cost of the interventions being implemented in the project:
 - In general, PCORI does not pay 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 materials costs associated with delivering the intervention. These are considered direct patient care costs, and PCORI expects these costs to be covered by the health delivery systems 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 requesting the use of PCORI funds for any portion of these costs, the applicant must clearly describe these in the LOI. If approved to include these costs in a full invited application, the applicant must include a detailed justification in the Budget Justification Template outlining the importance of the request to the project's overall success. The justification must also explain how costs will be covered in the future—post-PCORI funding—not only in the sites participating in the proposed project but also in other communities and healthcare settings that undertake the proposed strategies. Such a justification, however, will not guarantee that PCORI will approve the costs. Applicants should develop contingency plans in the event that PCORI does not approve the request.

For information related to administrative and technical requirements for LOI and application submission, please consult the PCORI [Submission Instructions](#) for this PFA.

Resubmissions

Applicants will have **one opportunity** to resubmit an application that completed the merit review process (i.e., for which the applicant received a summary statement) and was not funded in a previous cycle. Applicants may not resubmit an application for a previously submitted and reviewed application until they have received merit review feedback (i.e., a summary statement) from the initial submission.



All resubmitted applications require submission of a new LOI; applicants are responsible for ensuring their LOI is administratively and programmatically responsive to the current PFA.

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

Protection of Human Subjects

PCORI follows the Federal Regulation 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](#),¹³ issued by the US Department of Health and Human Services. Awardees must also comply with appropriate state, local, and institutional regulations and guidelines pertaining to the use of human subjects in research.

Applicants should consult the [PCORI Policy on Data and Safety Monitoring Plans for PCORI-Funded Research](#)¹⁴ to determine whether a Data and Safety Monitoring Plan, as well as Data and Safety Monitoring Board, may be needed for their proposed implementation project. Applicants may be asked to submit a full data and safety monitoring plan upon award, depending on the nature of the proposed project.

PCORI merit reviewers will examine plans for protection of human subjects in all applications and may provide comments regarding the plans (see [How to Evaluate Human Subjects Protections](#)). Reviewers’ comments on human subject research are not reflected in the overall application score, but PCORI staff may use them during potential funding negotiations. Final determinations about adequacy of human subject protections rest with the Institutional Review Board(s) that has jurisdiction over the study.

The awardee institution or organization, whether domestic or foreign, bears ultimate responsibility for safeguarding the rights and welfare of human subjects in PCORI-supported activities.

Required Education of Key Personnel on the Protection of Human Subject Participants

For those projects that require human subject protection, PCORI requires that all applicants adhere to the National Institutes of Health (NIH) policy on education in the protection of human subject participants in the conduct of research. This applies to all individuals listed as key personnel in the application. The policy and frequently asked questions are available on the [NIH website](#).¹⁵

Letter of Intent (LOI) Review

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

Responsive applicants must thoroughly address all LOI fields according to the instructions in the LOI Template. PCORI will screen all LOIs for programmatic responsiveness and to ensure compliance with

¹³ See <http://grants.nih.gov/sites/default/files/supplementalinstructions.docx>. Accessed April 27, 2020.

¹⁴ See <http://www.pcori.org/sites/default/files/PCORI-Policy-Data-Safety-Monitoring-Plans.pdf>

¹⁵ See <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-08-054.html>. Accessed January 3, 2019.



the [PCORI Submission Instructions](#). A minimum of two PCORI staff will review the LOIs, which are not scored during review. PCORI will invite only applicants whose LOIs are most responsive to this limited PFA to submit a full application. PCORI will not invite nonresponsive LOIs, including those submitted using an incorrect LOI template and those not adhering to the [Submission Instructions](#), to submit a full application. Please refer to the [Submission Instructions](#) for due dates and information on how to submit an LOI via PCORI Online.

Merit Review

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

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

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

Preliminary Review

PCORI conducts rigorous merit review of the full applications it receives. Note that PCORI may eliminate applications from the review process for programmatic reasons (e.g., nonresponsiveness) or for administrative reasons. An application may be administratively withdrawn if it is incomplete; is submitted past the stated due date and time; or does not meet the formatting criteria outlined in the [Submission Instructions](#), in the PCORI templates, and in PCORI Online. Note that applications proposing dissemination-focused projects undergo internal PCORI programmatic review (i.e., these applications do not undergo the PCORI Merit Review process) and are approved for funding by PCORI's Chief Engagement and Dissemination Officer. Funding decisions for dissemination-focused applications will be announced no later than March 2021.

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

Application Review Criteria

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

Criterion 1. Importance of research results

- If the application proposes to implement an SDM approach that was previously tested in a PCORI-funded study:
 - Does the application clearly describe the study results related to the SDM approach, including the effectiveness of the SDM approach in terms of impact on patient-centered decisional outcomes?
 - Does the application clearly describe the evidence supporting the effectiveness of the proposed SDM approach and, where applicable, how the PCORI-funded study findings on that approach contribute to the evidence base?
 - Does the application clearly and sufficiently describe the clinical evidence being summarized and presented to patients and/or clinicians within the proposed SDM approach?
 - If the applicant is proposing to update the clinical evidence being presented in the proposed SDM approach as part of the project, does the applicant provide sufficient rationale and detail about the process for updating and incorporating the revised evidence into the SDM approach?

