Cycle 2 2019 Funding Cycle

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

Published May 1, 2019

This PCORI Funding Announcement (PFA) applies to the funding cycle that closes on August 30, 2019, at 5 pm (ET). Application Guidelines, templates, and other resources are available at http://www.pcori.org/Cycle-2-2019-shared-decision-making/.

About PCORI

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

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

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Overview

Published	May 1, 2019
Letter of Intent Deadline	June 19, 2019, by 5 pm (ET) A Letter of Intent (LOI) is required prior to submission of a full application. LOIs will be screened for responsiveness to this Patient-Centered Outcomes Research Institute (PCORI) Funding Announcement (PFA) and fit to program goals. Notification of denial or approval to submit a full application will occur no later than July 12, 2019.
Summary	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.
Applicant Resources	See https://www.pcori.org/funding-opportunities/announcement/implementation-effective-shared-decision-making-approaches.
Key Dates	Online System Opens: May 1, 2019 LOI Deadline: June 19, 2019, by 5 pm (ET) LOI Screening Notification July 12, 2019 Application Deadline: August 30, 2019, by 5 pm (ET) Merit Review: October 2019 Awards Announced: February 2020 Earliest Project Start Date: May 2020
Maximum Project Budget (Direct Costs)	$1.5 million
Maximum Project Period	Up to three years
Funds Available	$6.5 million per cycle
Eligibility	To be eligible for this PFA, applicants may do one of the following: 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, and then implement the updated strategy in a practice setting Applicants that are 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. *Timing*: Applicants must propose to implement PCORI-funded results that are available at the time of the LOI due date. 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 PCORI-funded results being proposed for implementation must have been formally accepted for publication by a peer-reviewed

	scientific journal before the LOI due date for this announcement. Applicants relying on submission of the DFRR to meet the above requirement should be aware that PCORI will administratively withdraw LOIs that are 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. Applicants relying on publication of a peer-reviewed manuscript must be able to document formal acceptance for publication of the manuscript before the LOI deadline, or PCORI will administratively withdraw the LOI. Applicants will have **one opportunity** to resubmit an application that was reviewed and not funded in a previous cycle. See the resubmission policy for more detail. *Organization*: Applications may be submitted by a private-sector research organization, 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 US 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.
Review Criteria	Please note that the merit review criteria for this PFA are different from those PCORI uses when reviewing research applications: 1. Importance of research results in the context of the existing body of evidence 2. Readiness of the research results for implementation 3. Technical merit of the proposed implementation project 4. Project personnel and environment 5. Patient-centeredness 6. Patient and stakeholder engagement
Contact Us	**Programmatic Inquiries:** Please contact the PCORI Dissemination Helpdesk via email (disseminationquestions@pcori.org). PCORI will respond within two business days. However, we cannot guarantee that we can address all questions in two business days prior to an LOI or application deadline. **Administrative, Financial, or Technical Inquiries:** Please contact the PCORI Helpdesk at pfa@pcori.org. PCORI will respond within two business days. Please note that during the week of a deadline, response times may exceed two business days. Applicants may also call the PCORI Helpdesk (202-627-1885). It is the applicant's responsibility to submit the application on or before the application deadline.
Other	Deadlines are at 5 pm (ET). If deadlines fall on a weekend or a federal holiday, the deadline will be the following Monday or the next day after the federal holiday.

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What Has Changed for Cycle 2 2019:

- In past releases of this PFA, applicants were eligible if the DFRR was accepted into peer review or a manuscript was accepted at the time of the application due date. Starting with Cycle 2 2019, applicants will only be eligible if the DFRR was accepted into peer review or a manuscript was accepted at the time of the LOI due date. Specifically, (1) a draft final research report pertaining to the original PCORI-funded research award must have been accepted for entry in the peer-review process by PCORI, or (2) a manuscript reporting the PCORI-funded results being proposed for implementation must have been formally accepted for publication by a peer-reviewed scientific journal before the LOI due date.
- See the Application Guidelines for administrative and template changes.

I. Introduction

Summary of Program

The Patient-Centered Outcomes Research Institute (PCORI) has launched this PCORI Funding Announcement (PFA) to support investigator-initiated projects to implement patient-centered, clinical comparative effectiveness research (CER) findings obtained from PCORI-funded studies. 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 PFA supports projects that propose active, multicomponent approaches to implementing effective SDM strategies that address existing barriers and obstacles to uptake and maintenance, with the goal of 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.

