Cycle 2 2020 Funding Cycle

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

Published May 5, 2020

This PCORI Funding Announcement (PFA) applies to the funding cycle that closes on August 31, 2020, at 5 pm (ET). Submission Instructions, templates, and other resources are available at https://www.pcori.org/funding-opportunities/announcement/implementation-effective-shared-decision-making-cycle-2-2020.
About PCORI

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

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

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## Overview

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<th>Published</th>
<th>May 5, 2020</th>
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<td><strong>Summary</strong></td>
<td>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.</td>
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<td><strong>Key Dates</strong></td>
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<tr>
<td>Online System Opens:</td>
<td>May 5, 2020</td>
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<td>LOI Deadline:</td>
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<td>Earliest Project Start Date:</td>
<td>July 2021</td>
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<td><strong>Maximum Project Budget (Direct Costs)</strong></td>
<td>$1.5 million total direct costs</td>
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<td><strong>Maximum Project Period</strong></td>
<td>Up to three years</td>
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<td><strong>Funds Available Up To</strong></td>
<td>$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.</td>
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| **Eligibility** | To be eligible for this PFA, applicants must 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, then implement the updated strategy in a practice setting.  

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.  

**Timing:** Applicants must propose to implement PCORI-funded results that are available at the time of the Letter of Intent (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 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 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.

**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 & Implementation Helpdesk at disseminationquestions@pcori.org. PCORI will respond within two business days. However, we cannot guarantee that all questions will be addressed in two business days prior to an LOI or application deadline.

**Administrative, Financial, or Technical Inquiries:** Please contact the PCORI Helpdesk at pfa@pcori.org. PCORI will respond within two business days. Please note that during the week of a deadline, response times may exceed two business days. Applicants may also call the PCORI Helpdesk (202-627-1885). It is the applicant’s responsibility to submit the application on or before the application deadline.

**New or revised for the Cycle 2 2020 funding cycle:**

- The merit review criteria have been slightly modified.
- All policies and PCORI research requirements have been moved into a new section, called **PCORI Policies that Govern Awardees Related to Data Access, Privacy, and Public Reporting**, at the end of this document.
- All instructional information related to templates or the submission process has been removed from the PFA and now exists only in the **Submission Instructions** (formerly known as the Application Guidelines), which have been updated, including changes to templates.
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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 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 Submission Instructions 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 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.
- 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, and that also describes how frontline 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 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 recently 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 reviews7,8 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 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.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 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. 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 (i.e., 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.

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:\textsuperscript{10,11,12,13,14}

- **Evidence context** refers to the body of existing evidence relevant to the PCORI-funded research finding. A single finding rarely 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, community). Applicants should demonstrate that implementation sites are committed to improving healthcare quality and are willing to invest in SDM, such that they provide a supportive context and culture for undertaking the proposed project. At a minimum, the project should move findings out of a controlled research setting into 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.\textsuperscript{6} Project design should reflect relationships among the

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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 frontline 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, including 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.

PCORI 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. 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.

**Nonresponsiveness**

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

- 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

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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.
  - 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.
- 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.

For information related to administrative and technical requirements for Letter of Intent and application submission, please consult the PCORI Submission Instructions for this PFA.

**Protection of Human Subjects**

PCORI follows the Federal Policy for the Protection of Human Subjects (45 CFR part 46), including the Common Rule. For more detailed information, please see Section 5, “Human Subjects Research Policy,” in the Supplemental Grant Application Instructions for All Competing Applications and Progress Reports, issued by the US Department of Health and Human Services. Awardees must also comply with

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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). 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.\(^{21}\)

### III. Letter of Intent (LOI) Review

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

Responsive applicants must thoroughly address all LOI fields according to the instructions in the LOI Template. PCORI will screen all LOIs for programmatic responsiveness and to ensure compliance with the PCORI Submission Instructions. A minimum of two PCORI staff will review the LOIs, which are not scored during review. PCORI will invite only applicants whose LOIs are most responsive to this limited PFA to submit a full application. PCORI will not invite nonresponsive LOIs, including those submitted using an incorrect LOI template and those not adhering to the Submission Instructions, to submit a full application. Please refer to the Submission Instructions for due dates and information on how to submit an LOI via PCORI Online.

### IV. Merit Review

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


• Identify applications that have the strongest potential to lead to increased use and uptake of evidence from PCORI-funded studies and, ultimately, lead to improved health care and health outcomes.

• Ensure a transparent, fair, objective, and consistent process to identify these applications.

• Elicit high-quality feedback that reflects a diversity of perspectives to ensure that the PCORI-funded implementation projects reflect the interests and views of patients and other stakeholders and those who care for them, and have strong technical merit.

PCORI merit review is a multiphase process that includes the review panel’s preliminary 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 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 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 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 in the SDM approach?
- Have the proposed implementation sites been identified? If so, has the applicant demonstrated the readiness of the implementation sites, including the identification of site champions and key decision makers? If not, has the applicant provided a rationale for why this is not possible, along with acceptable assurances that all implementation sites can be activated within the initial project phase?
- 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?
- Does the application sufficiently address the relevance of the PCORI-funded evidence proposed for implementation to the targeted end-users and implementation settings?
Does the application sufficiently describe the target group of the proposed SDM project? Does it describe the setting in which the project will take place? Are the PCORI-funded results generalizable to these targeted users and settings?

Are these targeted end-users and settings representative of additional audiences who stand to benefit beyond this proposed implementation project?

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

- Does the application provide a well-described, comprehensive, and appropriate multicomponent strategy for implementing the proposed SDM approach into real-world clinical practice?
- Are the chosen implementation strategies appropriate for this effort? Consider the extent to which they are tested, evidence based, and consistent with principles and findings from implementation science.
- Do the proposed strategies consider factors that may help or hinder SDM uptake in the proposed project, including specific barriers to user implementation and how to mitigate them?
- Are the proposed project activities clearly described, and are these activities likely to result in successful uptake of the evidence and lead to meaningful changes in practice and improvements in health care and health outcomes?
- 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 address the 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 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. Patient and stakeholder engagement

• Does the application demonstrate that relevant stakeholder perspectives—including those of patients or caregivers—have informed the development of the proposal and 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 PCORI-funded research findings to broader venues? Does the application describe how the project will engage or work directly with these stakeholders?

In-Person Review

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

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

**Post-Panel Review and Funding Recommendations**

After the in-person meeting, PCORI program staff evaluate final merit review panel scores and comments, identify duplication or synergy among funded projects, and consider the fit of applications within the programmatic vision. 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 (progress, interim, final, etc.) until PCORI receives the overdue reports.**

**Summary Statements**

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 March 2021.

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

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

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

Standards for Privacy of Individually Identifiable Health Information

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

Decisions about the applicability and implementation of the Privacy Rule reside with the researcher and his or her institution. The Office for Civil Rights provides information on the Privacy Rule, including a complete Regulation Text and a set of decision tools related to “Am I a covered entity?” Information on the impact of the HIPAA Privacy Rule on NIH processes involving the review, funding and progress monitoring of grants, cooperative agreements, and research contracts is available from NIH.

Publication and Other Sharing of Information

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

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22 Available at http://www.hhs.gov/ocr/.