—OR—

- If the application proposes to incorporate new PCORI-funded CER evidence into an existing SDM approach:
 - Are the research results proposed for incorporation clearly described? Does the application describe the clinical relevance and strength of the findings from the PCORI-funded study?
 - Is the SDM approach and the evidence supporting the SDM approach sufficiently described? Does the evidence include impact of the SDM approach on patient-centered outcomes?
 - If the applicant is proposing to update the evidence presented in the proposed SDM approach as part of the project, does the applicant provide sufficient rationale and detail about the process for updating and incorporating the revised evidence into the SDM approach?

Criterion 2. Readiness for implementation

- Does the application demonstrate that the proposed SDM approach has been developed and tested with rigor and transparency per existing quality standards, as appropriate?

- Have the proposed implementation sites been identified? If so, has the applicant demonstrated the readiness of the implementation sites, including the identification of site champions and commitment of key decision makers? If not, has the applicant provided a rationale for why this is not possible, along with acceptable assurances that all implementation sites can be activated within the initial project phase?
- Does the application sufficiently address the relevance of the PCORI-funded evidence proposed for implementation to the targeted end-users and implementation settings?
 - Does the application sufficiently describe the target group for the proposed SDM project? Does it describe the setting in which the project will take place? Are the PCORI-funded results generalizable to these targeted end-users and settings?
 - Are these targeted end-users and settings representative of additional audiences who stand to benefit beyond this proposed implementation project?
- Does the application describe how understanding and broader use of these results, beginning with the proposed project, will lead to a meaningful change in practice and improved health care and health outcomes? How do these results add to the total evidence related to the choice among treatment or other healthcare options summarized and presented within the proposed SDM approach?

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

- Does the application provide a comprehensive and appropriate multicomponent strategy for implementing the proposed SDM approach into real-world clinical practice? 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 project activities clearly described, and are these activities likely to result in successful uptake of the evidence and lead to meaningful changes in practice and improvements in health care and health outcomes?
- If the application 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 an appropriate evaluation strategy that includes plans for the following?
 - Evaluating the effectiveness of the proposed implementation approach as well as the continued effectiveness of the SDM strategy
 - Measuring fidelity of the SDM approach as delivered, as well as its impact on relevant decisional, clinical, and healthcare utilization outcomes
 - Measuring the impact of these activities on end-users in the immediate and longer term (i.e., changes in knowledge, satisfaction, behavior change, healthcare utilization, and health outcomes)

- Does the application use a D&I framework or model to inform the project design and evaluation outcomes? Alternatively, does the application adequately describe a logic pathway that shows how the proposed implementation approach is likely to lead to meaningful changes in knowledge, behavior, and practice?
- Do the proposed strategies consider factors that may help or hinder SDM uptake 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 bring the SDM approach toward wider use across more systems, settings, or sites?
- Are the proposed timeline and specific project milestones realistic?

Criterion 4. Project personnel and environment

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

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

Criterion 5. Patient-centeredness

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

Criterion 6. Stakeholder engagement

- Does the application demonstrate that relevant stakeholder perspectives—including those of 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 SDM approaches 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 SDM or directly supporting the implementation activities) at the proposed implementation sites are

clearly interested in the proposed implementation project and are committed to participating as active partners in the project? Have these staff provided input on, or endorsed, the activities they will undertake during the project?

- Does the application indicate the relevant regional or national stakeholder organizations whose support will be critical to extending the impact of the proposed SDM approach and PCORI-funded research findings to broader venues? Does the application describe how the project will engage or work directly with these stakeholders?

In-Person Review

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

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

Post-Panel Review and Funding Recommendations

After the in-person meeting, PCORI program staff evaluate final merit review panel scores and comments, identify duplication or synergy among funded projects, and consider the fit of applications within the programmatic vision. Engagement/Dissemination Program staff members then recommend projects for funding approval. The Dissemination and Implementation Program, including its funded projects portfolio, is governed by the Engagement, Dissemination, and Implementation Committee—a subcommittee of PCORI’s Board of Governors.

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 (interim, final, etc.) until the overdue reports have been submitted to, and accepted by, PCORI.**

Summary Statements

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

- In-person panel discussion notes



- Final average overall score
- Preliminary reviewer critiques

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

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

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

PCORI Public Access Policy

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

Standards for Privacy of Individually Identifiable Health Information

On August 14, 2002, the Department of Health and Human Services (HHS) issued a final modification to the Standards for Privacy of Individually Identifiable Health Information, the “Privacy Rule.” The Privacy Rule is a federal regulation under the Health Insurance Portability and Accountability Act (HIPAA) of 1996 that governs the protection of individually identifiable health information and is administered and enforced by the HHS Office for Civil Rights.

Decisions about the applicability and implementation of the Privacy Rule reside with the researcher and his or her institution. The [Office for Civil Rights](#)¹⁶ 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](#).¹⁷

Publication and Other Sharing of Information

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

¹⁶ Available at <http://www.hhs.gov/ocr/>.

¹⁷ Available at <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-03-025.html>.