PCORI seeks to fund multiple SDM implementation projects that have all the following requisite features:

- Proposes to implement an SDM strategy that is consistent with the above definition
- Demonstrates that the proposed SDM strategy has been developed and tested in alignment with existing quality standards (Please see the SDM Application Guidelines and Shared Decision Making Approach Template under Applicant Resources for more detail.)
- Documents 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 with respect 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.
- Proposes to implement an SDM strategy informing a preference-sensitive decision

- Proposes a multicomponent implementation strategy that comprehensively addresses barriers and obstacles to SDM uptake, integration into practice, and maintenance of the intervention. The strategy should be guided by an established conceptual model or framework and, where possible, by evidence regarding the implementation of evidence-based practices and interventions.
- Conducts a rigorous evaluation that 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
    - Evaluation plans should include 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.
    - Additionally, all evaluation plans must include the CollaboRATE measure for SDM.
- Proposes a project team that draws on complementary expertise in SDM and implementation science sufficient to guide these central aspects of the proposed project
- Proposes an implementation strategy that incorporates the perspectives and experiences of patients and stakeholders, including individuals living with the disease or condition of interest; also, describes how front-line staff, care providers, and leadership of host delivery settings have been included, and explicitly demonstrates the commitment and involvement of those required to accomplish the project successfully

In addition, PCORI will consider the following elements of the proposed implementation strategy:

- Sites: Proposes implementation sites 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
- Setting: PCORI is interested in 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.
- Generalizability: Proposes an SDM strategy and corresponding implementation approach with potential for use and scalability beyond the targeted implementation settings
- Sustainability: PCORI is interested in implementing SDM strategies in the context of sustainable payment models in both fee-for-service and non-fee-for-service environments.

Background

Even with 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 patients in making choices that reflect their 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 has passed legislation incentivizing SDM as an alternative to traditional informed consent procedures for preference-based treatment decisions, the National Quality Forum recently published certification standards for patient decision aids, the Centers for Medicare and Medicaid have started requiring 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 do 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.

Multicomponent Implementation Approaches

Multicomponent implementation approaches that reflect a comprehensive view of the barriers and facilitators to using SDM in the proposed setting(s) will generally be required to ensure a proposed project's success. Using combinations of different implementation strategies to drive change among different stakeholders (e.g., patients and providers) at different levels (e.g., individual, clinical setting, or community) enhances the likelihood of implementation success.[9] 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 assure the 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

[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.

[9] 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.

strategic focus: (1) planning, (2) education, (3) financial, (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.

Resubmissions

Applicants will have **one opportunity** to resubmit an application that completed the merit review process (i.e., for which the applicant received a summary statement) and was not funded in a previous cycle. Applicants may not resubmit an application for a previously submitted and reviewed application until they have received merit review feedback (a summary statement) from the initial submission. All resubmitted applications require submission of a new Letter of Intent (LOI); applicants are responsible for ensuring their LOI is administratively and programmatically responsive to the current PFA. Resubmitted applications must include a Resubmission Letter. PCORI will deem applications that do not meet these requirements as nonresponsive and will withdraw them from merit review. LOIs that are not invited to submit a full application by PCORI do not count as a submission or resubmission.

Funds Available

PCORI has allotted up to $6.5 million in total costs for this 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.

II. Guidance for Preparing Applications

In developing an implementation strategy and PCORI application, applicants should pay attention to four fundamental concepts: (1) Evidence Context, (2) Setting, (3) Engagement, and (4) Evaluation.[10,11,12,13,14]

- *Evidence Context* refers to the body of existing evidence relevant to the PCORI-funded research finding. It is rare that a single finding warrants implementation independent of other research findings. 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.
- *Setting* refers to where the implementation will take place (e.g., primary care network, hospital, or community). Applicants should demonstrate that implementation sites have a commitment to improving healthcare quality and a willingness to invest in SDM, such that they provide a

[10] 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.
[11] 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.
[12] 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.
[13] Brownson RC, Colditz GA, Proctor EK, (Eds.). *Dissemination and Implementation Research in Health: Translating Science to Practice*. New York, NY: Oxford University Press; 2017.
[14] 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.

supportive context and culture for undertaking the proposed project. At a minimum, the project should move findings out of a controlled research setting to a more general setting, demonstrating the ability of the proposed strategy to bring PCORI-funded findings to targeted end-users in ways that promote uptake.[6] Project design should reflect relationships among the stakeholders within the setting because these will be critical to the project's success.

- *Engagement* is the meaningful involvement of stakeholders and interested patients in the project's design, execution, and evaluation. The project should involve stakeholders, including front-line staff, care providers and leadership of host delivery settings essential to successful implementation at project sites. Further, the project should involve regional and/or national stakeholders who can contribute to the implementation strategy's sustainability in the target setting and to broader implementation, if warranted, in the future. Proposed engagement approaches should ensure that the perspectives and experiences of interested patients and stakeholders, including individuals living with the disease or condition of interest and representatives from all levels within the host delivery setting, are included. Engagement should ensure that evidence and strategies are tailored appropriately to the target end-users and the setting. Plans for engaging stakeholders should reflect a spirit of partnership, trust, and reciprocity.
- *Evaluation* is essential to understanding how and why implementation activities are or are not successful, as a basis for adjustment, reconsideration, or future replication of strategies. Applicants should propose a rigorous evaluation of the proposed implementation effort's effectiveness, to include assessment of the implementation approach; fidelity of the SDM approach as implemented; and the impact of the SDM strategy on relevant decisional, clinical, and utilization outcomes. Evaluation plans should include an appropriate balance of measurable process outcomes and proximal and distal utilization and health outcomes. PCORI will not consider as sufficient proposed evaluation plans that are limited to measures of dissemination. The following resources may be helpful for identifying an appropriate evaluation strategy.[10,15]

PCORI encourages applicants to review recently published standards for reporting implementation studies (STaRI), which provide helpful guidance related to project planning, execution, evaluation, and reporting.[16,17,18] These standards promote using a dual-strands approach to describe (1) the strategies used to promote implementation and (2) the intervention being implemented. This approach is particularly relevant to this funding opportunity.

Non-responsiveness

PCORI may administratively withdraw as nonresponsive to this PFA any Letters of Intent (LOIs) and

[15] 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.
[16] Pinnock H, Epiphaniou E, Sheikh A, et al. Developing Standards for Reporting Implementation studies (StaRI): an e-Delphi. *Implement Sci.* 2015;(10):42.
[17] Pinnock H, Barwick M, Carpenter C, et al; StaRI team. Standards for Reporting Implementation Studies (StaRI) statement. *BMJ.* 2017;(356):i6795.
[18] 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

applications in which the proposed project does the following:

- Proposes to 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 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.
- Proposes to implement evidence that does not include a PCORI-funded CER or methods study result
- Proposes to translate or adapt an SDM approach without actively implementing it
- Proposes to develop or validate a new tool or system for patients or clinicians without the primary purpose of actively implementing evidence
    - Modification or adaptation of tools and systems previously found to be effective and proposed as the primary mechanism for actively disseminating and implementing evidence will be considered, as long as their development is not the primary activity proposed.
- Proposes to 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. These are direct patient care costs and PCORI expects health delivery organizations or other payers to cover these expenses. Intervention costs PCORI does not cover include, but are not limited to, compensation for personnel who are delivering the intervention and equipment and materials costs associated with delivery of the intervention. PCORI encourages all applicants to find support from sites, payers, or other stakeholders for these expenses. Only under special circumstances will PCORI consider an exception for coverage of patient care intervention costs.
    - If applicants are requesting the use of PCORI funds for any portion of these costs, the application 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 study but also in other communities and healthcare settings that undertake the proposed strategies. Applicants should develop contingency plans in the event that PCORI does not approve the request.

Protection of Human Subjects

If applicable, applicants should describe the protection of human subjects involved in their proposed research. If human subject protection is not applicable, applicants should justify why it is not necessary for their project. PCORI follows the Federal Policy for the Protection of Human Subjects (45 CFR part 46), including the Common Rule. For more detailed information, please see Section 5, "Human Subjects Research Policy," in the *Supplemental Grant Application Instructions for All Competing Applications and*

Progress Reports,[19] issued by the US Department of Health and Human Services. PCORI does not require that applicants comply with sections of this policy referring to requirements for federal-wide assurance or to standards for including women, minorities, and children. 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[20] 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"[21]). The overall application score does not reflect reviewers' comments on human subject research, but PCORI staff may use these comments during potential funding negotiations. Final determinations about adequacy of human subject protections rest with the Institutional Review Board (or Boards) that has jurisdiction for 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 projects requiring human subject protection, PCORI requires that all applicants adhere to the National Institutes of Health (NIH) policy on education in the protection of human subject participants in the conduct of research. This applies to all individuals listed as key personnel in the application. The policy and FAQs are on the NIH website.[22]

III. How to Submit an Application

Letter of Intent

Applicants should download the Letter of Intent Template for the Shared Decision Making (SDM) PFA from the PCORI Funding Opportunities webpage. The LOI has a three-page limit. You should number references in the text and provide full citations on a separate page following the LOI. PCORI suggests including all references as in-text citations using American Medical Association citation style, but other citation styles are acceptable. Complete the document and convert it to a PDF file. Do not upload additional documents, including Letters of Endorsement or Support, as part of your LOI, because they are not requested at this stage. Inclusion of additional documents will result in LOI rejection without review. Please visit the PCORI Funding Opportunities webpage for additional applicant resources, including the PFA and required templates. LOIs are a mandatory prerequisite for submitting a full

[19] See http://grants.nih.gov/sites/default/files/supplementalinstructions.docx.
[20] See http://www.pcori.org/sites/default/files/PCORI-Policy-Data-Safety-Monitoring-Plans.pdf
[21] See http://www.pcori.org/sites/default/files/PCORI-Checklist-for-Evaluating-Human-Subjects-Protections.pdf/.
[22] See http://grants.nih.gov/grants/guide/notice-files/NOT-OD-08-054.html.

application. Applicants that fail to submit an LOI cannot submit a full application to the corresponding award cycle.

The LOI for the proposed project should contain the following information:

- Title of proposed project
- Original PCORI-funded research award number, original research project title, and name of original Principal Investigator (PI)
- Clear indication of which of the following you are doing:
    1) Proposing to implement an SDM strategy that was formally tested and demonstrated to be effective in a PCORI-funded research award, **or**
    2) Proposing an implementation project that will incorporate new PCORI-funded CER evidence into an existing and tested SDM strategy, and then implementing the updated strategy
- Objective and specific aims of the proposed implementation project
- Description of the PCORI-funded research findings and related evidence most relevant to your proposed implementation project
    1) If the PCORI-funded project tested an SDM approach, describe the results of the PCORI-funded study, including effectiveness on patient-centered decisional outcomes. Describe the body of evidence associated with the SDM approach and how your study findings contributed to this evidence base.

       Further, describe the evidence that was summarized and presented within this SDM approach in your PCORI-funded research study and how it relates to the body of evidence related to this health decision. If the evidence will be updated for the proposed project, describe and explain the revised presentation of evidence.
    2) If the PCORI-funded project produced new evidence that will be incorporated into an existing effective SDM approach, describe the most relevant results of your PCORI-funded study, the evidence base surrounding those findings, and the evidence base that demonstrates the effectiveness of the chosen SDM approach.
- Identification of the preference-sensitive decision the proposed SDM strategy addresses and clear indication of how this new PCORI-funded evidence contributes to patient or provider decision making
- Description of the implementation problem (e.g., use of the evidence or gaps in informed decision making) that motivate the proposed project
- Identification and description of the setting(s) in which implementation will take place, the immediate target of the implementation activity, a logic pathway describing how affecting change in the proposed target audience and setting will ultimately change healthcare outcomes and delivery, number of participants, and the implementation sites and partners' demonstrated commitment
- Description of the multicomponent approach being proposed for implementing the SDM strategy
- Description of the evaluation plan that assess the effectiveness of the proposed implementation

approach as well as the continued effectiveness of the SDM strategy on relevant decisional, clinical, and utilization outcomes. The evaluation plan should include an appropriate balance of measurable process, proximal, and distal outcomes. Additionally, all evaluation plans must include the CollaboRATE measure for SDM.

- Description of how patients and other relevant stakeholder groups are involved in the planning and implementation of this effort

Please address all categories in the LOI Template and then upload the document into PCORI Online. **The deadline for LOI submission is June 19, 2019, by 5 pm (ET).**

Letter of Intent Review

An LOI is required for submission of a full application. PCORI screens LOIs for responsiveness to this PFA and to ensure compliance with administrative guidelines. PCORI invites only applicants whose LOIs are most responsive to this PFA to submit a full application. Nonresponsive LOIs and those not adhering to Application Guidelines will not be invited to submit a full application. Notification of denial or approval to submit an application will occur no later than July 12, 2019. Please refer to the Application Guidelines for information on how to submit your LOI via PCORI Online.

Submission Dates

You must submit LOIs and applications in accordance with the published dates and times listed in the Overview section of this document and on the PCORI Funding Opportunities webpage.

PCORI Online

To submit an application properly, you must register with PCORI Online and submit both an LOI and an application for each cycle to which you are applying. Please ensure that you are applying to the PFA titled "PCORI Funding Announcement: Implementation of Effective Shared Decision-Making (SDM) Approaches in Practice Settings."

Applicant Resources

PCORI Funding Opportunities	http://www.pcori.org/Cycle-2-2019-shared-decision-making
PCORI Online	https://pcori.force.com/engagement
PCORI Funding Awards	http://www.pcori.org/research-results-home

IV. Merit Review

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

- Identify applications that have the strongest potential to help patients, caregivers, clinicians, policy makers, and other healthcare system stakeholders make informed decisions to improve patient outcomes.
- Implement 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 research reflects the interests and views of patients and other stakeholders and those who care for them, and that it meets the criteria for scientific rigor.
- Fund projects that fill important evidence gaps and have strong implementation potential.
- Regularly evaluate and continually improve the merit review process and policies in support of PCORI's mission.

PCORI merit review is a multiphase process that includes staff evaluation of LOIs, preliminary review of full applications by review panels, in-person panel review of a subset of full applications (identified based on preliminary review and program priorities), final programmatic review, recommendation for approval of funding, and final PCORI approval.

Preliminary Review

PCORI conducts a rigorous merit review of the full applications it receives. Note that PCORI may eliminate applications from the review process for programmatic reasons (e.g., non-responsiveness) or for administrative reasons. PCORI may administratively withdraw an application if it is incomplete; is submitted past the stated due date and time; or does not meet the formatting criteria outlined in the Application Guidelines, in the PCORI templates, and in PCORI Online.

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

Application Review Criteria

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

Criterion 1. Importance of research results in the context of the existing body of evidence

- If the application proposes to **implement an SDM approach that was previously tested in a PCORI-funded study**:
  - Does the application clearly describe (with appropriate citations) 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 overall evidence base that could contribute to 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 (with appropriate citations) the clinical evidence related to the choice among treatment or other healthcare choices 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 a rationale and sufficient 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**:
  - Does the application clearly and sufficiently describe (with appropriate citations) the PCORI-funded CER evidence, including its strength in terms of clinical and statistical significance?
  - Will understanding and broader use of these results lead to a meaningful change in practice and improved outcomes that matter to patients? How do these results add to the total evidence related to the choice among treatment or other healthcare choices summarized and presented within the proposed SDM approach?
  - Is the SDM approach that the applicant proposes presented sufficiently clearly so that the tool or strategy can be evaluated by reviewers? Is the evidence supporting the SDM approach sufficiently described (with appropriate citations) to demonstrate the strength of evidence supporting the approach? 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 a rationale and sufficient detail about the process for updating and incorporating the revised evidence into the SDM approach?

Criterion 2. Readiness of the research results 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? Does the application describe efforts undertaken to eliminate bias in how the evidence is presented?
- Are the described PCORI-funded research results clinically meaningful, and do they warrant implementation as proposed in the application? Similarly, is the evidence supporting the proposed SDM approach sufficiently strong to warrant implementation as proposed in the application?
- Does the application sufficiently address the generalizability of the PCORI-funded research results to populations beyond the immediate study sample?
- Does the application identify the decision-making context in which the PCORI-funded results are most relevant beyond the initial study setting?

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

- Does the application use an implementation framework or model to anchor and inform the project design, outcomes, and evaluation plan?

- Does the applicant provide a clear logic pathway linking the implementation approach and SDM strategy to meaningful improvements in relevant healthcare and patient-centered outcomes?
- Does the application provide a well-described, comprehensive, and appropriate multicomponent strategy for implementing the proposed SDM approach into real-world clinical practice?
- Is the proposed implementation approach supported by existing evidence, best practices, or case examples of effective implementation approaches?
- Does the application sufficiently describe the group(s) that will be the immediate targets of the implementation activity and the end-users of the SDM strategy? Does it sufficiently describe the setting(s) in which the implementation will take place? Are these targeted groups and settings generalizable?
- Does the application describe and consider the existing barriers and obstacles to SDM uptake in the proposed implementation setting(s)? Does the proposed implementation plan effectively address those barriers and include plans to address new barriers as they arise?
- How will the proposed implementation plan lead to continued use of the SDM approach beyond the PCORI project period?
- 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?
- Does the application address the scalability and generalizability of the SDM approach to settings and populations beyond those proposed in the current implementation project?
- Is the proposed timeline realistic, including specific project milestones?

Criterion 4. Project personnel and environment

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

- How well-qualified is the project team (e.g., PIs, collaborators, and other stakeholders) to conduct the proposed activities? Does the project team include individuals with sufficient expertise in SDM, implementation science, and other relevant areas?
- Does the investigator (or co-investigator) have demonstrated experience conducting projects of similar size, scope, and complexity?
- If the project is collaborative or dual-PI, do the investigators have complementary and integrated expertise? Are the leadership, governance, and organizational structures appropriate for the project?
    - (Dual-PI Option Only) Does the Leadership Plan adequately describe and justify roles and areas of responsibility of the PIs?

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

Criterion 5. Patient-centeredness

- Is the SDM approach proposed for implementation of interest to patients, and is it likely to increase their involvement in their healthcare decisions? If so, how?
- Is the SDM approach likely to provide useful information to patients or their caregivers facing health-related decisions?

Criterion 6. Patient and stakeholder engagement

- Does the application demonstrate that stakeholders central to the proposed project, including targeted end-users or their representatives, informed the development of the proposal and will be meaningfully engaged throughout the project?
- Have the proposed implementation sites been identified? If not, has the applicant provided a rationale for why this is not possible and acceptable assurances that all implementation sites can be activated within the initial project phase?
- Does the application demonstrate sufficient commitment to the project from the decision makers, and other critical stakeholders, at the healthcare systems and settings in which implementation will occur, to promote and plan for sustaining the proposed SDM approach?
- Does the application demonstrate clear interest and support of personnel, including frontline staff, responsible for implementing SDM at target settings? In what ways is the application convincing that these personnel will participate as active partners in the project?
- Does the application demonstrate sufficient willingness and readiness by the healthcare settings in which implementation will occur to provide a supportive context and culture for undertaking the proposed project?
- Does the application propose to work with relevant regional or national stakeholder organizations whose support will be critical to extending the impact of the PCORI-funded research findings to broader venues?

In-Person Review

During preliminary review, all administratively compliant applications are evaluated and scored based on PCORI's merit review criteria. After the preliminary review is completed, PCORI program staff members evaluate panel scores and critiques to identify a subset of applications for merit reviewers to discuss 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 applications, clarify further the merits of the proposed Project Plan, 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

and ensure that all applications receive a fair and thorough review according to the standards outlined in the PFA.

Post-Panel Review

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 (D&I) 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, and timely achievement of milestones). Based on the risk assessment, PCORI may impose special terms and conditions on awardees or withhold contract issuance until such business risks are mitigated. **PCORI will not award new contracts to current awardees with overdue reports (progress, interim, final, etc.) until PCORI receives the overdue reports.**

Summary Statements and Funding Recommendations

Applicants receive summary statements approximately two weeks 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.

Funding recommendations are made by identifying meritorious applications that fit the programmatic needs and that satisfactorily address the merit review criteria. Program teams also consider the funds allotted for the current PFA when deciding which applications to recommend for approval. Applicants to this current cycle's PFA will receive summary statements and notification of the funding status of their application no later than February 2020.